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Confidential Treatment Requested
Under 17 C.F.R. §§ 200.80(b)(4) and 230.406



EXCLUSIVE LICENSE AND DISTRIBUTION AGREEMENT

THIS AGREEMENT is entered into on November 22, 2012 (the “**Effective Date**”)

BETWEEN:

- (1) **ERYtech Pharma S.A.**, a *Société Anonyme* existing and organized under the laws of the Republic of France, having its registered head office at 60 Avenue Rockefeller, Bâtiment Adenine, 69008 Lyon, France, with a registered capital of 315.355 Euros (“**ERYtech**”); and
- (2) **ORPHAN EUROPE**, a *société à responsabilité limitée* existing and organized under the laws of the Republic of France, having its registered head office at Immeuble Le Wilson, 70 Avenue du Général de Gaulle, 92800 Puteaux, France, registered with the Trade and Companies Registry of Nanterre under number 379 088 115 (“**OE**”).

ERYtech and OE are each referred to herein as a “**Party**” and together as the “**Parties**.”

WHEREAS:

- (A) ERYtech is a French specialty pharma company which is developing personalized cell therapy medicinal products such as therapeutic molecules or enzymes encapsulated into red blood cells. In particular, ERYtech develops the GRASPA® product which consists of a suspension of erythrocytes encapsulating L-asparaginase in a preservative solution.
- (B) OE is a pharmaceutical company focusing on the development, manufacturing and commercialization of orphan pharmaceutical products, and is controlled by Recordati Spa, which is a European pharmaceutical company dedicated to research, development, manufacturing and marketing of specialty and primary care pharmaceuticals.
- (C) ERYtech has agreed to appoint OE as its exclusive distributor of GRASPA® in the European Union and certain additional territories and to grant OE a license to further develop GRASPA® in relation to acute myeloid leukaemia by obtaining regulatory authorizations for such indication.



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1. Definitions and Interpretation

1.1 The following terms shall have the following meanings when used in this Agreement:

Additional Indications	shall mean any human health indication other than the Primary Indications in which ERYtech may wish to Develop the Product.
Additional Territories	shall mean any of Turkey, Russia and the Commonwealth of Independent States, the countries of the Middle East (excluding Israel) listed in Schedule 1.1.1 and all the countries of Africa.
Affiliates	shall mean, with respect to a Party, any entity that controls, is controlled by, or is under common control with such Party. For the purpose of this definition only, “control” shall mean: (a) the possession, directly or indirectly, of the power to direct the management or policies of such entity, whether through the ownership of voting securities, by contract or otherwise, or (b) the ownership, directly or indirectly, of more than fifty percent (50%) of the voting securities or other ownership interest of such Party.
ALL Indication	shall mean the treatment of acute lymphoblastic leukaemia.
ALL Marketing Plan	shall have the meaning set out in clause 9.2.
AML Development Plan	shall mean the Development plan for the Product in the AML Indication, an outline of which is set out in Schedule 1.1.2, as will be completed pursuant to clause 10.3.
AML Indication	shall mean the treatment of acute myeloid leukaemia.
AML Marketing Plan	shall have the meaning set out in clause 9.2.
Applicable Laws	shall mean any law, statute, regulation, rule, ordinance, principle of common law, order or decree of any domestic, foreign or supranational court or other judicial authority or governmental, administrative or regulatory body, department, agency, commission, authority or instrumentality (including any judicial or administrative interpretation thereof) in force.

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Approval Milestones	shall have the meaning set out in clause 11.2.
Centralized Procedure	shall mean the procedure for authorizing medicinal products as laid down in Regulation (EC) No 726/2004 and advanced therapy medicinal products as laid down by Regulation (EC) No 1394/2007.
cGMP	shall mean current good manufacturing practices, as set forth in Directive 2003/94/EC, as amended from time to time, and applicable regulations and guidance thereunder.
Commercial Milestones	shall have the meaning set out in clause 11.3.
Commercially Reasonable Efforts	shall mean, with respect to a Party and an activity, the efforts and resources which would be used (including the promptness with which such efforts and resources would be applied) by companies of similar size and resources as such Party and those of its Affiliates actually involved in the performance of such activity pursuant to this Agreement, which shall include all Affiliates controlled by OE in the Territory, in conducting such activity for their pharmaceutical products that are of comparable commercial potential and stage of Development to the applicable Product, provided that such efforts shall apply to the Territory as a whole and it being agreed that obtaining a Marketing Authorization, price or reimbursement approvals with a potential negative cross reference pricing impact or likely to affect the commercialization of the Product in one or more specific countries of the Territory, may impact in an adverse manner the economic success of the Product in the Territory as a whole, which is the agreed goal of the Parties.
Control or Controlled	means, with respect to any intellectual property rights, that a Party has or will have, the legal authority or right (whether by ownership, license or otherwise) to grant a license, sublicense, access or right to use (as applicable) under such intellectual property rights to the other Party on the terms and conditions set forth herein.
Develop and Development	“Development” shall mean all activities that relate to obtaining, maintaining or expanding a Marketing Authorization of the Product and to support appropriate usage for the Product, for one or more indications. This includes preclinical/nonclinical research and testing, toxicology, and clinical trials as well as all studies that are requested in writing by a Regulatory Authority as a

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	condition of, or in connection with, obtaining or maintaining a Marketing Authorization. “ Develop ” has a correlative meaning.
EMA	shall mean the European Medicines Agency or any successor thereto.
ERYtech Indemnitees	shall have the meaning set out in clause 17.7.
Firm Order	shall have the meaning set out in clause 7.6.
Force Majeure	shall have the meaning set out in clause 20.6.
GAAP	shall mean the international financial reporting standards (“ IFRS ”), or, with respect to ERYtech, generally accepted accounting principles applicable in France.
Improvements	shall mean all improvements, modifications or adaptations to any part of the Licensed IP Controlled by either Party during the term of this Agreement.
Information	shall have the meaning set out in clause 18.1.
Initial Term	shall have the meaning set out in clause 15.1.
Joint Steering Committee	shall mean the joint steering committee established by the Parties in accordance with clause 10.
Licensed IP	shall mean the Patents and Results, including any Improvement, Controlled by ERYtech at any time during the Term of this Agreement. Schedule 1.1.3 lists the Patents which are part of the Licensed IP as of the Effective Date.
Major Market	shall mean any or all of [***].
Marketing Authorization or MA	shall mean the approval by a Regulatory Authority in the Territory for the marketing of pharmaceutical products, including a marketing authorization as issued by the EMA and all amendments and supplements thereto. For the avoidance of doubt, Marketing Authorization does not include pricing and reimbursement approvals, import/export permits or other business licenses generally. “ Marketing Authorization Application ” or “ MAA ” shall mean an application for a Marketing Authorization.
Medac Agreements	shall mean the supply agreements first dated respectively as of December 10, 2008 (the “ 2008 Medac Agreement ”) and April 6, 2011 (the “ 2011 Medac Agreement ”) between ERYtech and Medac, pursuant to which ERYtech sources L-asparaginase for GRASPA®.

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Net Sales	shall mean, in relation to a Product, the gross amount invoiced by OE, its Affiliates and/or their respective Sub-Licensees to a Third Party, but deducting the following costs to the extent solely related to the Product and actually allowed, incurred or paid by OE, its Affiliates or Sub-Licensees with respect to the sale of such Product (all determined in accordance with GAAP in respect of OE and its Affiliates): [***] For clarity, in the case of transfers of Product between OE and its Affiliates or Sub-Licensees, for subsequent sale or other transfer of such Product to Third Parties, Net Sales shall be the gross amount invoiced to such Third Parties for that Product without double counting, less the deductions set forth above.
ODD	shall mean the orphan drug designation of the Product as granted by the EMA.
Patents	shall mean patent applications and patents, including without limitation any divisions, reissues, renewals, continuations (in whole or in part), revalidations, registrations, confirmations, substitutions, re-examinations, revisions, additions, supplementary protection certificates, and extensions thereof.
Primary Indications	shall mean the ALL Indication and the AML Indication.
Product	shall mean (i) a pharmaceutical product (designated hereunder as GRASPA®) consisting of a proprietary form and method of use of asparaginase encapsulated in erythrocytes as currently manufactured by ERYtech based on its Licensed IP and related know how, and (ii) any different dosage forms and different strengths (including for avoidance of doubts products based on different forms of asparaginase) or products obtained with a different manufacturing process of asparaginase encapsulated in erythrocytes, as may be manufactured by or for ERYtech based on its Licensed IP and related know how or otherwise available to ERYtech for use in the Primary Indications in the Territory.
OE Indemnitees	shall have the meaning set out in clause 17.8.
Regulatory Authority	shall mean any governmental entity of competent jurisdiction over the Development, manufacturing, marketing, promotion, sale, pricing or reimbursement of pharmaceutical products.

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Renewal Term	shall have the meaning set out in clause 15.2.
Results	shall mean all data, results, and information of any type whatsoever, in any tangible or intangible form, including know-how, trade secrets, practices, techniques, methods, processes, inventions, developments, specifications, formulations, formulae, materials or compositions of matter of any type or kind (patentable or otherwise), software, algorithms, marketing reports, expertise, stability, technology, test data including pharmacological, biological, chemical, biochemical, toxicological, and clinical test data, safety and pharmacovigilance data, analytical and quality control data, stability data, studies and procedures.
Royalty	shall have the meaning set out in clause 12.1.
Specifications	shall mean the finished product specifications of the Product as set forth in the relevant Marketing Authorizations in the Territory.
Sub-Licensee	shall mean any sub-licensee appointed by OE or its Affiliates in accordance with this Agreement.
Supply Price	shall mean the following unit costs incurred by ERYtech in connection with the manufacture and delivery of the Product to the customer stipulated in a Firm Order, as well as related activities (including interactions with OE, its Affiliates or Sub-Licensees with respect to the delivery and hemovigilance) (all determined in accordance with GAAP) [***]. For the sake of clarity, [***] shall be included in the Supply Price.
Target Population	shall mean fragile patients, (a) at first diagnosis, elderly patients, unfit patients, and patients allergic or intolerant to free asparaginase products, and (b) relapsing/refractory patients.
Term	shall mean the Initial Term and any Renewal Term.
Territory	shall mean the 27 countries currently forming the European Union, Norway, Switzerland, Liechtenstein, Croatia, Iceland, Serbia, Macedonia, Montenegro, Kosovo, Albania, and Bosnia and Herzegovina, including their current possessions and territories.
Third Party	shall mean any person or entity other than the Parties, any Affiliate of either of the Parties, or, with respect to OE or its Affiliates, any Sub-Licensee.

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Trade Mark shall mean the trade mark “GRASPA,” owned by ERYtech, together with such other trade marks pursuant to clause 14.3.

Upfront Payment shall have the meaning set out in clause 11.1.

1.2 Unless the context requires otherwise:

- (a) any definition of or reference to any agreement, instrument or other document herein shall be construed as referring to such agreement, instrument or other document as from time to time amended, supplemented or otherwise modified (subject to any restrictions on such amendments, supplements or modifications set forth herein or therein);
- (b) any reference to any laws, codes or regulations herein shall be construed as referring to such laws as from time to time enacted, repealed or amended;
- (c) any reference herein to any person shall be construed to include the person’s successors and assigns;
- (d) all references herein to clauses or schedules, unless otherwise specifically provided, shall be construed to refer to clauses and schedules of this Agreement, which are an integral part of this Agreement;
- (e) The definitions of the terms herein shall apply equally to the singular and plural forms of the terms defined. Whenever the context may require, any pronoun shall include the corresponding masculine, feminine and neuter forms;
- (f) The words “include” and “contain” (and their variant forms) shall be deemed to be followed by the phrase “without limitation;”
- (g) The word “will” shall be construed to have the same meaning and effect as the word “shall;”
- (h) The word “any” shall mean “any and all” unless otherwise clearly indicated by context; and
- (i) Where either Party’s approval or consent is required hereunder, except as otherwise specified herein, such Party’s approval or consent shall be in writing and may be granted or withheld in such Party’s discretion, but shall not be unreasonably denied, delayed or conditioned.

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2. Exclusive Appointment

2.1 Subject to the terms and conditions of this Agreement ERYtech hereby grants OE the exclusive rights under the Licensed IP and the Trade Mark solely to the extent necessary to:

- (a) Develop the Product for the AML Indication pursuant to the AML Development Plan;
- (b) apply for and hold the MA under the Trade Mark for the Primary Indications in accordance with clause 6; and
- (c) use, market and sell the Product under the Trade Mark for the Primary Indications in the Territory.

2.2 ERYtech shall not sell, and shall not appoint any other distributors of, or otherwise permit any Third Party to sell, the Products for the Primary Indications in the Territory. OE shall not sell the Product outside the Territory and shall not promote the Product outside of the Primary Indications.

2.3 OE may sub-license the rights granted to it pursuant to clause 2.1 provided that:

- (a) all sub-licenses shall be in accordance with the terms of this Agreement;
- (b) all sub-licenses granted shall terminate automatically on termination or expiry of this Agreement; and
- (c) OE shall be liable for all acts and omissions of any sub-licensee and shall indemnify ERYtech in accordance with clause 17.7 as though such act or omission was made by OE.

3. Right of First Negotiation for Additional Indications and Additional Territories

3.1 In the event that ERYtech intends to enter into a license or other arrangement with respect to the Product with any Third Party in relation to:

- (a) any country within the Additional Territories; or
- (b) any Additional Indication in the Territory or in the Additional Territories;

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ERYtech shall notify OE of such intention in writing. Such notification shall include all material information and documentation available to ERYtech and reasonably relevant for the evaluation by OE. Without limiting the generality of the foregoing, Schedule 3.1 lists certain matters to be so included to the extent available to ERYtech.

- 3.2 Within thirty (30) days (or within forty (45) days if the notice pursuant to clause 3.1 falls in August or December) of ERYtech's notice to OE pursuant to clause 3.1, OE shall notify ERYtech in writing whether it wishes to enter into discussions in relation to a license or other arrangement for such Additional Territories or Additional Indications with ERYtech. If OE notifies ERYtech that it does not wish to enter into discussions in relation to a license or other arrangement for such Additional Territories or Additional Indications, or in the absence of any notification by OE within such period, ERYtech shall be entitled to enter into a license or other arrangement in relation to such Additional Territories or Additional Indications with a Third Party.
- 3.3 If OE notifies ERYtech that it wishes to enter into discussions in relation to a license or other arrangement for such Additional Territories or Additional Indications the Parties shall [***]. Such negotiation shall be on the basis, to the extent reasonable, of specific additions or amendments to the provisions of this Agreement.
- 3.4 If the Parties have not entered into a definitive agreement in relation to such Additional Territories or Additional Indications within the [***] period referred to in clause 3.3, ERYtech shall be entitled to enter into a license or other arrangement in relation to such Additional Territories or Additional Indications with a Third Party provided that the terms and conditions of such license or other arrangement, taken as a whole, are not less advantageous for ERYtech than the last terms and conditions proposed by OE, taken as a whole.
- 3.5 If ERYtech enters into a license or other arrangement with a Third Party with respect to the Product in relation to any Additional Territories or Additional Indications and:
 - (a) such license or other arrangement provides for a lower supply price for the Product which may adversely impact OE's or its Affiliates' Net Sales price for the Product in the Territory or in the Primary Indications; or
 - (b) such license or other arrangement may lead to parallel exports (in the case of a license or other arrangement relating to an Additional Territory) or off-label promotion (in the case of a license or other arrangement relating to an Additional Indication) by the Third Party which may adversely impact OE's or its Affiliates' sales of the Product in the Territory or the Primary Indications;

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ERYtech shall then promptly notify OE in writing (provided that the Parties acknowledge and agree that ERYtech may not have all necessary information allowing it to determine whether the circumstances set forth in subclause (a) or (b) are met, and in such case, ERYtech shall request additional information from OE to make such determination, including as to the existence and materiality of the adverse impact) and [***] as from the first date of such adverse impact on the business of OE or its Affiliates, but such retroactive application shall not apply to a period which is longer than [***] before ERYtech's notice of the adverse impact.

If OE becomes aware of such adverse impact without having received a notice from ERYtech, it shall then notify ERYtech in writing and the Parties shall promptly negotiate in good faith [***], it shall be retroactively applied as from the first date of such adverse impact on the business of OE or its Affiliates, but such retroactive application shall not apply to a period which is longer than [***] before OE's notice to ERYtech of the adverse impact.

If, after having discussed in good faith pursuant to clause 3.5, ERYtech and OE fail to agree [***] as a consequence of ERYtech entering into a license or other arrangement with a Third Party as described in clauses 3.5 (a) or 3.5 (b) with respect to the Product in relation to any Additional Territories or Additional Indications. If ERYtech and OE cannot agree on the appointment of an expert within fifteen (15) days from the notice of disagreement, the expert shall be appointed by the president of the commercial court of Lyon at the request of either Party. The assessment of the expert shall be binding upon the Parties and the Supply Price or the Royalties shall be adjusted accordingly as from the date indicated in the preceding paragraph of this clause 3.5.

4. Non Compete

During the Term and without prejudice to any other obligations of OE hereunder, if OE is directly or indirectly (i.e. through its Affiliates or through any licenses or other commercial arrangements) involved in the Development, marketing, promotion, distribution, supply or sale in the Territory of any product [***].

In the event of a disagreement as to whether a product is a Competing Product, ERYtech and OE shall appoint an expert from a reputable firm to assess, in good faith, whether the Product is a Competing Product. If ERYtech and OE cannot agree on the appointment of an expert within fifteen (15) days from the notice of disagreement, the expert shall be appointed by the president of the commercial court of Lyon at the request of either Party.

Within fifteen (15) days from the acceptance by the expert of its appointment under this clause 4 (or such longer period of time that the expert may determine) each Party may provide any data or documents supporting its views.

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If after the notice to OE of the expert's determination that the product in question is a Competing Product, OE confirms its intention to continue the Development or the commercialization of the Competing Product and the Parties fail to reach an agreement after having discussed in good faith within fifteen (15) days, then ERYtech shall be entitled to terminate this Agreement upon written notice to OE pursuant to clause 15.6 (a).

5. Development of the Product

- 5.1 ERYtech shall, at its cost and expense, use Commercially Reasonable Efforts to complete the Development (including the clinical trials listed in Schedule 5.1) necessary to obtain a Marketing Authorization pursuant to the Centralized Procedure for the Product for the ALL Indication. ERYtech shall use Commercially Reasonable Efforts to ensure that [***] MA for the ALL Indication is [***] at the latest.
- 5.2 OE shall, at its cost and expense, use Commercially Reasonable Efforts to obtain a temporary authorization of use and a Marketing Authorization in countries of the Territory in which the Centralized Procedure is not available for the ALL Indication, provided that OE shall not be obliged to file an application for a Marketing Authorization prior to the issuance of the Marketing Authorization pursuant to the Centralized Procedure for the Product for the ALL Indication. To the extent preclinical activities and clinical trials are required in addition to those conducted by ERYtech pursuant to clause 5.1, for OE to comply with the obligations of the preceding sentence, the Parties will agree on an appropriate development plan and cost allocation, provided that if no agreement is reached with respect to any given country of the Territory, OE shall not be deemed in breach of its obligation to obtain temporary authorizations of use and a Marketing Authorization for the ALL Indication in such country.
- 5.3 Provided that the Development under clause 5.1 continues regularly, OE shall, at its cost and expense, use Commercially Reasonable Efforts to Develop the Product and to initiate and complete the clinical trials necessary to obtain an extension of the Marketing Authorizations in the Territory for the Product for the AML Indication in accordance with the AML Development Plan. OE shall use Commercially Reasonable Efforts to ensure that the extension of the [***] MA for the treatment of AML is [***]. OE may interrupt or discontinue the Development for the AML Indication and shall then terminate this Agreement in part with respect to the AML Indication, should it become clear, in OE's reasonable opinion, confirmed after receiving ERYtech's reasonable comments, that the Development for the ALL Indication or the Development for the AML Indication is not likely (i) to be successful within substantially the timelines and budget set out in this Agreement or (ii) to result in a commercially competitive product. The Parties will agree as to the most pragmatic handling of third party costs and expenses associated with the AML

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Development Plan, including, for example, that if such costs and expenses are paid by ERYtech, they will be reimbursed by OE to ERYtech within thirty (30) days of receipt of the corresponding invoice.

- 5.4 The Party responsible for a Development Plan shall maintain and make available at any time to the other Party (including, with respect to ERYtech for purposes of developing and registering directly or through licenses the Product outside of the Primary Indications or the Territory), without restrictions on use other than the scope of the license granted herein with respect to OE or as expressly provided herein, an electronic data base with respect to the Results of such Development Plan and provide access to all available data (including raw data) within fifteen (15) days of the request of the other Party, provided however that ERYtech shall not grant access to Results generated by OE to any of ERYtech's Third Party licensees unless ERYtech has obtained similar provisions from such other Third Party licensees with respect to the use by OE pursuant to this Agreement, provided that ERYtech shall use Commercially Reasonable Efforts to obtain such similar provisions and shall be obliged to do so with respect to safety data. For purposes of implementing the provisions of this clause 5.4., a complete electronic data base in respect of the Product shall be set by ERYtech, and upon transfer of the MA pursuant to clause 6.1, maintained by OE and available and accessible at all times to the Parties.

6. Marketing Authorizations, Pricing and Reimbursement Approvals

- 6.1 ERYtech shall apply for the MA with the EMA for the ALL Indication and transfer the MAA or the MA, as applicable, as well as the ODD to OE at the appropriate time agreed upon between the Parties, provided that ERYtech shall file the application for the MA transfer no later than within [***] of the MA issuance. If the transfer occurs following the issuance of the MA, pending such transfer, ERYtech shall hold the MA until its transfer to OE and, in the meantime, OE shall act as a distributor of the Product in the Primary Indications and the Territory. After issuance in OE's name or transfer to OE of the MA in the ALL Indication and completion of the Development in the AML Indication pursuant to clause 5.3, OE shall apply for an extension of the MA in the AML Indication. ERYtech shall bear the costs related to the preparation of the filing and the filing of the MA with the EMA respectively in the ALL Indication and in the AML Indication up to an amount equal to the EMA filing fees payable by a micro, small and medium-sized company (SME) for an orphan drug and all costs in excess shall be borne by OE and, if and to the extent borne by ERYtech, reimbursed to ERYtech within thirty (30) days of the submission by ERYtech to OE of the corresponding invoice. OE shall, at its own cost, maintain the MA and the ODDs (for clarity, for both ALL Indication and AML Indication) after their transfer. ERYtech and, after the transfer of the MA or MAA (as applicable) and of the ODDs to OE pursuant to this clause 6.1, OE shall:

- (a) to the extent lawful and practical, submit to the other Party all material correspondence received from the Regulatory Authorities as soon as available and no later than within 15 days following receipt as well as all draft filings (including all proposed variations, PSURs) or draft material correspondence with the Regulatory Authorities with enough lead time to allow the other Party to comment on such drafts, and take into account all of the other Party's reasonable comments on the same, provided that if the exchanges described in this clause 6.1 (a) are not practical, the Parties shall agree on a different procedure to maintain in substance the rights and interest of the Parties in connection therewith;

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- (b) to the extent permitted by the EMA, allow the other Party to participate in any meetings with the EMA relating to the Product;
- (c) not transfer, assign or grant any encumbrance on the MA and the ODDs, other than as expressly contemplated in this Agreement;
- (d) Satisfy all requirements and pay all fees to maintain the MA and the ODDs, [***];
- (e) [***].

6.2 After the transfer of the MA and the ODDs pursuant to clause 6.1, OE shall maintain and make available at any time to ERYtech (including for purposes of developing and registering directly or through licenses the Product outside of the Primary Indications or the Territory), without restrictions other than as expressly provided herein, an electronic data base with respect to all applications for such Marketing Authorization and all correspondence and files (including all underlying clinical data) relating to such Marketing Authorization, provided that if such information is not available in the electronic data base set forth in this clause 6.2 in a manner accessible to the other Party, each Party shall make available to the other Party within three (3) business days of such Party's request, a list of the countries in which a MA for the Product has been issued, together with the authorized indications and the identity of the holder.

6.3 [***].

6.4 OE shall, at its cost and expense, use Commercially Reasonable Efforts to obtain Marketing Authorizations for the Product for the Primary Indications from all competent Regulatory Authorities in countries within the Territory where the Centralized Procedure is not available, in its name. OE shall carry out, at its own cost and expense, any requirement by the relevant Regulatory Authority in relation to the grant of such Marketing Authorization or to be

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completed following such Marketing Authorization. At the request and expense of OE, ERYtech shall provide all reasonable assistance required by OE to obtain such Marketing Authorizations.

6.5 [***]

6.6 OE shall, at its own cost and expense, use Commercially Reasonable Efforts to obtain pricing and reimbursement approvals for the Product for the Primary Indications in all countries of the Territory [***]. To the extent lawful and practical (subject to the last sentence of this clause 6.6), OE shall submit to ERYtech its proposed pricing and reimbursement strategy in the Major Markets and all material correspondence received from the Regulatory Authorities in the Major Markets as soon as available and no later than within 15 days following receipt as well as all draft filings and material draft correspondence of OE and its Affiliates with the Regulatory Authorities with enough lead time to allow ERYtech to comment on such drafts, and OE shall take into account all of ERYtech's reasonable comments on the same. [***]. Subject to the preceding provisions of this clause 6.6 and without limiting OE's other obligations herein, OE shall use Commercially Reasonable Efforts to seek pricing and reimbursement approvals in at least one Major Market within [***] of the transfer to OE or issuance in OE's name of the MA for the Product and shall thereafter continue to seek pricing and reimbursement in the other Major Markets. If the exchanges described in this clause 6.6 are not practical, the Parties shall agree on a different procedure to maintain in substance the rights and interest of the Parties in connection therewith.

6.7 Within three (3) months after the Effective Date, ERYtech and OE shall enter into a Safety Data Exchange Agreement defining the responsibilities of the Parties to protect patients and promote their well-being in connection with the use of the Product. These responsibilities shall include mutually acceptable guidelines and procedures for the receipt, investigation, recordation, communication, and exchange (as between the Parties) and regulatory submission of adverse event reports and any other information concerning the safety of any Product. Such guidelines and procedures shall be in accordance with, and enable the Parties and their Affiliates to fulfil local and international regulatory reporting obligations. Until such Safety Data Exchange Agreement is entered into, ERYtech shall be responsible for the timely reporting to the appropriate Regulatory Authorities of all adverse events and any other information concerning the safety of Products, in each case, in accordance with Applicable Laws of the relevant countries.

7. Manufacture and Supply of Product

7.1 ERYtech shall manufacture or have manufactured, packaged and labeled the Product in accordance with the Specifications and cGMP.

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- 7.2 ERYtech shall use Commercially Reasonable Efforts to manufacture and supply the Product in the quantities required by OE. From date of issue of the first named patient authorization for the Product, OE shall provide to ERYtech a good faith rolling forecast covering its indicative requirements in Product over twelve (12) months and shall update such forecast within fifteen (15) days following the beginning of each calendar quarter. The Parties acknowledge and agree that ERYtech's current manufacturing capacity for the Product is [***] batches per month. To the extent that OE estimates that its requirements in Product will exceed such capacity, OE shall notify ERYtech at least [***] in advance.
- 7.3 ERYtech shall communicate, prior to implementation, any Product Change and shall take into account OE's reasonable comments (which shall not be unreasonably withheld or delayed) on such Product Change. For the purposes of this clause 7.3, "Product Changes" shall mean changes to the Specifications required by Applicable Laws (including, without limitation, cGMP) in France or at the European Union level or by the Regulatory Authority competent in France, or by medical or scientific concerns as to the quality, safety and/or efficacy of the Product. No change other than a Product Change may be implemented by ERYtech without the prior written consent of OE and the Parties shall agree such changes on a commercially reasonable basis. For the avoidance of doubt, ERYtech shall be free to implement minor changes which do not require any change to the MA, provided that ERYtech shall inform OE of any such changes.
- 7.4 ERYtech shall exclusively sell to OE the Product in the Primary Indications and the Territory. OE shall exclusively purchase from ERYtech, all of OE's, its Affiliates' or Sub-Licensees' requirements of the Product at the Supply Price, [***] subject to clause 7.5 below. ERYtech will supply the Product to OE and its Affiliates (including for resale by them to the Sub-Licensees) in finished packaged form, including outer packaging, ready to be sold and used.
- 7.5 OE or its Affiliates shall provide ERYtech with orders for Product specifying the following information:
- (a) the administration date for the Product, taking into account that the minimum time between the order and the administration date is [***] (for purposes of this Agreement, the administration date is the anticipated date of injection of the Product in the patient as notified by the clinician (or any other duly authorised representative) in the prescription form); and
 - (b) a valid prescription form signed by a clinician (or any other duly authorised representative) of the customer hospital containing the information set out in Schedule 7.5(b).

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- 7.6 Promptly following receipt of such order, ERYtech shall inform OE or its Affiliates of the acceptance of such order, which shall not unreasonably be withheld or delayed, or of any further information required prior to acceptance. Upon acceptance by ERYtech, such order shall become binding on both Parties (a “**Firm Order**”).
- 7.7 ERYtech has provided to OE the details of calculation of the initial Supply Price. Prior to the beginning of each calendar quarter, ERYtech shall notify OE of the Supply Price and details of its calculation, which shall apply to deliveries made during such calendar quarter. OE shall have the right as provided for under clause 13.5.
- 7.8 ERYtech shall invoice OE or its Affiliates for products at the time of delivery at the then applicable Supply Price and OE or its Affiliates shall pay all invoices within [***] after the end of the month in which the relevant invoices are issued.
- 7.9 OE acknowledges that, pursuant to this Agreement, it shall purchase and sell the Product for its own account and is not, and shall not hold itself out as, an agent of ERYtech.
- 7.10 The Parties shall agree special prices applicable to the supply of Product for clinical studies and other uses related to the Development of the Product and for pre-Marketing Authorization compassionate use programs. The special prices for the supply of the Product for the AML studies provided for in the current AML Development Plan are set forth in Schedule 1.1.2.
- 7.11 Within [***] following (i) OE’s submission of its first yearly sale forecast pursuant to clause 7.2 and thereafter (ii) OE’s submission of its yearly marketing plan, the Parties shall agree on a yearly manufacturing plan describing the manufacturing infrastructure, labor configuration and manufacturing cost forecast for the coming year based on the sale forecast of OE and pursuant to which ERYtech shall use Commercially Reasonable Efforts to reduce the manufacturing costs of the Product.

8. Delivery of Product

- 8.1 ERYtech shall deliver the Product to the customer stipulated in the Firm Order:
 - (a) on or before the administration date specified in the Firm Order; and
 - (b) ensuring that the Product has a remaining shelf-life of not less than [***] hours on the administration date specified in the Firm Order.

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- 8.2 Unless otherwise agreed, ERYtech shall deliver or arrange for the delivery of Products at the address of the customer stipulated in the Firm Order in accordance with conditions of [***] published by the International Chamber of Commerce, 2010 edition. Transportation of the Product shall be performed in accordance with any and all transportation instructions specified in the applicable Marketing Authorization.
- 8.3 Title and risks to Products sold pursuant to this Agreement shall pass to OE or its Affiliates upon delivery in accordance with clause 8.2.
- 8.4 Prior to the first delivery of a Product in any country, the Parties shall agree on a blood product traceability program in accordance with local regulatory requirements, which shall be updated from time to time in accordance with local regulatory requirements. By way of example, the program applicable to France is attached as Schedule 8.4.
- 8.5 OE or its Affiliates shall notify ERYtech of any claim that the Product did not meet the Specifications (a “**Claim**”) within [***] of being advised by the customer to whom the Product is delivered or its representative or otherwise becoming aware of such defect. OE shall request and shall use its Commercially Reasonable Efforts to obtain directly or through Affiliates or Sublicensees an acknowledgment of receipt of the Product by customers. The Product delivered by ERYtech shall contain a notice stating the expiry date of the Product and requesting the customer to promptly inform OE or its Affiliates and Sublicensees, as the case may be, of its failure to use the Product by expiry date. ERYtech shall then conduct investigations on the concerned shipment or batch. If ERYtech agrees with the Claim, ERYtech, at the claimant’s option, shall either replace such shipment of Product as soon as reasonably possible at no cost to the claimant or give credit for payment made by the claimant for such shipment including any related reasonable expenses to the claimant. If the Parties are unable to resolve their differences with respect to whether the Products meet the Specifications, then either Party may refer the matter to an independent laboratory or technical assessment organization, in order to resolve the matter. Unless otherwise agreed in writing, the cost of the independent laboratory or organization shall be borne by the Party in error,
- 8.6 If either Party determines that a Product needs to be recalled, it shall inform and consult with the other Party concerning the proposed manner in which the recall is to be carried out. In the event of a disagreement, the Party which is the MA holder in the country of the Territory where the recall is proposed shall have the final decision making authority as to such recall and the other Party shall provide all necessary assistance to proceed expeditiously with the recall in such a way as to comply with good public health practices, to attempt to cause the least disruption of sales of the Products in the Territory and to preserve the goodwill and reputation of the Products and reputation of OE, its

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Affiliates, and ERYtech. If the recall is attributable to a failure to meet the Specifications or cGMP requirements at delivery of the Product, then ERYtech shall bear all reasonable and documented costs of such recall. If the recall is due to marketing and selling activities, then OE shall bear all reasonable and documented costs of such recall. If the recall is due to other reasons each Party shall bear 50% of the costs of such recall.

9. Diligence Obligations, Advertising and Promotion

- 9.1 OE shall, at its own cost and expense, use Commercially Reasonable Efforts to market and promote the Product in the Primary Indications in the Territory.
- 9.2 Not later than [***] after the submission of the application for a Marketing Authorization for the Product in the Territory, respectively, in the ALL Indication and the AML Indication, OE shall prepare and submit to ERYtech for review and comments (which reasonable comments of ERYtech shall be taken into account by OE) a marketing plan for the Product in the ALL Indication or the AML Indication (respectively, the “**ALL Marketing Plan**” and the “**AML Marketing Plan**”), which shall be consistent with the regulatory profile and market potential of the Product and the obligations of OE pursuant to clause 9.1. Such marketing plan shall [***]. Subject to clauses 6.5 and 6.6, OE shall launch the Product in each of the Primary Indications in each country of the Major Markets no later than [***] following the later of the issue of the MA or the pricing and reimbursement approvals if needed for effective market access in such country.
- 9.3 No later than [***] prior to the end of each calendar year following the grant of the MA of the Product in the Territory respectively in the ALL Indication and the AML Indication, OE shall prepare and submit to ERYtech for review and comments (which reasonable comments shall be taken into account by OE), a revised marketing plan for the Product in the ALL Indication or the AML Indication, which shall become respectively the ALL Marketing Plan and the AML Marketing Plan.
- 9.4 At any time, in the event of likely delays or shortcomings in the ALL Marketing Plan or AML Marketing Plan, OE shall promptly inform ERYtech and provide sufficient information to reasonably explain such delay or shortcoming in light of OE’s diligence obligations under this Agreement. OE shall take into account ERYtech’s reasonable suggestions to mitigate these delays or shortcomings.
- 9.5 Without limitation to the provisions of clause 9.4, once a calendar year following the grant of the MA of the Product in the Territory respectively in the ALL Indication and the AML Indication and during the first quarter of each such calendar year, ERYtech has the right to request a written report setting out the principal marketing and promotional activities conducted in the Major Markets by OE in the preceding calendar year.

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- 9.6 OE shall market and promote the Product in the ALL Indication in accordance with the ALL Marketing Plan and in the AML Indication in accordance with the AML Marketing Plan.
- 9.7 In connection with the marketing and promotion of the Products in the Territory, OE shall use only advertising and promotional materials in accordance with the MA and Applicable Laws, and, if practicable and limited to the Major Markets, shall communicate a copy of all such advertising and promotional materials (in original language) to ERYtech.
- 9.8 OE shall be responsible for training its personnel who market and promote the Product so that they are knowledgeable about the Product and can properly present the Product. ERYtech shall provide assistance to OE in providing such training at OE's request, cost and expense.
- 9.9 Any significant communication from any Regulatory Authority in connection with Products, concerning their medical profile, safety, efficacy or regulatory status shall be included in the electronic database maintained as provided in clause 6.2.

10. Joint Steering Committee

- 10.1 Promptly following the Effective Date the Parties shall establish a joint steering committee consisting of two (2) representatives of each Party (the “**Joint Steering Committee**”) to oversee the Development activities and the activities concerning the grant of the Marketing Authorization and in relation to the pricing and reimbursement and market access and launch activities of Products under this Agreement. Each Party may, from time to time, replace its representatives by written notice to the other Party specifying the prior representative and the replacement.
- 10.2 The Joint Steering Committee shall meet via teleconference, or, if agreed by the Parties, in person, at least once each calendar quarter during the Term of this Agreement (until the dissolution of the Joint Steering Committee pursuant to clause 10.4) at a frequency and times mutually agreed upon by the Parties. Each Party shall have the right to appoint one (1) of its representatives to alternate for periods of twelve (12) months as the chairman of the Joint Steering Committee. ERYtech shall appoint the first chairman. A specific agenda shall be drawn up before each meeting of the Joint Steering Committee by the chairman, consulting the representatives of the other Party. Subsequent to each meeting, the chairman shall draw up the minutes and distribute such minutes for signature by both Parties. All decisions of the Joint Steering Committee shall be made by consensus, with each Party's representatives on the Joint Steering Committee collectively having one (1) vote. [***].

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10.3 The Joint Steering Committee shall have responsibility for:

- (a) reviewing and supervising the Development of the Product for the ALL Indication;
- (b) adopting and then, from time to time, revising the AML Development Plan;
- (c) reviewing and supervising the Development of the Product pursuant to the AML Development Plan;
- (d) ensuring that the data generated by the Parties is adequate for the purposes of applications to the EMA for Marketing Authorizations for the Product for the Primary Indications;
- (e) overseeing Development, registration and market access activities for the Product in the Primary Indications in the Territory.

10.4 The Joint Steering Committee shall be dissolved upon the later to occur of the following events:

- (a) the commercial launch of the Product in the ALL Indication in all Major Markets; and
- (b) the grant of a Marketing Authorization for the Product in the AML Indication in all Major Markets.

11. Upfront and Milestone Payments

11.1 Within three (3) business days of the Effective Date, OE shall pay to ERYtech the sum of five million Euros (€5,000,000) (the “**Upfront Payment**”).

11.2 Upon the issue of the Marketing Authorization for the Product pursuant to the Centralized Procedure in:

- (a) ALL Indication, OE shall owe ERYtech an approval milestone of [***] Euros (€[***]);
 - (b) AML Indication, OE shall owe ERYtech an approval milestone of [***] Euros (€[***]);
- (the payment in (a) and (b) being referred to as the “**Approval Milestones**”).

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11.3 In addition to the Upfront Payment and the Approval Milestones, the following amounts shall be due by OE to ERYtech upon occurrence (if applicable) of the events triggering the following commercial milestones:

- (a) [***] Euros (€[***]) when cumulative Net Sales in the Territory in the Primary Indications first exceed [***] Euros (€[***]);
- (b) [***] Euros (€[***]) when cumulative Net Sales in the Territory in the Primary Indications first exceed [***] Euros (€[***]); and
- (c) [***] Euros (€[***]) when cumulative Net Sales in the Territory in the Primary Indications first exceed [***] Euros (€[***])

(together, the “**Commercial Milestones**”, the Approval Milestones and the Commercial Milestones being individually and collectively referred to as the “**Milestones**”).

11.4 OE shall respectively pay the Approval Milestones and the Commercial Milestones to ERYtech within [***] after the end of the month in which the event triggering the relevant Approval Milestone or Commercial Milestone occurred.

11.5 The Upfront Payment and, subject to clause 17, the Approval Milestones and Commercial Milestones shall be [***].

12. Royalties and Supply Price

12.1 OE shall pay to ERYtech a royalty of [***] percent ([***]%) on Net Sales (the “**Royalty**”), subject to and in accordance with the provisions of this clause 12.

12.2 In the event that the total of the Supply Price for Products supplied to OE and its Affiliates in any calendar quarter and the Royalty in any calendar quarter is greater than an amount equal to forty five percent (45%) of Net Sales for such calendar quarter:

- (a) if the total of the Supply Price for Products supplied to OE and its Affiliates in any calendar quarter is lower than an amount equal to forty five percent (45%) of Net Sales for such calendar quarter, OE’s payment obligations for such quarter shall be capped at forty five percent (45%) of Net Sales for such quarter by reducing the Royalty due for that quarter to an amount such that the sum of the Supply Price for Products supplied to OE and its Affiliates in any calendar quarter and the Royalty in any calendar quarter is equal to forty five percent (45%) of Net Sales for such calendar quarter;

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- (b) if the total of the Supply Price for Products supplied to OE and its Affiliates in any calendar quarter is itself already greater than an amount equal to forty five percent (45%) of Net Sales for such calendar quarter, OE's payment obligations for such quarter shall be capped at forty five percent (45%) of Net Sales for such quarter and any excess shall be credited back to OE by means of the issuance, by ERYtech, of a credit note of corresponding amount (subject to clause 12.2 (c)) and, consequently, no Royalty shall be due for that quarter;
- (c) notwithstanding any other provisions of this Agreement, if, starting [***] after the issuance of the MA granted by the EMA in the ALL Indication, the Supply Price is higher than forty five percent (45%) of Net Sales (the "**Cap**") in any given calendar quarter after such [***] period, ERYtech may request by notice to OE that the Parties enter into good faith negotiations to adjust the Cap, in order to preserve ERYtech's ability to perform the Agreement [***]. In the event that the Parties fail to agree on the above adjustment of the Cap within six (6) months following the date of ERYtech's notice, each Party shall submit its final and best offer with respect to such adjustment to an expert appointed by mutual agreement of the Parties or, in the absence of such agreement, by the President of the Lyon commercial court, and such expert shall, within three (3) months of his appointment, select the offer that, in his opinion, most closely reach the aim above described; the decision of the expert shall be final and binding on the Parties.

12.3 All Royalty payments shall be payable in Euros, regardless of the countries in which sales of Product are made. For the purposes of calculating Net Sales of Product for which currencies other than Euros are received, such currency shall be converted into Euros [***].

12.4 Calculation of Royalty shall occur as follows:

Within [***] from the end of each calendar quarter, OE shall provide to ERYtech a written report setting out:

- (a) the number of units of Product sold, details of the countries in which they were sold by OE, its Affiliates or its Sub-Licensees during the applicable quarter;
- (b) the gross amount invoiced by OE, its Affiliates and its Sub-Licensees to Third Parties for such Product in the applicable quarter;

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- (c) the deductions made, and the basis for such deductions, from such gross invoiced amount for the applicable quarter;
- (d) the resulting amount of Net Sales for the applicable quarter;
- (e) the theoretical Royalty due to ERYtech with respect to such quarter;
- (f) the total Supply Price of Products supplied to OE and its Affiliates by ERYtech in such quarter;
- (g) the amount actually payable to ERYtech for such quarter, after application of clause 12.2 (a); and
- (h) if applicable, the amount of the credit note to be issued by ERYtech in favour of OE in accordance with clause 12.2 (b).

Without prejudice to ERYtech's right to dispute the report within [***] of its receipt, OE shall effect the payment or ERYtech, if applicable, shall issue the credit note under clause 12.2 (b) no later than within [***] calendar days from the end of the corresponding quarter.

In case of disputes, the provision of clauses 13.4 and 13.5 shall apply and the additional payment or, if applicable, the issuance of the additional credit note shall be effected after thirty (30) calendar days from the determination of the independent reputable certified public accountant, which shall be binding upon the Parties save the case of manifest error or fraud.

13. General Payment Provisions

- 13.1 If a credit note is issued by ERYtech pursuant to clause 12, OE shall be entitled to set off the amount of such credit note against any amount due by OE to ERYtech.
- 13.2 If OE fails to make any payment within the time period for payment established herein, such failure will constitute a breach of the Agreement and grounds for termination by ERYtech pursuant to clause 15 hereof, unless it is cured by OE pursuant to clause 15 hereof.
- 13.3 Notwithstanding ERYtech's right to terminate this Agreement for non-payment by OE in accordance with clause 13.2 above, ERYtech shall be entitled to charge OE interest on any late payments from the due date until the date on which payment is actually received at [***], on the last business day of each month [***] (but not more than the highest rate allowed by applicable law and no less than the lowest rate required by applicable law). OE shall be entitled to charge ERYtech the same interest on any late issuance of credit notes or other payment due by ERYtech under this Agreement, if applicable.

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- 13.4 During the Term of this Agreement and for a period of [***], ERYtech, or an independent reputable certified public accountant selected by and retained at the expense of ERYtech with the approval of OE (such approval not to be unreasonably withheld), shall have the right to examine during normal working hours, at a date previously agreed upon with OE, but not more than once in each calendar year, the books and records of the current calendar year and the [***] as kept by OE necessary to verify the accuracy of the Product sales made in the Territory, reports presented and payments made to ERYtech hereunder. If the discrepancy between the payments made to ERYtech and the payments due to ERYtech hereunder exceeds [***], the cost of such audit shall be borne by OE.
- 13.5 During the Term of this Agreement and for a period of [***], OE, or an independent reputable certified public accountant selected by and retained at the expense of OE with the approval of ERYtech (such approval not to be unreasonably withheld), shall have the right to examine during normal working hours, at a date previously agreed upon with ERYtech, but not more than once in each calendar year, the books and records of the current calendar year and the [***] as kept by ERYtech necessary to verify the accuracy of the Supply Price and its calculation made and notified by ERYtech under this Agreement. If the discrepancy between the payments made to ERYtech and the payments due to ERYtech hereunder resulting from the determination of the Supply Price by OE exceeds [***], the cost of such audit shall be borne by ERYtech.

14. Trade Marks; Intellectual Property Rights

- 14.1 ERYtech hereby grants OE an exclusive license to use the Trade Mark in connection with the marketing and sale of the Product for the Primary Indications in the Territory as permitted by this Agreement.
- 14.2 OE shall not use any trade mark other than the Trade Mark in connection with the marketing and sale of the Product for the Primary Indications in the Territory. OE shall not use, apply for and register, without ERYtech's prior consent, the Trade Mark as part of its corporate name, trade name, trading style or other means of corporate or business identification including use and registration of domain names and other internet key words. Subject to Applicable Laws, OE shall respect the visual style guidelines communicated by ERYtech to OE in writing in order to use the Trade Mark.
- 14.3 In the event that OE reasonably determines that it is not appropriate to use the Trade Mark in any country within the Territory it shall notify ERYtech and propose a different trade mark of OE, to be registered in the name of OE and used in connection with the marketing and sale of the Product for the Primary Indications in that country of the Territory, provided that ERYtech shall consent, without delay, to the use of such different trade mark. Such trade mark shall thereafter be considered to be a "Trade Mark" for the purposes of this Agreement for that country of the Territory only.

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- 14.4 ERYtech shall retain all right, title and interest in and to all of Patents and Results that relate to the Product and OE shall have no right to Licensed IP except under the license granted pursuant to this Agreement.
- 14.5 ERYtech shall own all Improvements that are generated by or on behalf of ERYtech or its Affiliates or OE, its Affiliates or their Sublicensees and/or their respective employees, agents and independent contractors in the course of conducting its activities under this Agreement (including pursuant to the AML Development Plan). OE shall provide, and shall cause its Affiliates, Sublicensees and their respective employees to provide, any and all assignments or other documents reasonably required by ERYtech to vest in ERYtech ownership of all such Improvements.
- 14.6 Each Party shall report to the other, as soon as reasonably possible, any information, which may come to its attention with respect to Trade Mark in the Territory or the Licensed IP (whether in or outside the Territory), including potential infringement of or challenge to the validity or ownership by a Third Party.
- 14.7 ERYtech shall, at its own expense, prosecute and maintain the Trade Mark (provided that the Trade Mark is owned by ERYtech) and the Licensed IP in the Territory, including the payment of all renewal fees, take all such steps, including initiating proceedings, as OE may reasonably require to stop any alleged infringement of the Trade Mark or the Licensed IP in the Territory or to defend the Trade Mark or the Licensed IP from any attack, including any invalidity or revocation proceedings; at ERYtech's request, OE shall give ERYtech all reasonable assistance in respect of any such proceedings, subject to ERYtech meeting all reasonable costs and expenses incurred by OE in giving such assistance. If ERYtech is not willing or interested in initiating action against an infringer, OE shall be entitled, but not obligated, to enter an action in its own name based on the infringement of the Trade Mark or the Licensed IP in the Territory subject to ERYtech's consent. ERYtech may only refuse its consent for good cause and will give OE all assistance, at ERYtech's cost, as OE may reasonably request in connection with any such action. Additionally, ERYtech agrees to keep OE informed regarding the status and maintenance of the Licensed IP and the Trade Mark in the Territory, the prosecution of any application therein, and without limiting the foregoing shall not allow any Licensed IP or Licensed IP application, Trade Mark or Trade Mark application in the Territory to lapse without OE's consent.

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- 14.8 In addition to what is provided under clause 14.7, [***] any litigation related thereto which challenges the validity or scope of the Licensed IP covering the Product (but excluding any infringement claims made by a Third Party, which will be dealt with pursuant to clause 17), ERYtech shall,
- (a) conduct the defence of [***] any litigation related thereto which challenges the validity or scope of the Licensed IP covering the Product (unless it involves OE pursuant to clause 14.9) and pursue and/or defend the claim or litigation until its final stage (unless it is settled in the meantime subject to the following paragraph (d)), be fully and solely responsible for prosecuting and appropriately and diligently defending any counterclaims, asserting affirmative defences and addressing any other issues [***], including without limitation: (i) selection of the litigation counsel and assumption of all costs and expenses concerning [***] any litigation related thereto (including lawyers' and experts' fees and costs) and (ii) payment of any damages, award, fine, or other damages that may be assessed against ERYtech;
 - (b) keep OE duly and promptly informed of any substantive notice, communication or other information however received by ERYtech in relation to [***] any litigation related thereto which challenges the validity of the Licensed IP covering the Product and shall take into account any reasonable comments of OE concerning the selection of the lawyer, the conduct or the defence of [***] any litigation resulting therefrom before any activities or actions are taken or performed by ERYtech;
 - (c) co-operate with OE in respect of any judicial or administrative remedies and/or actions OE may take or seek [***], by giving, amongst others, OE full access to all records, files and data relating thereto and by bearing all reasonable out-of-pocket costs and expenses thereto (including, reasonable expert, legal counsel and lawyer fees);
 - (d) promptly and regularly consult with OE in the settlement negotiations and/or other initiatives in relation thereto, it being understood that ERYtech shall not enter into any settlement or similar arrangement (including, but not limited to, a license agreement relating to a Third Party's intellectual property or know-how) that may adversely affect the validity or term of the Licensed IP or any other provisions of this Agreement or the rights of OE or its Affiliates, without OE's prior written consent, which shall not be unreasonably withheld;
 - (e) hold OE fully harmless and indemnified against any Third Party's claims against OE causing any liability, damages, or losses incurred by OE [***] (including settlement).

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- 14.9 In addition to what is provided under clause 14.8, in the event that OE is sued or involuntarily joined in [***] any litigation, settlement or action related thereto which challenges the validity of the Licensed IP covering the Product (but excluding infringement claims made by a Third Party, which will be dealt with pursuant to clause 17) (all above circumstances, collectively, the “**OE Action**”), OE shall have the right to direct, conduct and prosecute the OE Action at its reasonable discretion, keeping ERYtech informed on the status of such OE Action. ERYtech shall (i) reasonably assist OE, (ii) give OE full access to all records, files and data relating to the OE Action and the subject matter thereof, (iii) reimburse all OE’s out-of-pocket costs and expenses (including reasonable lawyers and experts’ fees and costs) regarding the OE Action and (iv) without prejudice to clause 17.11, hold OE fully harmless and indemnified against any liability, damages, or losses incurred by OE in respect of, or in relation to, the OE Action, provided that OE shall use Commercially Reasonable Efforts to mitigate any such liability, damages, or losses.
- 14.10 Subject to clause 14.9, each Party will, upon the reasonable request of the other Party, provide such assistance and execute such documents as are reasonably necessary for such Party to exercise its rights and perform its obligations pursuant to this clause 14.

15. Duration and Termination

15.1 This Agreement shall come into force on the Effective Date and shall continue, on a country-by-country basis:

- (a) in those countries of the Territory subject to Centralized Procedure, a period of ten (10) years from the date of grant of a Marketing Authorization for the Product in the ALL Indication, which shall be extended until the expiry of a period of ten (10) years from the date of grant of a Marketing Authorization for the Product in the AML Indication but solely to the extent that such grant in the AML Indication occurs no later than [***]; and
 - (b) in those countries of the Territory not subject to the Centralized Procedure, a period of ten (10) years from the date of grant of a Marketing Authorization for the Product in the ALL Indication or in the AML Indication by the competent Regulatory Authority in such country, provided that, in any event, the term of this Agreement in those countries of the Territory not subject to the Centralized Procedure shall expire no later than [***] following the expiry of the term set forth in subclause (a);
- (the “**Initial Term**”)

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- 15.2 On the expiry, on a country-by-country basis, of the Initial Term or the then current Renewal Term, if OE is in compliance with its material obligations under this Agreement, OE shall be entitled to request an extension of the Initial Term for a further period of ten (10) years on a country-by-country basis. ERYtech may agree or refuse such extension (each a “**Renewal Term**”) in its absolute discretion.
- 15.3 If ERYtech refuses a request by OE to extend the Initial Term pursuant to clause 15.2 or the then current Renewal Term in the countries of the Territory subject to Centralized Procedure, OE shall be entitled to receive from ERYtech, as its sole remedy in connection with such refusal, an amount equal to the greater of:
- (a) the [***] in such countries of the Territory subject to Centralized Procedure for the [***]; or
 - (b) the sum of the [***] properly paid or incurred by OE pursuant to this Agreement during the preceding Initial Term or Renewal Term,
- provided that the [***] in such countries of the Territory subject to Centralized Procedure shall be calculated by OE and agreed by ERYtech [***] from the date of refusal of such extension, failing which the [***] shall be determined by an independent expert from a reputable audit or accounting firm appointed by both Parties. If ERYtech and OE cannot agree on the appointment of an expert within fifteen (15) days from the notice of disagreement, the expert shall be appointed by the president of the commercial court of Lyon at the request of either Party.
- 15.4 In the event that a Party has committed a serious breach (*faute grave*) (the “**Breach**”) of any of its essential obligations under this Agreement (the “**Breaching Party**”), the other Party (the “**Other Party**”) shall notify the Breaching Party within [***] days of becoming aware of the Breach and shall require that the Breaching Party cure the Breach within [***] business days from receipt of such notice, and shall describe in reasonable details the Breach. [***].
- 15.5 Either Party may terminate this Agreement immediately upon written notice to the other Party in the event that the other Party:
- (a) becomes insolvent or ceases to carry on its business;
 - (b) goes into liquidation, whether voluntary or compulsory (other than a voluntary liquidation for the purposes of reconstruction or amalgamation);

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(c) has a receiver, trustee, *administrateur judiciaire*, *mandataire ad hoc*, or other officer with similar powers appointed with respect to it or with respect to the whole or any substantial part of its assets; or

(d) enters into an arrangement or composition with its creditors or becomes bankrupt.

15.6 ERYtech may terminate this Agreement upon [***] days written notice to OE if:

(a) [***]; or

(b) [***].

15.7 OE may terminate this Agreement by giving ERYtech [***] days prior written notice (i) for reasons related to [***].

16. Consequences of Termination

16.1 Upon expiry or termination of this Agreement in all or part:

(a) all rights granted to OE under this Agreement (or in case of partial termination, all rights granted to OE under this Agreement in connection with the terminated indication or country) shall immediately cease and terminate on a country-by-country basis provided that pending orders for the Product transmitted to ERYtech prior to the termination shall be satisfied pursuant to the terms of this Agreement;

(b) (provided such termination or expiry relates to all countries within the Territory) each Party shall immediately return to the other any Information in documentary or printed form and shall cease all use of such Information, provided that each Party shall be entitled to retain a copy to the extent required by Applicable Laws;

(c) OE shall transfer (or cause the transfer of) any Marketing Authorizations and ODDs for the Product and related correspondence and files which are in the name of OE, its Affiliates or Sublicensees, to ERYtech, and shall provide any authorizations, certificates or other documents that ERYtech may reasonably require in this connection (or in case of partial termination, all Marketing Authorizations for the Product and related correspondence and files and any other authorizations, certificates or other documents in connection with the terminated indication or country, provided that a copy of correspondence and files shall be retained by OE, its Affiliates or Sublicensees).

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- (d) If upon expiry or termination of this Agreement, the Product is marketed under a Trade Mark other than GRASPA® pursuant to clause 14.3, then OE shall, or shall cause its Affiliates to grant to ERYtech [***] license, with a right to sublicense, under such Trade Mark, solely for use to market the Product in the countries in which OE, its Affiliates or sublicensees have marketed the Product under such Trade Mark and for a term of [***] in order to allow a smooth switch to another trade mark, it being understood that ERYtech shall hold OE harmless and indemnified in case of infringement of the Trade Mark or any action against such Trade Mark resulting from the commercialization by or on behalf of ERYtech or any actions or omissions of ERYtech or its sublicensees in connection with such Trade Mark.

- 16.2 Termination or expiry of this Agreement shall not affect either Party's obligation to pay to the other Party any amount accruing prior to or on the date of termination or expiry and shall not relieve either Party of any liability which may have accrued hereunder prior to or on the date of termination or expiry.

17. Covenants, Warranties, Limitation of Liability, Indemnities and Insurance

17.1 ERYtech, on its behalf and on behalf of its Affiliates, covenants, represents and warrants the following:

- (a) as at the Effective Date, ERYtech has the power to enter into and perform, and has taken all necessary action to authorise the entry into and performance of, this Agreement and the transactions contemplated herein and this Agreement constitutes a legal and valid obligation binding upon ERYtech and enforceable against it in accordance with its terms;
- (b) as at the Effective Date, the execution, delivery and performance of the Agreement by ERYtech does not conflict with any agreement, instrument or understanding, oral or written, to which it is a party or by which it is bound, nor violate any law or regulation of any court, governmental body or administrative or other agency having jurisdiction over it. Subject to clause 6, as at the Effective Date, all authorizations required by it in connection with the entry into, performance, validity and enforceability of, and the transactions contemplated by, this Agreement have been obtained or effected (as appropriate) and are in full force and effect;
- (c) the Product delivered under this Agreement will be manufactured in accordance with cGMP requirements and conform to the Specifications at the time of delivery thereof in accordance with clauses 8.1 and 8.2;

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- (d) [***];
- (e) as of the Effective Date, ERYtech is the lawful owner of the Licensed IP and the Trade Mark and has the sole right and authority to enter into this Agreement and grant the rights and licenses hereunder;
- (f) the Licensed IP is not used and will not be used in connection with the Product in the Primary Indications and in the Territory by ERYtech or by any ERYtech's Affiliate or Third Party during the term of this Agreement (other than in the performance of this Agreement). To this end, ERYtech hereby undertakes not to transfer the Licensed IP or grant any rights deriving therefrom in the Primary Indications and the Territory to any Third Party or apply for, directly or indirectly, patents other than patents which become part of the Licensed IP in relation to the Product in the Primary Indications and the Territory (directly or indirectly, including through the intermediary of Affiliates or Third Parties), during the term of this Agreement;
- (g) the Trade Mark is not used and will not be used in the Territory by ERYtech or by any ERYtech's Affiliate or Third Party during the term of this Agreement (other than in the performance of this Agreement). To this end, ERYtech hereby undertakes not to transfer the Trade Mark or to grant any rights deriving therefrom in the Territory to any Third Party, including through the intermediary of Affiliates or Third Parties, during the term of this Agreement;
- (h) ERYtech has not previously granted, and during the period of this Agreement will not grant, any rights in the Licensed IP or the Trade Mark that are inconsistent with the rights and licenses granted to OE herein. ERYtech shall not suffer or permit any liens or restrictions (other than any licenses outside of the Territory or of the Primary Indications) to be imposed on the Patent Rights or the Trade Mark, without the prior written consent of OE;
- (i) to ERYtech's actual knowledge as of the Effective Date, [***] (i) the use of the Licensed IP and the Trade Mark and the supply of the Product in the Territory by OE as contemplated pursuant to this Agreement does not infringe any patent or trade mark of any Third Party, (ii) there are no intellectual property rights of any Third Party which may prevent or hinder the performance of obligations

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or exercise of rights under this Agreement, and (iii) none of the patents within the Licensed IP or the Trade Mark is invalid, unenforceable or has been misused;

- (j) (1) the information provided to OE and its consultants in relation to [***] is, in ERYtech's actual knowledge, comprehensive, true and correct.

(2) In particular, ERYtech, on its behalf and on behalf of its Affiliates, represents and warrants that the statements on process and product properties in Schedule 17 (j) (2) are true and correct.
- (k) the Product delivered under this Agreement will be manufactured with the process disclosed in international patent application WO 2006/016247 unless agreed upon between the Parties;
- (l) as of the Effective Date, there are no existing actions, suits or proceedings, and [***] ERYtech has not received any written claim or demand from a Third Party, that challenges ERYtech's rights with respect to the Licensed IP, the Trademark and/or the Product or ERYtech's rights to enter into this Agreement or that asserts that development, manufacture or sale of the Products would infringe the intellectual property rights of a Third Party;
- (m) as of the Effective Date, the [***] is a valid, enforceable and binding obligation of [***] to [***] ERYtech with [***] until [***]. The [***] cannot be [***] by [***] unless (i) for [***] in the [***] of the [***] or (ii) with [***].
- (n) as of the Effective Date, [***] of the [***] or [***];
- (o) ERYtech (i) will not [***] of the [***], in a way reasonably allowing and actually resulting in [***] or [***] of [***] of the [***]; (ii) will not [***] to the [***] of the [***] unless [***], which [***], having in mind its interest in marketing the Product, and maximizing its margin from such marketing, under this Agreement; and (iii) will not [***] to be delivered to OE under this Agreement, whether for clinical trials or for commercial use, (or, if applicable, to be supplied directly by ERYtech for clinical trials, including - for the avoidance of doubt - clinical trials for the AML Indication and for the ALL Indication) the [***], in particular with [***] ("["***]"), unless [***] is required by Applicable Laws, or it has received [***];
- (p) in view of obtaining a Marketing Authorization, (i) ERYtech is currently performing in Europe a Phase II/III clinical trial with GRASPA® in relapse acute lymphoblastic leukaemia in children

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and adults and (ii) has completed a Phase II clinical trial with Graspa in first line acute lymphoblastic leukaemia in adults over 55 years old; and

- (q) ERYtech has or will have the ability, capacity, knowledge, experience, facilities, warehouse, equipment, qualified personnel and financial resources to, directly or indirectly, carry out and perform all acts necessary to perform its obligations under this Agreement.

17.2 ERYtech makes no other warranty of any kind, express or implied, including but not limited to warranties of merchantability and fitness for a particular purpose.

17.3 OE, on its behalf and on behalf of its Affiliates, represents and warrants the following as at the Effective Date:

- (a) OE has the power to enter into and perform, and has taken all necessary action to authorise the entry into and performance of, this Agreement and the transactions contemplated herein and this Agreement constitutes a legal and valid obligation binding upon OE and enforceable against it in accordance with its terms;
- (b) the execution, delivery and performance of the Agreement by OE does not conflict with any agreement, instrument or understanding, oral or written, to which it is a party or by which it is bound, nor violate any law or regulation of any court, governmental body or administrative or other agency having jurisdiction over it. Subject to clause 6, all authorizations required by it in connection with the entry into, performance, validity and enforceability of, and the transactions contemplated by, this Agreement have been obtained or effected (as appropriate) and are in full force and effect; and
- (c) OE has or will have the ability, capacity, knowledge, experience, facilities, warehouse, equipment, qualified personnel and financial resources to carry out and perform, directly or indirectly, all acts necessary to perform its obligations under this Agreement;
- (d) If a trade mark other than the Trade Mark owned by ERYtech is used for the Product in any given country of the Territory pursuant to clause 14.3, such trade mark shall not be used in such country by OE, its Affiliates or Third Party during the term of this Agreement other than for the Product in the performance of this Agreement. To this end, OE hereby undertakes not to transfer said trade mark, to grant any rights deriving therefrom in such country of the Territory to any Third Party, including through the intermediary of Affiliates or Third Parties, during the term of this Agreement.

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- 17.4 OE makes no other warranty of any kind, express or implied, including but not limited to warranties of merchantability and fitness for a particular purpose.
- 17.5 OE acknowledges it has been informed of the [***] contained in [***] of the [***].
- 17.6 OE covenants that, if OE should give its written approval to [***] under this Agreement, OE will then [***] as set out in [***] of the [***] ([***) in marketing the Product in the Territory during the term of this Agreement, provided that the [***] is [***].
- 17.7 OE shall indemnify, defend and hold ERYtech, its Affiliates and the officers, directors and employees of each of them (“**ERYtech Indemnitees**”), harmless from any and all losses, liabilities, obligations, claims, fees or expenses, including reasonable attorneys’ fees, that stem from claims brought by Third Parties that are based upon the following circumstances other than to the extent indemnifiable by ERYtech pursuant to clauses 14.8, 14.9 and 17.8:
- (a) the use or sale or other distribution of Product by or on behalf of OE, its Affiliates or its Sub-licensees;
 - (b) the material breach of any obligations, covenants or representations and warranties made by OE hereunder; or
 - (c) the negligence, recklessness or willful misconduct of OE or its Sub-licensees hereunder.
- The indemnification obligations set forth in this clause 17.7 shall not apply to the extent that any loss is the result of a breach of this Agreement (including a breach of any representation or warranty) by ERYtech or the negligence or wilful misconduct of any ERYtech Indemnitees. For the avoidance of doubt, [***].
- 17.8 Without prejudice to clauses 14.8 and 14.9, ERYtech shall indemnify, defend and hold OE and its Affiliates and the officers, directors and employees of each of them (“**OE Indemnitees**”), [***] liabilities, obligations, claims, fees or expenses, including reasonable attorneys’ fees, that stem from claims brought by Third Parties that are based upon the following circumstances other than to the extent indemnifiable by OE pursuant to clause 17.7:
- (a) the manufacturing of the Product and the delivery of Product to customers;

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- (b) the infringement, or alleged infringement, by OE or its Affiliates or Sub-licensees of any intellectual property rights of any Third Party in relation to the use or sale or other distribution of Product by or on behalf of OE, its Affiliates or its Sub-licensees pursuant to this Agreement;
- (c) the material breach of any obligations, covenants or representations and warranties made by ERYtech hereunder; or
- (d) the negligence, recklessness or willful misconduct of ERYtech or its Affiliates.

17.9 The Party claiming indemnity under clauses 17.7 or 17.8 (the “**Indemnified Party**”) shall give written notice to the Party from whom indemnity is being sought (the “**Indemnifying Party**”) promptly after learning of the claim, suit, proceeding or cause of action for which indemnity is being sought (a “**Claim**”), and shall permit the Indemnifying Party to control and assume the defense of any litigation relating to such Claim and disposition of any such Claim.

- (i) If the Indemnifying Party does assume the defense of any Claim, it: shall act diligently and in good faith with respect to all matters relating to the settlement or disposition of any Claim as the settlement or disposition relates to the Indemnified Party; (b) shall cause such defense to be conducted by counsel reasonably acceptable to the Indemnified Party; and (c) shall not settle or otherwise resolve any Claim without prior notice to the Indemnified Party and the consent of the Indemnified Party if such settlement involves anything other than the payment of money by the Indemnifying Party. The Indemnified Party shall reasonably cooperate with the Indemnifying Party in its defense of any claim for which the Indemnifying Party has assumed the defense in accordance with this clause 17.9, and shall have the right (at its own expense) to be present in person or through counsel at all legal proceedings giving rise to the right of indemnification. The Indemnified Party shall not settle any such Claim without the prior written consent of the Indemnifying Party.
- (ii) If the Indemnifying Party does not assume the defense of the Claim, the Indemnified Party may decide to assume the defense of such Claim and if it decides so, then it: (a) shall act diligently and in good faith with respect to all matters relating to the settlement or disposition of such Claim; and (b) shall not settle or otherwise resolve any such Claim

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without prior notice to the Indemnifying Party and the consent of the Indemnifying Party if such settlement involves anything other than the payment of money by the Indemnifying Party, in any case, without prejudice to the indemnification obligation of the Indemnifying Party pursuant to clauses 17.7 or 17.8. The Indemnifying Party shall reasonably cooperate with the Indemnified Party in the defense of such Claim, and shall have the right (at its own expense) to be present in person or through counsel at all related legal proceedings.

In no event shall either Party be liable to the other Party for any indirect, incidental, special, exemplary, punitive or consequential damages in connection with this Agreement or the transactions contemplated by this Agreement, however caused, under any theory of liability.

- 17.10 Notwithstanding any other provision of this Agreement, in the event of a breach of the representations, warranties and covenants set out in paragraphs 17.1 (d), (e), (f), (k), (l) or (o), ERYtech shall give OE a prompt notice of such breach and shall have [***] days to cure such breach. If ERYtech has not provided notice of the breach to OE pursuant to the preceding sentence, then OE shall provide notice of the breach to ERYtech within [***] days of OE's awareness of the breach and ERYtech shall have [***] days to cure such breach. If ERYtech does not cure the breach pursuant to the two preceding sentences, then, without prejudice to the right of OE to claim damages under this Agreement, [***].
- 17.11 Without prejudice to clause 17.8, (A) in the event of a breach of the representations, warranties and covenants set out in paragraphs 17.1 (i) or (j), or (B) should [***] any claim in relation to the Licensed IP result, at any time, in a decision by a court in the Major Markets or the European Patent Office (other than a temporary injunction which is not repealed or overturned within six (6) months) finding as to a significant reduction in scope, withdrawal, cancellation, and/or invalidity of the Patents listed under Patent Family 1 in Schedule 1.1.3 or (C) should [***] any litigation grounded on the performance of any activity pursuant to this Agreement, including any manufacture, use, sale or other distribution of the Product, result, at any time, in a court decision (other than a temporary injunction which is not repealed or overturned within six (6) months) in the Major Markets finding as to a infringement of Third Party's intellectual property rights (any of the circumstances under (A), (B) and (C), the "**Event**"), the following shall apply (provided that several of the following provisions may apply for different Events or subsequently):
- (i) [***];

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(ii) [***];

(iii) [***].

(iv) [***].

(v) [***].

- 17.12 If the Product is sold and distributed by OE, its Affiliates and Sublicensees pursuant to this Agreement and legal proceedings claiming infringement of Third Party's intellectual property in the Territory as a consequence of the above activities are started against any of them, then OE may elect to pay [***] of the Royalty and up to [***] of the Milestones [***]. Direct payment to Erytech of amounts owing as Royalties or Milestones shall resume when a non appealable decision or settlement of the action takes place and all amounts owing to a Third Party [***] are paid. If the provisions of this clause 17.12 apply, the Parties shall enter into [***] in accordance with the provisions of this clause 17.12 and customary market practices.
- 17.13 (i) The provisions of clause 17.11 with respect to Events referred to in clause 17.11 (C) and of clause 17.12 shall automatically terminate if (x) [***] of [***] and (y) there is no pending litigation claiming an infringement of Third Party's intellectual property rights in connection with the performance of any activity pursuant to this Agreement, including any manufacture, use, sale or other distribution of the Product in the Major Markets.
- (ii) The provisions of clause 17.11 with respect to Events referred to in clause 17.11 (B) shall automatically terminate if (x) [***] and (y) there is no pending litigation in relation to the Patents listed under Patent Family 1 in Schedule 1.1.3 in the Major Markets or at the European Patent Office.
- (iii) The provisions of clause 17.11 with respect to Events referred to in clause 17.11 (A) shall automatically terminate upon termination of both of the provisions set forth in subclauses (i) and (ii) above.
- 17.14 Each Party shall obtain and keep in force policies of insurance at its sole cost and expense from reputable insurers of such types, in such amounts and covering such risks as are in accordance with normal and customary industry practice generally for companies similarly situated and engaged in similar business.

18. Confidentiality

- 18.1 During the Term of this Agreement, OE and ERYtech may receive or have access to information that is confidential and proprietary to the other Party (as to either Party, its "**Information**"). The existence and terms of this Agreement shall be deemed Information of both Parties. For the purpose of this clause,

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Recipient refers to the Party receiving the Information from Discloser and Discloser refers to the Party disclosing the Information to Recipient. Recipient acknowledges the proprietary and sensitive nature of the Information, and the importance of maintaining the secrecy and confidentiality of such Information. The Information includes proprietary and confidential matters related to the Discloser's current and/or proposed products, operations and business plans with respect to the Product, including but not limited to research, products, clinical data, developments, inventions, processes, technology information, security controls, marketing, finances and pricing. Recipient shall use the Information only for the purpose specified or permitted by this Agreement and shall not accumulate in any way or make use of the Information for any other purpose. Recipient shall ensure that only its employees, authorized agents, or subcontractors who need to know the Information will receive the Information and that such persons agree to be bound by the provisions of this clause 18.

18.2 During the Term of this Agreement and thereafter, Recipient:

- (a) shall not, without the Discloser's prior written consent, disclose, use or permit to be used the other Party's Information in any manner except as expressly authorized by this Agreement;
- (b) shall treat such Information with at least the same degree of care that it treats its own confidential Information but in no event with less than a reasonable degree of care; and
- (c) shall use its reasonable efforts to prevent disclosure of Information to unauthorized parties.

18.3 Upon demand, or upon expiration or termination of this Agreement, the Parties shall comply with each other's reasonable instructions regarding the disposition or return of the Information in its possession or control.

18.4 The obligations of Recipient under this clause 18 shall not apply to:

- (a) Information which is or becomes part of the public domain through no fault of the Recipient or its Affiliates;
- (b) Information which was known by the Recipient or any of its Affiliates, as evidenced by written records, at the time of disclosure to the Recipient;
- (c) Information which becomes known to the Recipient from a source other than the Discloser without breach of this Agreement by the Recipient or any of its Affiliates;

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- (d) Information which is disclosed pursuant to the order or requirement of a court, administrative agency or other governmental body; and
 - (e) Information which is independently developed by the Recipient or any of its Affiliates as shown by written records.
- 18.5 Recipient shall not, without the express prior written consent of Discloser, provide or disclose the Information to any person, with the exception of (a) any Affiliate or Sub-Licensee, provided that such Affiliate or Sub-Licensee agrees to be bound to retain the confidentiality of the Information, (b) employees or consultants who have a need to know in the course of performing services pursuant to this Agreement, provided that such employees or consultants agree to maintain the confidentiality of the Information, (c) Third Party vendors as necessary for either Party to fulfil its obligations vis-à-vis the other under this Agreement, provided that such vendors are bound in writing to maintain the confidentiality of the Information in accordance with this clause 18, and (d) pursuant to requirements of law, in particular to the extent necessary for the implementation of the provisions of this Agreement.
- 18.6 Notwithstanding the provisions of this clause 18, ERYtech may provide a copy of this Agreement to any potential or actual investor, investment banker, acquirer, merger partner or other potential or actual financial partner as long as each discloser agrees to be bound by similar terms of confidentiality and non-use at least as protective as those set forth in this clause 18.
- 18.7 The Parties agree that any unauthorized use or disclosure of Information may cause immediate and irreparable harm to the other for which money damages may not constitute an adequate remedy. In such event, the Parties agree that the injured Party may seek injunctive relief or an *astreinte* as appropriate.
- 18.8 Promptly following the Effective Date, each Party shall be entitled to issue a press release, substantially in the form attached as Schedule 18.8, to announce the execution of this Agreement. Neither Party nor any of its Affiliates shall disclose any information not included in such press release (or any other public announcements or statements that are subsequently approved as provided herein) concerning the existence, terms, conditions or status of the transactions contemplated herein, or make any public statement which includes the name of the other Party or any of its Affiliates, or otherwise use the name of the other Party or any of its Affiliates in any public statement or document, without the prior written approval of the other Party, except as may be required (i) to register or commercialize the Product or (ii) by law or judicial order or applicable regulations, including as is reasonably necessary to comply with applicable securities exchange listing requirements (and then, to the extent feasible, only following consultation with the other Party).

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- 18.9 Notwithstanding anything to the contrary in this Agreement, to the extent required by Applicable Laws, as interpreted by the relevant oversight authority (*Consob* or *AMF*, as applicable) and the relevant stock exchange or for financial reporting purposes, OE and its controlling company Recordati Industria Chimica e Farmaceutica S.p.A., a listed company, and ERYtech, as applicable, may disclose certain events, including the conclusion of this Agreement (or termination as the case may be) and provide details, including in its periodic reports.
- 18.10 In the event that either Party intends to publish a paper in a peer reviewed journal (including an abstract) or make a scientific oral presentation containing Information relating to the Product or the Results, such Party shall provide the other Party with a draft of such publication for prior review (or, in the case of a public oral presentation, use reasonable efforts, to the extent practicable under the circumstances, to provide the other Party with a summary of the proposed oral presentation for prior review). Within fifteen (15) business days after receipt of a draft publication (or within five (5) days in the case of a public oral presentation) (the “**Review Period**”), the receiving Party may review the draft and may give its written comments on the draft to the publishing Party. The publishing Party shall prepare the final version of the publication or the oral presentation, taking the comments into consideration if appropriate. Thereafter, the publishing Party may disclose to Third Parties the information disclosed in such publication or oral presentation (i.e., in that or any subsequent publication or presentation) without the need for further approval by the other Party. In the event that no response is given by the receiving Party to the publishing Party within the applicable Review Period, the receiving Party shall be deemed to have no comment on the draft. Notwithstanding the foregoing, as OE has been granted the exclusive right to commercialize the Products in the Primary Indications and the Territory, OE shall have the right to make the final decision whether to proceed with any publication or oral presentation related to the Product in the Primary Indications and the Territory, provided that ERYtech shall be entitled to request that (i) such publication or presentation shall not contain Information of ERYtech other than Information relating to the Products or the Results and/or (ii) shall be delayed by the time necessary for ERYtech to protect any Improvements contained in such publication or presentation. OE shall have the right to approve (but shall not unreasonably withhold such consent) to any publication or oral presentation requested by ERYtech in the Primary Indications and the Territory and, if no response is given by OE to ERYtech within the applicable Review Period, OE shall be deemed to consent to the publication or oral presentation. It is understood that OE shall have no right to make publications or oral presentation with respect to the Product outside of the Primary Indications or the Territory and ERYtech shall not be restricted (subject to the prior information and prior review obligations stated above) from making publications or oral presentation with respect to the Product outside of the Primary Indications or the Territory. With respect to

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publications or oral presentation by Third Parties (other than for the avoidance of doubt, with respect to OE, Sub-Licensees), it is understood that the foregoing rights of review shall apply only to the extent the Party hereto has the right to require such Third Party to comply. ERYtech shall take action itself or ensure that similar provisions bind its other licensees, if any, outside of the Primary Indications or the Territory, such that OE is enabled to comment on any intended publication or presentation which may reasonably affect the prescription or sale in the Primary Indications in the Territory or the general reputation of the Product in the Territory.

It is agreed that at a mutually convenient time at the end of each year the Parties shall share and discuss their respective publication plans for the coming year.

19. Governing Law and Jurisdiction

- 19.1 This Agreement shall be governed by and construed in accordance with [***] (without application of its conflict of laws, rules and principles). [***].
- 19.2 Any dispute, controversy or claim arising out of or in relation with this Agreement (including in relation to the validity, invalidity, breach, enforcement or termination of this Agreement) (a “**Dispute**”) that could not be amicably resolved within thirty (30) days of a dispute notice shall be finally settled in accordance with the Rules of Arbitration of the International Chamber of Commerce (the “**Rules**”) in force on the date when a request for arbitration is submitted. The tribunal shall be composed of three (3) arbitrators appointed by the International Court of Arbitration of the International Chamber of Commerce in accordance with said Rules. The venue of the arbitration shall be [***]. The language of the arbitration shall be English. If the value of the Dispute that is notified by the referring Party is less than [***] Euros (€[***]), the Dispute shall be resolved by a single arbitrator appointed in accordance with the Rules.

20. Miscellaneous

20.1 Amendment

No amendment, modification or addition hereto shall be effective or binding on either Party unless set forth in writing and executed by duly authorised representatives of both Parties.

20.2 Waiver

No failure or delay by a Party to exercise any right or remedy provided under this Agreement or by law shall constitute a waiver of that or any other right or remedy, nor shall it preclude or restrict the further exercise of that or any other right or remedy. No single or partial exercise of such right or remedy shall preclude or restrict the further exercise of that or any other right or remedy.

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20.3 Severability

If any court or competent authority finds that any provision of this Agreement (or part of any provision) is invalid, illegal or unenforceable, that provision or part-provision shall, to the extent required, be deemed to be deleted, and the validity and enforceability of the other provisions of this Agreement shall not be affected. The Parties shall thereupon promptly meet to negotiate in good faith, a replacement provision or part-provision that meets as closely as possible in substance, the intent of such provision or part-provision found to be invalid, illegal or unenforceable.

20.4 Assignment

This Agreement shall be binding upon and inure to the benefit of the Parties hereto and their respective corporate successors and shall not be assigned by either Party without the consent of the other Party. Notwithstanding the foregoing, each Party may assign this Agreement to any of its Affiliates listed in Schedule 20.4 provided that such Affiliates agree to be bound by all the provisions of the Agreement and the assignor shall not be relieved of any of its obligations under this Agreement.

20.5 Further Assurance

Each Party agrees to execute, acknowledge and deliver such further instruments, and to do all such other acts as may be necessary or appropriate in order to carry out the purposes and intent of this Agreement.

20.6 Force Majeure

No Party shall be liable for any failure or delay in performance under this Agreement to the extent such failure or delay arises from “**Force Majeure**”. Force Majeure shall mean any circumstance out of the control of the concerned Party and preventing such Party from performing its obligations under this Agreement, including, to the extent that they satisfy the conditions of the preceding sentence, any fire, explosion, earthquake, storm, flood, war, insurrection, riot, act of God or the public enemy, act of terrorism, export or import control regulations, governmental action, orders, legislation, regulations or restrictions and not otherwise arising out of breach by such Party of this Agreement. In the event of the occurrence of such an event, the Party so affected shall give prompt written notice to the other Party, stating the period of time the occurrence is expected to continue and shall use best efforts to end the failure or delay and ensure that the effects of such Force Majeure are minimised.

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20.7 No Partnership or Agency

Nothing herein contained shall be deemed to create an agency, joint venture, amalgamation, partnership, or similar relationship between the Parties. The relationship between the Parties established by this Agreement is that of independent contractors.

20.8 Entire Agreement

This Agreement constitutes the whole agreement between the Parties in relation to the subject matter hereof and supersedes any previous agreement between the Parties relating to its subject matter. No representations, inducements, promises or agreements, whether oral or otherwise, between the Parties not contained in this Agreement shall be of any force or effect. No agreement or understanding extending this Agreement or varying its terms (including any inconsistent terms in any purchase order, acknowledgment or similar form) shall be binding upon either Party unless it is in a writing specifically referring to this Agreement and signed by a duly authorized representative of the applicable Party.

20.9 No Third Party Rights

No person, other than the Parties and their permitted assignees or successors hereunder, shall have any rights, to enforce any of its terms.

20.10 No Implied Grants of Intellectual Property Rights

Except as explicitly provided herein, no license or other right, express or implied, is granted or shall be deemed granted by implication, estoppel or otherwise, by one Party under any of its intellectual property to the other Party.

Made in two (2) originals.

ORPHAN EUROPE

ERYTECH Pharma

/s/ Walter Bevilacqua

/s/ Pierre-Olivier Goineau

By: Walter Bevilacqua

By: Pierre-Olivier Goineau

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SCHEDULE 1.1.1: List of Countries in [*]**

[***]

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SCHEDULE 1.1.2: AML Development Plan

[***]

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SCHEDULE 1.1.3: List of Patents in Licensed 113

Patent Family 1

	<u>Country</u>	<u>Filing Number</u>	<u>Filing date</u>	<u>Grant Number</u>	<u>Grant Date</u>	<u>Expiration date</u>	<u>Status</u>
***	***	***	***	***	***	***	***
....							
***	***	***	***	***	***	***	***

Patent Family 2

	<u>Country</u>	<u>Filing Number</u>	<u>Filing Date</u>	<u>Grant Number</u>	<u>Grant Date</u>	<u>Expiration date</u>	<u>Status</u>
***	***	***	***	***	***	***	***

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SCHEDULE 1.1.4: Cost items in the Supply Price calculation

[***]

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SCHEDULE 3.1: List of material information needed to evaluate additional territories and Additional Indications

For Additional Territories

[***]

For Additional Indications

[***]

[***]

[***]

[***]

[***]

[***]

[***]

[***]

[***]

[***]

[***]

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SCHEDULE 5.1: Clinical Trials for ALL Indication

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PROTOCOL SUMMARY

PHASE I/II CLINICAL TRIAL

GRASPALL 2005-01 STUDY

***Administration of allogenic red blood cells loaded L-asparaginase in
cases of relapse of acute lymphoblastic leukaemia.***

[***]

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SCHEDULE 7.5 b): Information to be contained on prescription form:

[***]

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Schedule 8.4: Example of requirements for traceability program in France

[***]

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SCHEDULE [*]**

[***]

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SCHEDULE [*]: [***]**

[***]

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SCHEDULE 18.8: Press release

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PRESS RELEASE

November 22, 2012

ERYTECH Pharma signs licensing and distribution agreement with Orphan Europe for GRASPA® in Europe

Lyon (France) - November 22, 2012 - ERYTECH Pharma, a late stage biopharmaceuticals company focused on orphan oncology and rare diseases, announced today that it has entered into a definitive agreement and Orphan Europe, part of the Recordati Group, granting Orphan Europe exclusive rights for the commercialization and distribution of GRASPA® in Acute Lymphoblastic Leukemia (ALL) and Acute Myeloid Leukemia (AML) in Europe.

GRASPA®, L-asparaginase encapsulated into human erythrocytes, for the treatment of hematological malignancies, is in pivotal Phase II/III clinical trial for ALL and will enter a Phase IIb trial in AML in Europe. The product holds orphan designation in Europe and the US for ALL. GRASPA® is intended to satisfy the important unmet medical needs of frail cancer patients, patients suffering relapses and other patient groups for whom the current treatments are not suitable.

“We are very pleased to announce this agreement with Orphan Europe” said Pierre-Olivier Goineau, Chief Executive Officer of Erytech. “We believe we have found in Orphan Europe a partner that is uniquely positioned to ensure market access and commercial success of our lead product in ALL, and to advance the product in AML. Erytech will manufacture the product. This agreement is a major milestone for Erytech, and a clear recognition of the potential of our technology. It will allow us to focus on our developments in the US, in solid tumors and in other rare disease indications”

Marco Liguori, CEO of Orphan Europe, is delighted with this new partnership “The Orphan Europe team has considerable experience in the orphan drug field and the special requirements of rare diseases. We are committed and prepared to ensure that these treatments become available for patients in Europe rapidly”.

For more information:

*Pierre-Olivier Goineau, CEO
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contact@erytech.com*

*Caroline Carmagnol, ALIZE RP
Tel.: +33 142 688 643 // +33 664 189 959
caroline@alizerp.com*

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About Erytech

Erytech Pharma SA is a late-stage French biopharmaceutical company developing medicinal products for orphan oncology and rare diseases. The company's proprietary core technology is based on the use of human red blood cells (RBCs) to improve the pharmacokinetic (PK) and pharmacodynamic (PD) properties of therapeutic molecules. Its lead product, GRASPA® is in pivotal Phase II/III clinical trial for ALL and will enter a Phase IIb trial in AML in Europe. The product holds orphan designation in Europe and the US for ALL.

The company is expanding the use of its technology in oncology to Acute Myeloid Leukemia and solid tumors, and outside oncology in rare immunology and haematology indications.

About Orphan Europe

Orphan Europe was founded in 1990 and acquired by Recordati in 2007. For the past two decades Orphan Europe has developed and marketed orphan drugs for patients with rare diseases. In 2000 orphan drugs were defined by the European Drug Regulation as a treatment for a life-threatening or chronically debilitating condition affecting no more than five in 10,000 persons. The parameters involved in the development of an orphan drug are very different to the development of conventional drugs, for example there is a limited number of patients and a scarcity of expertise. Therefore Orphan Europe's approach is based on combined efforts between the company, patients and the medical community with the overall aim to improve the life of affected persons. Orphan Europe has also built the Orphan Europe Academy with the aim to further the understanding of rare diseases and provide a forum for sharing knowledge and developing new ideas.

About Recordati

Recordati, established in 1926, is a European pharmaceutical group, listed on the Italian Stock Exchange (Reuters RECI.MI, Bloomberg REC 1M, ISIN IT 0003828271), with a total staff of over 3,200, dedicated to the research, development, manufacturing and marketing of pharmaceuticals. Headquartered in Milan, Italy, Recordati has operations in the main European countries, in Central and Eastern Europe, and in Turkey. A field force of around 1,700 medical representatives promotes a wide range of innovative pharmaceuticals, both proprietary and under license, in a number of therapeutic areas including a specialized business dedicated to treatments for rare diseases. Recordati is a partner of choice for new product licenses from companies which do not have a European presence. Recordati is committed to the research and development of new drug entities within the cardiovascular and urogenital therapeutic areas and of treatments for rare diseases. Consolidated revenue for 2011 was € 762.0 million, operating income was € 163.5 million and net income was € 116.4 million.

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NEWS RELEASE

RECORDATI LICENSES GRASPA® FROM ERYTECH IN EUROPE

Milan, xx xxxxx 2012 — Recordati announces that its subsidiary Orphan Europe and Erytech Pharma, a late development stage French biopharmaceutical company focused on orphan oncology and rare diseases, have entered into an agreement granting Orphan Europe the exclusive rights for the commercialization and distribution of Graspas® for the treatment of Acute Lymphoblastic Leukemia (ALL) and Acute Myeloid Leukemia (AML) in Europe. Graspas®, human erythrocytes encapsulating L-asparaginase, for the treatment of hematological malignancies, is currently in pivotal Phase II/III clinical trial for ALL and will enter a Phase IIb trial in AML in Europe. The product has obtained an orphan drug designation in Europe and the USA for ALL.

Graspas® is a new formulation of L-asparaginase with a safer and broader range of clinical use than existing forms due to the entrapment and protection of the enzyme inside homologous red blood cells. The added value of Graspas® (by encapsulating L-asparaginase in red blood cells) relates to its ability to overcome existing limitations associated with conventional L-asparaginase via longer efficacy, better compliance, reduced doses and a better safety profile. Graspas® is intended to satisfy the unmet medical needs of frail patients, patients suffering relapses and other patient groups for whom the current treatments are not suitable.

Marco Liguori CEO of Orphan Europe is delighted with this new partnership “The Orphan Europe team has considerable experience in the orphan drug field and the special requirements of rare diseases. We are committed and prepared to ensure that these treatments become available for patients in Europe rapidly”.

“We are very pleased to announce this agreement with Orphan Europe (Recordati Group)” said Pierre-Olivier Goineau, Chief Executive Officer of Erytech. “We believe we have found a partner that is uniquely positioned to ensure market access and commercial success of our lead product in ALL, and to advance the product in AML. Erytech will manufacture the product. This agreement is a major milestone for Erytech, and a clear recognition of the potential of our technology. It will allow us to focus on our developments in the US in solid tumors and in other rare disease indications”.

About Orphan Europe

Orphan Europe was founded in 1990 and acquired by Recordati in 2007. For the past two decades Orphan Europe has developed and marketed orphan drugs for patients with rare diseases. In 2000 orphan drugs were defined by the European Drug Regulation as a treatment for a life-threatening or chronically debilitating condition affecting no more than five in 10,000 persons. The parameters involved in the development of an orphan drug are very different from the development of conventional drugs, for example there is a limited number of patients and a scarcity of expertise. Therefore Orphan Europe's approach is based on combined efforts between the company, patients and the medical community with the overall aim to improve the life of affected persons.

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Orphan Europe has also built the Orphan Europe Academy with the aim to further the understanding of rare diseases and provide a forum for sharing knowledge and developing new ideas.

About Erytech

Erytech Pharma SA is a late-stage French biopharmaceutical company developing medicinal products for orphan oncology and rare diseases. The company's proprietary core technology is based on the use of human red blood cells (RBCs) to improve the pharmacokinetic (PK) and pharmacodynamic (PD) properties of therapeutic molecules.

Erytech has established a cGMP approved manufacturing facility that can meet the demand for Grasper® products in Europe. The company is expanding the use of its technology in oncology to Acute Myeloid Leukemia and solid tumors, and outside oncology in enzyme replacement therapy, immunology and haematology indications.

For more information:

Erytech Pharma:

RECORDATI INDUSTRIA CHIMICA E FARMACEUTICA S.p.A.

Sede Legale

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20148 MILANO, ITALIA
TEL (39) 0248787.1
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CAPITALE SOCIALE € 26.140.644,50 I.V.
REG. IMP. MILANO N. 00748210150
CODICE FISCALE/P IVA 007482210150
R.E.A. MILANO N. 401832

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Orphan Europe Recordati Group
Samantha Parker, Director of External Affairs and Rare Disease Partnerships,
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Recordati, established in 1926, is a European pharmaceutical group, listed on the Italian Stock Exchange (Reuters RECI.MI, Bloomberg REC 1M, ISIN IT 0003828271), with a total staff of over 3,200, dedicated to the research, development, manufacturing and marketing of pharmaceuticals. Headquartered in Milan, Italy, Recordati has operations in the main European countries, in Central and Eastern Europe, and in Turkey. A field force of around 1,700 medical representatives promotes a wide range of innovative pharmaceuticals, both proprietary and under license, in a number of therapeutic areas including a specialized business dedicated to treatments for rare diseases. Recordati is a partner of choice for new product licenses from companies which do not have a European presence. Recordati is committed to the research and development of new drug entities within the cardiovascular and urogenital therapeutic areas and of treatments for rare diseases. Consolidated revenue for 2011 was € 762.0 million, operating income was € 163.5 million and net income was € 116.4 million.

For further information:

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Statements contained in this release, other than historical facts, are “forward-looking statements” (as such term is defined in the Private Securities Litigation Reform Act of 1995). These statements are based on currently available information, on current best estimates, and on assumptions believed to be reasonable. This information, these estimates and assumptions may prove to be incomplete or erroneous, and involve numerous risks and uncertainties, beyond the Company’s control. Hence, actual results may differ materially from those expressed or implied by such forward-looking statements. All mentions and descriptions of Recordati products are intended solely as information on the general nature of the company’s activities and are not intended to indicate the advisability of administering any product in any particular instance.

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SCHEDULE 20.4: List of Affiliates to which the Agreement can be assigned:

[***]

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ERYTECH
Bâtiment Adenine
60 Avenue Rockefeller,
69008 Lyon

February 22 2013

By Registered Letter with return receipt and duplicated by electronic mail

To the attention of Mr Pierre-Olivier GOINEAU — President & CEO

Re: First Amendment to the Exclusive License and Distribution Agreement between ORPHAN EUROPE SARL and ERYTECH dated November 22 2012 (“the Agreement”), effective as of February 22 2013 (the Effective Date).

Dear Mr Goineau,

This letter is to serve as First Amendment to the Agreement and all defined (capitalized) terms used herein shall have the same meaning as those set out in the Agreement, unless expressly otherwise provided for herein.

Following discussions between respective representatives of the Parties, we hereby set forth the terms and conditions that were agreed upon by ORPHAN EUROPE and ERYTECH.

1 Understanding

Reference is made to section 6.7 of the Agreement which stipulates that the Parties shall enter into a Safety Data Exchange Agreement (the SDEA), within three (3) months after the date of execution of the Agreement, that is to say on February 22 2013 at the latest.

On the date of the present letter, the SDEA is still under negotiation between the Parties however close to finalization.

Therefore the Parties hereby agree to extend the allotted period and to enter into such SDEA no later than on March 15 2013.

2 No Other Changes

Except as expressly set forth by this First Amendment, all terms and conditions of the Agreement shall remain unchanged and in full force and effect.

3. Counterparts.

This First Amendment shall be executed in two counterparts, one for ORPHAN EUROPE, one for ERYTECH, each of which shall be deemed an original but all of which together shall constitute one and the same document.

This First Amendment shall enter into force as of the Effective Date upon your signature.

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Should you agree with the content of this First Amendment please sign and return one original to us for acknowledgement and acceptance thereof.

For and on behalf of ORPHAN EUROPE SARL

Sophie LEGER COLLOMB
General Manager of EMEA Operations

For and on behalf of ERYTECH
“Acknowledged and accepted”

Pierre-Olivier GOINEAU
CEO

Date:

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Orphan Europe SARL
Immeuble « Le Wilson »,
70, avenue du Général de Gaulle
92058 Paris la Défense

Lyon, 5th February 2015

BY REGISTERED LETTER

OBJECT: SECOND AMENDMENT TO THE EXCLUSIVE LICENSE AND DISTRIBUTION BETWEEN ORPHAN EUROPE SARL AND ERYTECH PHARMA DATED NOVEMBER 22ND, 2012 AS FURTHER AMENDED (“THE AGREEMENT”), EFFECTIVE AS OF 4TH AUGUST 2014

This letter is to serve as second amendment to the Agreement (the “Second Amendment”) and all defined (capitalized) terms used herein shall have the same meaning as those set out in the Agreement, unless expressly otherwise provided herein.

Following discussions during the Joint Steering Committee held between January and July 2014 and the positive feedback of the CPP (*Comité pour la Protection des Personnes*) and ANSM (*L’Agence Nationale de Sécurité du Médicament et des produits de santé*) on a new amendment to GRASPALL 2009-06 Study Protocol (as incorporated via PDF format in Schedule 5.1 to the Agreement), we hereby set forth the terms and conditions already discussed by the Parties in order to further amend the GRASPALL 2009-06 Study Protocol (GRASPALL2009-06_V3_100428_FR) dated 28 April 2010 attached to the Agreement (the “Protocol”), pursuant to Section 20.1 of the Agreement.

1. Understanding and background

Reference is made to Schedule 5.1 of the Agreement which set out, amongst others, the ongoing and envisaged clinical trials for ALL Indication according to the Protocol. Following the execution of the Agreement the Protocol was modified by the document named Amendment 2 dated 24/04/2013 hereto attached (“Protocol Amendment 2”):

On 4 August 2014 the CPP and the ANSM accepted the content and terms of the document dated 02/07/2014 submitted by ERYTECH Pharma as proposed third amendment to the Protocol and hereto attached (the “Protocol Amendment 3”).

Therefore, the Parties hereby acknowledge that the Protocol and, consequently, the Agreement were amended by adding Protocol Amendment 2 to the Protocol and, further, agree to hereby amend the Protocol by adding Protocol Amendment 3 to the Protocol in the form and content attached to this Second Amendment.

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Furthermore, ERYTECH Pharma represents and warrants that the activities and studies under the Protocol as amended by Protocol Amendment 2 have been duly and timely carried out in full accordance with the Protocol, the Protocol Amendment 2 and applicable laws.

2. No other changes

Except as expressly set forth by this Second Amendment, all terms and conditions of the Agreement shall remain unchanged and in full force and effect.

3. Counterparts

This Second Amendment shall be executed in two counterparts, one for each Party, each of which shall be deemed an original but all of which together shall constitute one and the same document.

This Second Amendment shall enter into force as of the Effective Date upon your signature. Should you agree with the content of this Second Amendment, please sign and return one original to us for acknowledgment and acceptance thereof.

For and on behalf of ERYTECH Pharma

/s/ Gil Beyen

Mr. Gil Beyen
Chief Executive Officer

For and on behalf of ORPHAN EUROPE SARL
“Acknowledged and accepted”

/s/ Andrea Recordati

Mr. Andrea Recordati
Gérant
Date: 6/3/2015

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 LOGO

/s/ Corrado Castellucci

Mr. Corrado Castellucci

Gérant

Date: March 2nd, 2015

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