

## **ERYTECH Announces Withdrawal of its European Marketing Authorization Application for GRASPA for Acute Lymphoblastic Leukemia and Prepares for Resubmission**

Conference call and webcast scheduled for  
Tuesday, November 15<sup>th</sup> at 15:00 pm CET/9:00 am ET

- **Withdrawal of European Marketing Authorization Application (MAA) for eryaspase (GRASPA®); additional data requested by the Committee for Human Medicinal Products (CHMP) will take more time to provide than allowed in the CHMP's approval procedures**
- **Intention to resubmit the MAA mid-2017**

**Lyon (France), November 14, 2016** – ERYTECH Pharma (Euronext Paris: ERYP), the French biopharmaceutical company developing ‘tumor starvation’ treatments for acute leukemia and other oncology indications with unmet medical needs, today announced its decision to withdraw the current MAA for GRASPA for the treatment of acute lymphoblastic leukemia (ALL). The Company determined that the time allowed in the CHMP procedure was not sufficient to provide the additional data requested in the CHMP’s Day 180 List of Outstanding Issues (LOI). The Company intends to resubmit an MAA around mid-2017.

Following positive efficacy and safety results from the completed European Phase 2/3 pivotal study in patients with relapsed and refractory ALL, ERYTECH submitted an MAA for GRASPA in September 2015. The Company received the Day 180 LOI in September 2016 and has been in discussion with the Rapporteur/Co-rapporteur and the CHMP to provide the requested additional data regarding the comparability between the old and new form of asparaginase encapsulated in GRASPA and the development of a new immunogenicity assay, as well as the pharmacodynamics effects of eryaspase. Given the fact that the generation of these additional data will require more time than allowed in the CHMP’s approval procedures, the Company has notified the CHMP of the withdrawal of the application at this time. The Company intends to resubmit the MAA mid-2017, as soon as the newly generated data are available.

*“It is disappointing that assembling the data necessary to properly address the remaining questions is requiring longer time than we were actually granted at this stage. Our pivotal trial demonstrated improved clinical outcome and an excellent safety profile with eryaspase compared to native asparaginase. We are committed to pursuing regulatory approval for GRASPA and intend to work closely with our investigators and advisors to generate the additional information requested and to resubmit an MAA next year”* said Iman El-Hariry, Chief Medical Officer of ERYTECH.

*“The decision to withdraw at this stage was not an easy one, but does not change our commitment to bringing eryaspase to the market.”* comments Gil Beyen, ERYTECH’s Chairman and Chief Executive Officer. *“We believe we have generated strong clinical data in our different programs of eryaspase, and we continue to execute our plans towards making the product available to patients with aggressive forms of cancer, such as acute lymphoblastic leukemia, acute myeloid leukemia and pancreatic cancer. We are not aware of any safety issues and our other clinical trials are not affected. We will continue to pursue our planned clinical strategy in ALL and AML in close collaboration with our European partner Orphan Europe (Recordati Group)”*.

## Conference Call Details

ERYTECH management will hold a conference call and webcast on Tuesday, November 15, 2016 at 15:00 pm CET / 9:00am ET to discuss the withdrawal decision and plan forward. Gil Beyen, Chairman and CEO, Eric Soyer, CFO and COO, and Iman El-Hariry, CMO, will deliver a brief presentation, followed by a Q&A session.

Investors and analysts wishing to participate can access the call via the following teleconferencing numbers:

**USA:** +1 8778874163

**United-Kingdom:** +44 2030432440

**Switzerland:** +41 225809022

**Germany:** +49 69222229031

**France:** +33 172001510

**Belgium:** +32 24029640

**Sweden:** +46 850334664

**Finland :** +358 942599700

**Netherlands:** + 31 107138194

Confirmation Code: **57436962#**

The webcast can be followed live online via the link:

<http://www.anywhereconference.com?UserAudioMode=DATA&Name=&Conference=135305205&PIN=57436962>

Following the live call, a replay will be available for 90 days. To listen to the replay, please dial:

**USA:** +1 877 64 230 18

**United-Kingdom:** +44(0) 2033679460

**France:** +33(0)1 72 00 15 00

Confirmation Code: **305205#**

Additionally, an archive of the webcast will be available on the “Webcast” section of the Company’s investor relations site at [www.erytech.com](http://www.erytech.com)

## About ERYTECH and eryaspase (GRASPA®): [www.erytech.com](http://www.erytech.com)

Founded in Lyon, France in 2004, ERYTECH is a clinical-stage biopharmaceutical company developing innovative therapies for rare forms of cancer and orphan diseases. Leveraging its proprietary ERYCAPS platform, which uses a novel technology to encapsulate therapeutic drug substances inside red blood cells, ERYTECH has developed a pipeline of product candidates targeting markets with high unmet medical needs. ERYTECH’s initial focus is on the treatment of blood cancers, including acute lymphoblastic leukemia (ALL) and acute myeloid leukemia (AML), by depriving tumors of nutrients necessary for their survival. ERYTECH plans to pursue regulatory approvals for its lead product candidate, eryaspase, also known as ERY-ASP or under the trade name GRASPA®, having achieved positive efficacy and safety results from its completed Phase 2/3 pivotal clinical trial in Europe in children and adults with relapsed or refractory ALL. ERYTECH also has an ongoing Phase 1 clinical trial of eryaspase in the United States in adults with newly diagnosed ALL, and a Phase 2b clinical trial in Europe in elderly patients with newly diagnosed AML, each in combination with chemotherapy. ERYTECH believes that eryaspase also has the potential as a treatment approach in solid tumors and is conducting a Phase 2 clinical trial in Europe in patients with metastatic pancreatic cancer.

Eryaspase consists of an enzyme, L-asparaginase, encapsulated inside donor-derived red blood cells. L-asparaginase depletes asparagine, a naturally occurring amino acid essential for the survival and proliferation of cancer cells, from circulating blood plasma. ERYTECH produces eryaspase at its own GMP-approved and operational manufacturing site in Lyon (France), and at a site for clinical production in Philadelphia (USA). ERYTECH has entered into licensing and distribution partnership agreements for eryaspase for ALL and AML in Europe with Orphan Europe (Recordati Group), and for ALL in Israel with TEVA, which will market the product under the GRASPA® brand name. The European Medicines Agency (EMA) and the U.S. Food and Drug Administration (FDA) have granted orphan drug designations for eryaspase for the treatment of ALL, AML and pancreatic cancer.

In addition to eryaspase, ERYTECH is developing two other product candidates that focus on using encapsulated enzymes to induce tumor starvation. The company is also exploring the use of its ERYCAPS platform for developing cancer immunotherapies and enzyme replacement therapies.

ERYTECH is listed on Euronext regulated market in Paris (ISIN code: FR0011471135, ticker: ERYP) and is part of the CAC Healthcare, CAC Pharma & Bio, CAC Mid & Small, CAC All Tradable, EnterNext PEA-PME 150 and Next Biotech indexes. ERYTECH is also listed in the U.S. under an ADR level 1 program (OTC, ticker EYRY).

## CONTACTS

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## Forward-looking information

This press release contains forward-looking statements, forecasts and estimates with respect to the clinical development plans, business and regulatory strategy, and anticipated future performance of ERYTECH and of the market in which it operates. Certain of these statements, forecasts and estimates can be recognized by the use of words such as, without limitation, “believes”, “anticipates”, “expects”, “intends”, “plans”, “seeks”, “estimates”, “may”, “will” and “continue” and similar expressions. They include all matters that are not historical facts. Such statements, forecasts and estimates are based on various assumptions and assessments of known and unknown risks, uncertainties and other factors, which were deemed reasonable when made but may or may not prove to be correct. Actual events are difficult to predict and may depend upon factors that are beyond ERYTECH's control. There can be no guarantees with respect to pipeline product candidates that the candidates will receive the necessary regulatory approvals or that they will prove to be commercially successful. Therefore, actual results may turn out to be materially different from the anticipated future results, performance or achievements expressed or implied by such statements, forecasts and estimates. Documents filed by ERYTECH Pharma with the French Autorité des Marchés Financiers ([www.amf-france.org](http://www.amf-france.org)), also available on ERYTECH's website ([www.erytech.com](http://www.erytech.com)) describe such risks and uncertainties. Given these uncertainties, no representations are made as to the accuracy or fairness of such forward-looking statements, forecasts and estimates. Furthermore, forward-looking statements, forecasts and estimates only speak as of the date of this press release. Readers are cautioned not to place undue reliance on any of these forward-looking statements. ERYTECH disclaims any obligation to update any such forward-looking statement, forecast or estimates to reflect any change in ERYTECH's expectations with regard thereto, or any change in events, conditions or circumstances on which any such statement, forecast or estimate is based, except to the extent required by law.