# ERYTECH Announces Launch of Investigator-Initiated Phase 2 Study of eryaspase (GRASPA®) for ALL

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LYON, France--(BUSINESS WIRE)--Apr. 4, 2017-- Regulatory News:

**ERYTECH Pharma (Paris:ERYP) (ADR:EYRYY) a French clinical-stage biopharmaceutical company developing innovative therapies by encapsulating therapeutic drug substances inside red blood cells, today announced the launch of an investigator-initiated study to evaluate eryaspase, also known by the trade name GRASPA®, in patients with acute lymphoblastic leukemia (ALL). The study will take place in seven Nordic countries and be conducted in collaboration with the Nordic Society of Pediatric Hematology and Oncology (NOPHO).**

The single arm, multi-center, multi-national Phase 2 study is expected to enroll approximately 30 patients at 23 sites across seven Nordic and Baltic countries: Denmark, Finland, Norway, Sweden, Iceland, Lithuania and Estonia. The main objectives of the study are to evaluate the biological (pharmacokinetic and pharmacodynamic) activity, safety, and immunogenicity profile of eryaspase in combination with the NOPHO ALL 2008 multi-agent chemotherapy protocol administered as second-intention treatment for children or adult ALL patients (1 to 45 years old) who experience hypersensitivity reactions to PEG-asparaginase or silent inactivation. The study is expected to start in April 2017 and continue for approximately 2 years.

Dr. Birgitte Klug Albertsen, Principal Investigator of the trial, commented, *"Depending on the asparaginase preparation, hypersensitivity reactions can occur at frequencies between 13% and 30% of children and adults with ALL, making the therapy ineffective. Eryaspase, or L-asparaginase encapsulated in red blood cells, may be able to limit these reactions and maintain treatment effectiveness. We look forward to evaluating this combination therapy to determine its clinical benefits for both pediatric and adult patients with hypersensitivity reactions to the PEG-asparaginase chemotherapy."*

Dr. Iman El-Hariry, Chief Medical Officer of Erytech Pharma, added, *"Collaborating with NOPHO is an exciting opportunity for Erytech to evaluate eryaspase in this specific patient population, with the potential to demonstrate expanded application of our technology to treat blood cancers where drug resistance and hypersensitivity clinical reactions to first-line chemotherapies is common. This study aligns with our global strategy to develop the ERYCAPS® technology with an increased tolerability and efficacy profile for patients who may respond to L-asparaginase when it is delivered through encapsulated red blood cells."*

**About ERYTECH: 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 leveraging the ERYCAPS platform for developing cancer immunotherapies (ERYMMUNE) and enzyme therapies beyond oncology (ERYZYME).

*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 EYRYY).*

**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), also available on ERYTECH's website ( 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.

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