



ERYTECH Announces Resubmission of European Marketing Authorization Application for GRASPA in Acute Lymphoblastic Leukemia

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LYON, France--(BUSINESS WIRE)--Oct. 10, 2017-- Regulatory News:

ERYTECH Pharma (Paris:ERYP) (ADR:EYRY), a clinical-stage biopharmaceutical company developing innovative therapies by encapsulating therapeutic drug substances inside red blood cells, today announced that it has resubmitted to the European Medicine Agency (EMA) its Marketing Authorization Application (MAA) for eryaspase (GRASPA®) for the treatment of patients with relapsed or refractory (R/R) acute lymphoblastic leukemia (ALL). The MAA resubmission includes the data from ERYTECH's GRASPALL 2009-06 Phase 2/3 clinical trial in children and adults with R/R ALL as well as additional data to address the outstanding questions of the Committee for Medicinal Products for Human Use (CHMP) of the EMA.

The GRASPALL Phase 2/3 trial, showed positive efficacy and safety results with GRASPA in combination with chemotherapy as compared to native L-asparaginase in patients with R/R ALL. The patients treated with GRASPA experienced a mean duration of L-asparaginase activity that was almost twice as long as for patients receiving native L-asparaginase. GRASPA also had a favorable safety profile in the trial and no patients who received GRASPA experienced an allergic reaction, as compared to 46% of the patients who received native L-asparaginase. Patients in the GRASPA treatment arm also had overall higher complete remission rates during induction, and GRASPA was associated with fewer drug-related adverse events.

In November 2016, ERYTECH withdrew its original MAA to allow sufficient time to provide the additional data requested in the CHMP's Day 180 List of Outstanding Issues. ERYTECH has now resubmitted its MAA with additional data from studies on comparability, immunogenicity, and pharmacodynamic effects.

Gil Beyen, CEO and Chairman of ERYTECH, said: *"Our teams have worked hard over the past weeks and months to address and compile additional data for the resubmission of the MAA for potential approval of GRASPA as a treatment for ALL. We believe these data have further strengthened our dossier for European marketing authorization. We strongly believe in the potential of our drug candidate and are looking forward to working with the EMA during the review process."*

Dr. Iman El-Hariry, Chief Medical Officer of ERYTECH, added: *"We are delighted to complete the resubmission of the MAA for GRASPA in R/R ALL. Asparaginase continues to play an important role in treatment of newly diagnosed patients with R/R ALL. ERYTECH is committed to developing an effective therapy to patients with ALL and improving patient outcomes."*

About Acute Lymphoblastic Leukemia

Acute Lymphoblastic Leukemia (ALL) is a blood cancer affecting mainly the white blood cells. ALL is most prevalent in children between the ages of two and five, although adults are also affected. The American Cancer Society estimates that approximately 5,970 new cases of ALL will be diagnosed in the United States in 2017, resulting in approximately 1,440 deaths. Based on incidence data published in scientific literature, ERYTECH estimates that there are at least as many new cases of ALL diagnosed each year in Europe as in the United States. The risk for developing ALL declines slowly after the age of five until the mid-20s and then begins to rise again slowly after the age of 50. Although most cases of ALL occur in children, approximately 80% of deaths from ALL occur in adults. Pediatric ALL patients have a five-year survival rate of approximately 90%, while the five-year survival rate for adults drops to approximately 30% and for seniors to approximately 15%.

About ERYTECH and eryaspase (GRASPA®): 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 development of products that target the amino acid metabolism of cancer, depriving them of nutrients necessary for their survival.

The company's lead product, eryaspase, also known under the trade name GRASPA®, 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. L-asparaginase has been a standard component of multi-agent chemotherapy for the treatment of acute lymphoblastic leukemia (ALL), but side effects limit treatment, especially in adults and patients with weak performance status. With its improved safety profile, eryaspase aims to provide L-asparaginase to patients who cannot tolerate current non-encapsulated asparaginases.

Eryaspase demonstrated positive efficacy and safety results in various studies in ALL, including in a Phase 2 study in elderly patients with ALL and a Phase 2/3 study in children and adults with relapsed or refractory ALL, as well as in pancreatic cancer, where it achieved positive results in a Phase 2b study of second-line treatment of patients with metastatic pancreatic cancer. ERYTECH believes that the positive results of its Phase 2b clinical study in second-line metastatic pancreatic cancer are significant indicators of eryaspase as a potential treatment approach in solid tumors. ERYTECH also has an ongoing Phase 1 clinical study of eryaspase in the United States in adults with newly diagnosed ALL and a Phase 2b clinical study in Europe in elderly patients with newly diagnosed acute myeloid leukemia (AML), each in combination with chemotherapy.

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, erymethionase and eryminase, that focus on using encapsulated enzymes to target cancer metabolism and induce tumor starvation. ERYTECH is also exploring the use of its ERYCAPS platform for developing cancer immunotherapies (ERYMMUNE) and enzyme replacement therapies (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.

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 ERYTECH's resubmission of the MAA or that its product candidates will receive the necessary regulatory approvals or that they will prove to ultimately 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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