

ERYTECH submits EMA Marketing Authorization Application for GRASPA to treat acute lymphoblastic leukemia

Lyon (France), September 14, 2015 – ERYTECH Pharma (Euronext Paris: ERYP), the French biopharmaceutical company that develops innovative ‘tumor starvation’ treatments for acute leukemia and other oncology indications with unmet medical needs, announces today the submission of a centralized Marketing Authorization Application (MAA) to the European Medicines Agency (EMA) for ERY-ASP (Invented Name: GRASPA®) for the treatment of patients with acute lymphoblastic leukemia (ALL).

The MAA for GRASPA, ERYTECH’s lead product, consisting of asparaginase encapsulated in red blood cells, is based on the positive findings of the pivotal GRASPALL 2009-06 Phase 2/3 study in children and adults with relapsed ALL.

In the GRASPALL Phase 2/3 study, the results of which were reported in December 2014, GRASPA in combination with chemotherapy was observed to result in improved clinical activity and tolerability as compared to native L-asparaginase in patients with relapsed ALL. The mean duration of asparaginase activity above 100 IU/L was 20.5 days in the GRASPA group versus 9.6 days in the control arm of patients treated with native L-asparaginase in combination with chemotherapy ($p < 0.001$), and patients in the study treated with GRASPA also demonstrated a significantly lower incidence of hypersensitivity reactions as compared to those in the control arm ($p < 0.001$). Patients treated with GRASPA also experienced an improvement in complete remission (CR) rate ($p = 0.024$) as compared to those in the control arm. Treatment with GRASPA was generally well tolerated, and those treated with GRASPA also had a lower incidence of adverse events, such as coagulation disorders, pancreatic toxicities and hepatic toxicities, than those treated with native L-asparaginase.

Gil Beyen, CEO and Chairman of ERYTECH Pharma, commented: *"I am delighted that we have submitted this application to the EMA. It represents an important achievement in the company's efforts to bring a meaningful therapeutic option to patients and families with acute lymphoblastic leukemia and a significant milestone in ERYTECH's development."*

Dr. Iman El-Hariry, Chief Medical Officer of ERYTECH Inc., added: *"We were able to reach this point because of the extraordinary effort of the employees at ERYTECH, the investigators for the clinical trials and most importantly, the patients who participated in the clinical trials and their families. We are looking forward to the potential to offer patients with ALL another effective treatment option with a favorable safety profile."*

About Acute Lymphoblastic Leukemia

Acute Lymphoblastic Leukemia (ALL) is a blood cancer affecting mainly the white blood cells. ALL is most prevalent for children between the ages of two and five, although adults are also affected. The American Cancer Society estimates that approximately 6,250 new cases of ALL will be diagnosed in the United States in 2015, resulting in over 1,400 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 ERY-ASP (GRASPA®): www.erytech.com

Created 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. The company has recently announced positive efficacy and safety results from its completed Phase 2/3 pivotal clinical trial in Europe with its lead product, ERY-ASP, also known under the trade name GRASPA®, in children and adults with relapsed or refractory ALL. ERYTECH also has an ongoing Phase 1 clinical trial of ERY-ASP in the United States in adults with newly diagnosed ALL, and a Phase 2 clinical trial in Europe evaluating GRASPA as a first-line therapy for the treatment of elderly patients with AML, each in combination with chemotherapy.

ERY-ASP 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.

Every year over 50,000 patients in Europe and the United States are diagnosed with ALL or AML. For about 80% of these patients, mainly adults and relapsing patients, current forms of L-asparaginase cannot be used due to their toxicity or as a result of allergic reactions. ERYTECH believes that the safety and efficacy profile of ERY-ASP/GRASPA, as observed in its Phase 2/3 pivotal clinical trial, offers an attractive alternative option for the treatment of leukemia patients.

ERYTECH believes that ERY-ASP 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. In addition to its current product candidates that focus on using encapsulated enzymes to induce tumor starvation, ERYTECH is exploring the use of its platform for developing cancer vaccines and enzyme replacement therapies.

The EMA and the US Food and Drug Administration (FDA) have granted orphan drug designations to ERY-ASP/GRASPA for the treatment of ALL, AML and pancreatic cancer. ERYTECH produces ERY-ASP at its own GMP-approved and operational manufacturing site in Lyon (France), and at a site for clinical production in Philadelphia (USA). The Company has entered into licensing and distribution partnership agreements for ERY-ASP for ALL and AML in Europe with Orphan Europe (Recordati Group), and for ALL in Israel with TEVA, who will market the product under the GRASPA® brand name.

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 US under an ADR level 1 program (OTC, ticker EYRY).

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