

## **ERYTECH Completes Patient Enrollment in Phase 2b Trial for eryaspase (GRASPA®) in Acute Myeloid Leukemia**

Primary data read-out for the European trial expected in 2H2017

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**Lyon (France), August 29, 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 that it has reached full patient enrollment in the Phase 2b trial of eryaspase, also known as ERY-ASP or GRASPA®, for the treatment of acute myeloid leukemia (AML).

The open-label, randomized, multi-center clinical trial, which is being conducted at more than 20 sites in Europe, has completed enrollment of a total of 123 patients and is on track for reporting of primary data in the second half of 2017. Patients enrolled in the trial are over the age of 65, newly-diagnosed with AML, and unable to receive intensive chemotherapy. The primary endpoint is overall survival (OS) at one year.

*“We are pleased to have reached this important clinical milestone of complete enrollment in our trial for AML and expect to reporting primary data from the trial in the second half of 2017,” said Gil Beyen, Chairman and CEO of ERYTECH. “AML is a very aggressive cancer. We are developing eryaspase with the goal of contributing to the treatment of these patients, many of whom may respond to L-asparaginase, but have difficulty with the side effects associated with the current available forms. Therefore, we believe the increased tolerability profile obtained through the encapsulation of L-asparaginase in the red blood cells could result in a new innovative approach to treatment of AML patients.”*

Eryaspase, or GRASPA®, consists of the L-asparaginase enzyme encapsulated inside donor-derived red blood cells through ERYTECH’s proprietary ERYCAPS technology platform. The enzyme degrades asparagine, an amino acid that is essential for the tumor cells to grow and multiply, which starves and eventually kills the cancer cells. The Phase 2b trial was designed to evaluate the efficacy of GRASPA® when added to low-dose cytarabine, the current standard of care. The study is performed in collaboration with Orphan Europe (Recordati Group), ERYTECH’s partner for the anticipated commercialization of GRASPA® for the treatment of ALL and AML in Europe.

### **About acute myeloid leukemia (AML)**

With about 34 000 new patients per year in Europe and the US, AML is the most common type of acute leukemia. Affecting mainly the adult and senior patient population that often cannot tolerate the existing forms of asparaginase products, AML represents one of the highest mortality rates among all type of cancers and an important unmet medical need.

### **About ERYTECH and eryaspase (eryasp/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 has recently filed for European Marketing Authorization for its lead product candidate, eryaspase, also known as eryasp or GRASPA®, following 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.

Eryaspase (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, 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 eryaspase (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 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.

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 immunotherapy and enzyme replacement therapies.

The 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. ERYTECH produces the product 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 GRASPA® 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.

*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).*

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