

ERYTECH announces third DSMB safety review and continuation of its Phase 2b study in Acute Myeloid Leukemia

Lyon (France), January 6, 2016 – ERYTECH (Euronext Paris: FR0011471135 - ERYP), the French biopharmaceutical company that develops innovative ‘tumor starvation’ treatments for acute leukemia and other oncology indications with unmet medical needs, announces that an independent Data and Safety Monitoring Board (DSMB¹) completed its third safety assessment of the company’s Phase 2b ENFORCE 1 study in acute myeloid leukemia (AML) and that enrollment will continue until completion.

The ENFORCE 1 study is a multinational, randomized, controlled Phase 2b trial evaluating the efficacy and tolerability of GRASPA in the treatment of newly diagnosed AML patients over 65 years of age and unfit for intensive chemotherapy. The primary endpoint of the study is overall survival (OS) following a recently approved protocol amendment, changing the endpoint from progression free survival (PFS) to OS. OS is considered a more robust endpoint in this indication.

Today, more than 90% out of a total of 123 patients to be treated have been enrolled in the study in over 20 active centers in France, Spain, Finland, Norway and Italy.

Two safety assessments had already been performed by an external DSMB when 30 patients and 60 patients were treated in the study with no safety concerns identified. The third DSMB safety review, now with 105 patients treated, again raised no safety concerns. The DSMB noted that their observations regarding the main endpoints are unlikely to change with the additional patients, although the statistical power should be improved. Based on the DSMB comments, ERYTECH decided to continue enrolment into the trial until completion, which is expected during the first quarter of 2016. Primary results are expected in 2017.

About ERYTECH and ERY-ASP (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 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 announced positive efficacy and safety results from its completed Phase 2/3 pivotal clinical trial in Europe with its lead product candidate, 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 in elderly patients with newly diagnosed 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.

¹ A DSMB is an external committee of independent clinical research experts who review data in ongoing clinical trials with particular attention to safety.

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 U.S. Food and Drug Administration (FDA) have granted orphan drug designations for 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). ERYTECH 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, 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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