

ERYTECH announces enrollment of first patient in Phase I/II study of ERY-ASP in Acute Lymphoblastic Leukemia in the United States

Lyon (France), July 22, 2014 – ERYTECH Pharma (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 the enrollment of the first patient in its Phase I/II study with ERY-ASP in Acute Lymphoblastic Leukemia in the United States of America.

ERY-ASP, in Europe known as GRASPA^{®1}, is a new L-asparaginase product, with a safer and broader range of clinical use than existing forms thanks to the entrapment and protection of the enzyme inside red blood cells. In Europe, ERY-ASP is in a Phase III clinical trial in relapsing Acute Lymphoblastic Leukemia (ALL), in Phase IIb in Acute Myeloid Leukemia (AML) and in Phase II in pancreas cancer.

In the USA, the safety profile of ERY-ASP is being confirmed in a dose escalating Phase I/II study in 12 to 18 ALL patients. The study has been authorized by the FDA in 2013 and three centers are currently open for patient recruitment: The University of Chicago, Duke University Medical Center and Ohio State University. Professor Larson, Director of the Hematological Malignancies Clinical Research Program at the University of Chicago is the principal investigator of the study.

The first patient has been enrolled and treated last week in Columbus, Ohio. The investigational product has been produced at ERYTECH’s manufacturing facility in Philadelphia. Thanks to a manufacturing agreement with the American Red Cross, this facility is fully operational at GMP level for the production of clinical batches.

“L-asparaginase is an important weapon in the treatment of patients with ALL, but we are often limited by the toxicities related to this drug. Erytech’s formulation in red blood cells looks promising, and may open opportunities to treat the more fragile and older patients. I am very enthusiastic to participate in this clinical trial”, says Dr Rebecca Klisovic, investigator at the Ohio State University.

“The start of this clinical trial in the United States is an important step in ERYTECH’s value creation strategy. Entering the world largest healthcare market was one of the key value drivers put forward in our IPO. We have in the meantime set up ERYTECH Inc, a wholly owned subsidiary in the US, added a US based board member and added specialized US investors to our shareholder base. With this trial we are continuing to build our foothold in the US.” adds Pierre-Olivier Goineau, COO of ERYTECH Pharma.

¹ GRASPA[®] is the future tradename of the product in for use in ALL and AML in Europe; ERY-ASP is the development name in other regions

About ERYTECH and ERY-ASP/GRASPA®: www.erytech.com

Created in Lyon in 2004, ERYTECH is a French biopharmaceutical company providing new prospects for cancer patients, particularly those with acute leukemia and selected solid tumors.

By encapsulating the asparaginase enzyme in red blood cells, ERYTECH has developed ERY-ASP/GRASPA®, an original treatment that targets cancer cells through “tumor starvation” while significantly reducing the side effects for patients. ERY-ASP/GRASPA® is currently completing Phase III clinical development in Acute Lymphoblastic Leukemia (ALL) and is in Phase IIb clinical trial in Acute Myeloid Leukemia (AML) in Europe. The product is also in Phase I/II clinical development in ALL in the USA.

Every year about 50,000 patients are diagnosed with Acute Lymphoblastic Leukemia (ALL) or Acute Myeloid Leukemia (AML), the two forms of acute leukemia. Today, for about 80% of these patients, mainly adults and relapsing patients, current forms of asparaginase cannot be used due to their toxicity. With a presumed improved safety profile, ERY-ASP is being developed to allow all leukemia patients to be treated, even the most fragile ones, representing a market opportunity of more than EUR 1 billion. ERYTECH has concluded licensing and distribution partnership agreements for ALL and AML in Europe with Orphan Europe (Recordati Group), and for ALL with TEVA in Israël.

The company is also developing other indications in solid tumors and certain orphan indications outside oncology. The company is currently launching a Phase II study in pancreas cancer and it exploring other solid tumor indications.

ERYTECH has its own GMP-approved and operational manufacturing site in Lyon (France), and a site for clinical production in Philadelphia (USA).

ERYTECH is listed on Euronext regulated market in Paris. (ISIN code: FR0011471135, ticker: ERYP) and is part of the CAC Healthcare, CAC Pharm. & Bio and Next Biotech indexes.

Forward-looking information

This document may contain forward-looking statements and estimates with respect to the financial situation, the results of operations, the strategy, the project and to the 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 the Company's control. Therefore, actual results, the financial condition, performance or achievements of ERYTECH, or industry results, may turn out to be materially different from any 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 our 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 the publication of this document. ERYTECH disclaims any obligation to update any such forward-looking statement, forecast or estimates to reflect any change in the Company'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 French law.

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