

ERYTECH receives authorization to start its Phase II clinical study in pancreatic cancer

- **Phase II clinical study authorized in France**
- **Patient enrollment expected to start in Q2 2014**

Lyon (France), May 6, 2014 – ERYTECH Pharma (Euronext Paris: FR0011471135 - ERYP), a French biopharmaceutical company that develops innovative treatments for acute leukemia and other oncology indications with unmet medical needs, announces that the ANSM, French healthcare agency, has granted the authorization to start a Phase II study in second line treatment of patients affected by pancreatic cancer.

As part of its strategy to broaden the scope of its lead product ERY-ASP, ERYTECH has retained pancreatic cancer, a very aggressive form of cancer with few treatment options, as the first indication for the product in solid tumors. In Europe and the USA alone, every year about 125,000 patients are newly diagnosed with pancreatic cancer. With an overall 5 year survival of less than 10%, pancreas cancer is one of the most aggressive forms of cancer.

Having already successfully completed a Phase I study in late stage pancreas cancer, in which the tolerability of ERY-ASP has been confirmed in this very fragile patient population, ERYTECH decided to continue the development in solid tumors by performing a Phase II study in second-line therapy for patients with progressive metastatic pancreas cancer.

Scientific advice had been obtained at the end of last year from the European Medicines Agency (EMA) and a clinical trial application (CTA) was subsequently submitted to the ANSM (Agence Nationale de Sécurité du Médicament, the French healthcare agency), who now gave its green light for the study.

In a study of about 100 patients, ERY-ASP in addition to the best standard of care will be compared to the best standard of care alone in a 2 to 1 randomization. The primary endpoint will be progression free survival (PFS) at 4 months. Patients will be stratified according to the expression of asparaginase synthetase (ASNS) of their primary tumor. Low expression of ASNS is believed to be an indicator of tumor sensitivity to asparaginase. ERYTECH estimates that around 70% of patients are low on ASNS and could be responders to the treatment. Patient enrollment is expected to start in Q2 2014.

Professor Pascal Hammel, gastroenterologist specialized in digestive oncology at Hôpital Beaujon (Clichy-Paris, France), is the principal investigator of the study. He comments: *"We observe an increasing number of pancreas cancer patients eligible to a second-line therapy, where we have an important medical need. Tumor starvation is an interesting approach and with the anticipated limited toxicity profile thanks to the encapsulation in red blood cells, we are hopeful ERY-ASP can contribute to enlarge our therapeutic arsenal for these patients."*

"The approval of this new study is an important step for ERYTECH, fully along the lines of the strategy outlined in our IPO to broaden the scope of our technology platform to solid tumor indications. With our unique formulation in red blood cells we hope to be able to contribute to extending the toolbox in treating patients affected by this terrible disease" adds Gil Beyen, Chairman & CEO of ERYTECH.

About pancreas cancer:

Pancreatic cancer is a disease in which malignant (cancer) cells are found in the tissues of the pancreas. Every year about 45,000 patients are diagnosed with pancreatic cancer in the US, and about 80,000 in Europe. According to the American Cancer Society, for all stages of pancreatic cancer combined, the one-year relative survival rate is 20%, and the five-year rate is 6% to 10%. Pancreatic cancer is currently the fourth most common cause of cancer death in the EU for men and women. Death rates from the disease are predicted to rise from 7.8 in 2009 to 8.0 in 2013 per 100,000 among men, and from 5.3 to 5.5 per 100,000 among women in same period. In fact, the pancreas is the only major cancer site for which no improvements in mortality rates is predicated¹.

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.

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, there is no adequate solution due to the toxicity of existing treatments. By encapsulating the asparaginase enzyme in red blood cells, ERYTECH has developed ERY-ASP/GRASPA®, an original and effective treatment that targets leukemia cells through “starvation” while significantly reducing the side effects for patients, and allowing all patients to be treated, even the most fragile ones, representing a market opportunity of more than EUR 1 billion. 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). The product also received FDA clearance to start clinical development in ALL in the USA. ERYTECH has concluded distribution partnership agreements for Europe with Orphan Europe (Recordati Group), and with TEVA for Israel.

The company is also developing other indications in solid tumors and certain orphan indications outside oncology. ERYTECH is launching a Phase II study in pancreas cancer in Europe. The company holds orphan drug designation for ERY-ASP/GRASPA® in ALL, AML and pancreas cancer in Europe and the USA. ERYTECH has its own GMP-approved and operational manufacturing sites in Lyon (France) and Philadelphia (USA).

ERYTECH is listed on Euronext regulated market in Paris. (ISIN code: FR0011471135, ticker: ERYP) and is part of the CAC All Shares, CAC Healthcare, CAC Pharma & Bio, CAC Small, CAC Mid&Small, CAC All Tradable and Next Biotech indexes. ERYTECH shares are eligible to PEA-PME (French share savings plan for SMEs).

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.

¹ Malvezzi M et al., *Annals of Oncology* 2013, 1-9

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