



ERYTECH Announces FDA's Authorization to Proceed with Phase 3 Trial for Eryaspase in Pancreatic Cancer in the United States

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- **Investigational New Drug Application reviewed and accepted**
- **Enrollment of US patients expected to begin in Q3 2019**
- **Clinical trial authorizations now obtained in all twelve participating countries**

LYON, France and CAMBRIDGE, Mass. , May 13, 2019 (GLOBE NEWSWIRE) -- **ERYTECH Pharma (Euronext: ERYP - Nasdaq: ERYP)**, a clinical-stage biopharmaceutical company developing innovative therapies by encapsulating drug substances inside red blood cells, today announced the acceptance by the US Food and Drug Administration (FDA) of its Investigational New Drug (IND) application for eryaspase, consisting of the enzyme L-asparaginase encapsulated inside donor derived red blood cells. The acceptance of the IND will enable ERYTECH to initiate enrollment at US trial sites for its ongoing pivotal Phase 3 TRYbeCA1 trial evaluating eryaspase in second-line pancreatic cancer.

TRYbeCA1 is expected to enroll approximately 500 patients with second-line metastatic pancreatic cancer at more than 120 clinical sites in Europe and the United States. In this trial, eligible patients are randomized 1-to-1 to receive eryaspase in combination with standard chemotherapy (gemcitabine/nab-paclitaxel or an irinotecan-based regimen) or chemotherapy alone. The primary endpoint of TRYbeCA1 is overall survival. An interim efficacy analysis is planned for when approximately two-thirds of events have occurred. The trial started enrolling patients in Spain in September 2019 and is now actively enrolling patients in several European countries. The notification for the study to proceed in the US comes in addition to clinical trial authorizations received in eleven European countries.

"There is a high unmet need for therapeutic options in pancreatic cancer, particularly in metastatic patients who have progressed on first-line chemotherapy. With the FDA's acceptance of the eryaspase IND, we are excited to initiate US trial sites and to begin enrolling patients in TRYbeCA1," stated Iman El Hariry, Chief Medical Officer of ERYTECH. *"We have been pleased with the level of interest and enrollment from European TRYbeCA1 sites thus far and will look to build upon the momentum we have in Europe with investigators in the US. We anticipate that the first US patient enrolled in TRYbeCA1 will be in the third quarter of 2019."*

"We are very pleased to learn that the FDA has reviewed our IND and is allowing ERYTECH to proceed with the initiation of the TRYbeCA1 study in the United States. This is good news for patients with pancreatic cancer in the USA that now have another clinical trial opportunity to combat this deadly disease" commented Dr. Manuel Hidalgo, Chief, Division of Hematology and Medical Oncology at Weill Cornell Medicine and New York Presbyterian Hospital.

About pancreatic cancer

Pancreatic cancer is a disease in which malignant (cancer) cells are found in the tissues of the pancreas. Every year, there are approximately 150,000 new cases of pancreatic cancer diagnosed in Europe and the United States. Advanced pancreatic cancer is a particularly aggressive cancer, with a five-year survival rate of less than 10%. It is currently the fourth leading cause of cancer death in Europe and the United States and is projected to rise to the second leading cause by 2030. Limited therapeutic options are currently available for this indication, thereby reinforcing the need to develop new therapeutic strategies and rational drug combinations with the aim of improving overall patient outcomes and quality of life.

About ERYTECH: www.erytech.com

ERYTECH is a clinical-stage biopharmaceutical company developing innovative red blood cell-based therapeutics for severe forms of cancer and orphan diseases. Leveraging its proprietary ERYCAPS platform, which uses a novel technology to encapsulate drug substances inside red blood cells, ERYTECH is developing a pipeline of product candidates for patients with high unmet medical needs.

ERYTECH's primary focus is on the development of product candidates that target the altered metabolism of cancer cells by depriving them of amino acids necessary for their growth and survival. The Company's lead product candidate, eryaspase, which consists of L-asparaginase encapsulated inside donor-derived red blood cells, targets the cancer cells' altered asparagine and glutamine metabolism. Eryaspase is in Phase 3 clinical development for the treatment of second-line pancreatic cancer and in Phase 2 for the treatment of triple-negative breast cancer. ERYTECH is also developing erymethionase, which consists of methionine-gamma-lyase encapsulated in red blood cells to target methionine-dependent cancers.

ERYTECH produces product candidates at its GMP-approved manufacturing site in Lyon, France, and at the American Red Cross in Philadelphia, USA. A large-scale GMP manufacturing facility has recently completed construction in Princeton, New Jersey, USA.

ERYTECH is listed on the Nasdaq Global Select Market in the United States (ticker: ERYP) and on the Euronext regulated market in Paris (ISIN code: FR0011471135, ticker: ERYP). ERYTECH is part of the CAC Healthcare, CAC Pharma & Bio, CAC Mid & Small, CAC All Tradable, EnterNext PEA-PME 150 and Next Biotech indexes.

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Forward-looking information

This press release contains forward-looking statements, forecasts and estimates with respect to the clinical results from and the development plans of eryaspase, business and regulatory strategy, expansion of manufacturing capacity and 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. All statements contained in this press release other than statements of historical facts are forward-looking statements, including, without limitation, statements regarding the potential of ERYTECH's product pipeline, its clinical development of eryaspase, and the timing of ERYTECH's preclinical studies and clinical trials and announcements of data from those studies and trials. 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 ERYTECH's control. There can be no guarantees with respect to pipeline product candidates that the candidates will receive the necessary regulatory approvals or that they will prove to be commercially successful. Therefore, actual results may turn out to be materially different from the anticipated future results, performance or achievements expressed or implied by such statements, forecasts and estimates. Further description of these risks, uncertainties and other risks can be found in the Company's regulatory filings with the French Autorité des Marchés Financiers (AMF), the Company's Securities and Exchange Commission (SEC) filings and reports, including in the Company's 2018 Document de Référence filed with the AMF on March 29, 2019 and in the Company's Annual Report on Form 20-F filed with the SEC on March 29, 2019 and future filings and reports by the Company. 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 this press release. Readers are cautioned not to place undue reliance on any of these forward-looking statements. ERYTECH disclaims any obligation to update any such forward-looking statement, forecast or estimates to reflect any change in ERYTECH'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 law.



Source: Erytech Pharma S.A.