

ERYTECH Announces Enrollment of First Patients in Phase 3 Clinical Trial Evaluating Eryaspase for the Treatment of Second Line Pancreatic Cancer

Lyon (France) and Cambridge, Mass. (U.S.), September 20, 2018 – ERYTECH Pharma (Euronext Paris: ERYP - Nasdaq: ERYP), a clinical-stage biopharmaceutical company developing innovative therapies by encapsulating drug substances inside red blood cells, today announced that the first three patients have been enrolled in its pivotal Phase 3 clinical trial, named ‘TRYbeCA1’, evaluating its lead product candidate eryaspase for the treatment of second line metastatic pancreatic cancer.

The TRYbeCa1 (NCT03665441) trial will enroll approximately 500 patients with second line metastatic pancreatic cancer in 120-130 clinical sites in Europe and the US. Patients who meet the eligibility criteria are randomized 1-to-1 to receive eryaspase in combination with standard chemotherapy (gemcitabine/abraxane or irinotecan -based regimen) or chemotherapy alone until disease progression. The primary endpoint is overall survival. An interim analysis is foreseen when approximately two-thirds of events have occurred.

The launch of the TRYbeCA1 Phase 3 trial follows the positive Phase 2b results in the same patient population, that were reported in September 2017. This open-label, multi-center, 2-to-1 randomized study in 141 patients demonstrated significant improvement in both overall survival and progression-free survival. Overall, eryaspase was well tolerated and showed a safety profile comparable to that of standard chemotherapy.

“The results from our landmark Phase 2b study are highly promising and underscore the importance of targeting tumor metabolism pathways in pancreatic cancer. We are hopeful to provide a novel treatment modality for this highly unmet medical need. We are very pleased that eryaspase has now moved into Phase 3 and patient enrollment has started as planned. Our first three enrolled patients mark the initiation of the trial in Europe. Early next year, we expect sites in the United States will begin enrolling as well,” commented Iman El-Hariry, Chief Medical Officer.

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 and eryaspase (GRASPA®): www.erytech.com

Founded in Lyon, France in 2004, ERYTECH is a clinical-stage biopharmaceutical company developing innovative therapies for 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 development of products that target the altered amino acid metabolism of cancer cells, depriving them of nutrients necessary for their survival.

The Company's lead product, eryaspase, also known under the trade name 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. L-asparaginase has been a standard component of multi-agent chemotherapy for the treatment of pediatric acute lymphoblastic leukemia (ALL), but excessive toxicities have limited clinical development in solid tumors.

Eryaspase demonstrated promising efficacy and safety results in various clinical trials in ALL, as well as in a Phase 1 and a Phase 2b trial in second-line pancreatic cancer. A pivotal Phase 3 clinical trial in second line pancreatic cancer is ongoing and a Phase 2 in triple-negative breast cancer is being launched. Additional solid tumor indications are being evaluated.

ERYTECH produces eryaspase at its own GMP-approved and operational manufacturing site in Lyon (France), and at a site for clinical production in Philadelphia (USA). A large-scale manufacturing facility is under construction in New Jersey (USA).

In addition to eryaspase, ERYTECH is developing erymethionase, methionine- γ -lyase encapsulated in red blood cells, to target cancer cells' amino acid metabolism and induce tumor cell starvation. ERYTECH is also exploring the use of its ERYCAPS platform for developing cancer immunotherapies (ERYMMUNE) and enzyme replacement therapies (ERYZYME).

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: FRO011471135, 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 and regulatory plans for eryaspase, the timing of ERYTECH's clinical studies and trials and announcements of data from those studies and trials, and the contents and timing of decisions by the FDA and EMA regarding ERYTECH's product candidates. 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 2017 Document de Référence filed with the AMF in April 2018 and in the Company's Annual Report on Form 20-F filed with the SEC on April 24, 2018 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.