

ERYTECH Achieves Milestones in TRYbeCA1 Phase 3 Trial of Eryaspase in Second-line Pancreatic Cancer

- Trial opened for patient enrollment in the United States
- Independent Data Monitoring Committee recommends continuation of the trial as planned

Lyon (France) and Cambridge, MA (U.S.), November 4, 2019 – ERYTECH Pharma (Euronext: ERYP - Nasdaq: ERYP), a clinical-stage biopharmaceutical company developing innovative therapies by encapsulating therapeutic drug substances inside red blood cells, announced two important milestones for the TRYbeCA1 Phase 3 clinical trial of eryaspase in second line metastatic pancreatic cancer.

TRYbeCA1 was opened for patient enrollment in the United States last week, and the first of a planned total of 30 U.S. sites was activated. This marks an important step to expand the trial to approximately 100 sites across several European countries and the U.S. The manufacturing of eryaspase for the patients to be treated in the U.S. will take place at the newly established manufacturing facility in Princeton, N.J.

Separately, on October 29, further to its review of the safety data of the first 150 enrolled and treated patients in the TRYbeCA1 trial, the Independent Data Monitoring Committee (IDMC) identified no safety issues and recommended the trial to continue as planned.

“We are very pleased with the progress of our pivotal Phase 3 program in pancreatic cancer,” said Gil Beyen, Chief Executive Officer of ERYTECH Pharma. “The addition of leading clinical sites in the U.S. should further boost the already strong enrollment in the trial.”

“The positive safety review by the IDMC of the first 150 patients in the study confirms the favorable safety profile of the eryaspase product candidate, which is key because in this trial, eryaspase is combined with chemotherapy regimens that carry significant inherent toxicity,” said Dr Iman El-Hariry, Chief Medical Officer of ERYTECH Pharma.

About TRYbeCA1

TRYbeCA 1 is a randomized, controlled Phase 3 clinical trial evaluating eryaspase in second-line metastatic pancreatic cancer. The trial is planned to enroll approximately 500 patients at approximately 100 clinical sites in Europe and the United States. 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 superiority analysis, planned for when approximately two-thirds of events have occurred, is anticipated to be conducted in the third quarter of next year.

About ERYTECH and eryaspase: 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 cell's 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. An investigator-sponsored Phase 2 study in acute lymphoblastic leukemia is ongoing in the Nordic countries of Europe.

ERYTECH produces its product candidates for treatment of patients in Europe at its GMP-approved manufacturing site in Lyon, France, and for patients in the United States at its recently opened GMP manufacturing site 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 ERYTECH's business strategy including its clinical development of eryaspase; the status of the TRYbeCA 1 trial including the timeline for patient enrollment, expansion of trial into the United States and intended activities with respect to the interim analysis; the potential of ERYTECH's product pipeline; the timing of ERYTECH's preclinical studies and clinical trials and announcements of data from those studies and trials; ERYTECH's anticipated manufacturing capacity and ability to meet future demand and ERYTECH's anticipated cash runway and sufficiency of cash resources. 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 in March 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.