

ERYTECH Announces TRYbeCA-1 Phase 3 Trial in 2L Pancreatic Cancer to Continue to Final Analysis

- The Independent Data Monitoring Committee (IDMC) recommends trial to continue to final analysis, expected in Q4 2021
- No safety issues identified, consistent with observations in previous IDMC reviews

Lyon (France) and Cambridge, MA (U.S.), February 8, 2021 – ERYTECH Pharma (Nasdaq & Euronext: ERYP), a clinical-stage biopharmaceutical company developing innovative therapies by encapsulating therapeutic drug substances inside red blood cells, today announced that TRYbeCA-1, a Phase 3 clinical trial evaluating eryaspase in second-line pancreatic cancer, will continue without modification following a planned interim superiority analysis conducted by an Independent Data Monitoring Committee (IDMC).

The interim analysis was triggered when two-thirds of the total number of events had occurred and allowed the potential for stopping the trial early if the primary endpoint reached statistical significance, adjusting the statistical threshold for the interim review. As with the three previous IDMC reviews, no safety issues have been identified and the Company remains blinded to the primary and secondary endpoint efficacy data. The TRYbeCA-1 trial is fully enrolled and the Company continues to expect the final analysis in the fourth quarter of 2021.

"This IDMC review was the first combined efficacy and safety review. We are pleased that no safety issues were raised." said Gil Beyen, Chief Executive Officer of ERYTECH Pharma. "The trial will now continue to the final efficacy analysis. With 512 patients enrolled, the trial has approximately 90% power to detect the trial's design hazard ratio of 0.725. Second-line pancreatic cancer is a devastating disease and remains a large unmet medical need. We are hopeful that TRYbeCA-1 can confirm the survival benefit we observed in the Phase 2b clinical trial and eryaspase can be a potential treatment for these patients. We look forward to sharing final results later this year."

About TRYbeCA-1

TRYbeCA-1 is a randomized, controlled Phase 3 clinical trial evaluating eryaspase in second-line metastatic pancreatic cancer. The trial has enrolled 512 patients, slightly above the target enrollment of 482 patients, at approximately 90 clinical sites in Europe and the United States. Eligible patients were 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 is overall survival (OS). At the target enrollment of 482 patients, the trial is powered to detect an OS benefit, measured as a hazard ratio (HR), of 0.725 (i.e. a reduction in risk of death rate by 27.5%) with 88% probability. The trial protocol includes one interim efficacy analysis, to be performed by the IDMC upon the accrual of 261 death events, and a final efficacy analysis upon reaching a total of 390 events.

About Pancreatic Cancer

Pancreatic cancer is a disease in which malignant (cancer) cells are found in the tissues of the pancreas. It is a particularly aggressive cancer, with a five-year survival rate below 10%. Pancreatic cancer currently the fourth leading cause of cancer death in the United States and is projected to rise to the second leading cause by 2030.

Every year, approximately 200,000 new cases of pancreatic cancer are diagnosed in the United States and Europe. Approximately half of these patients are diagnosed with metastatic disease for which limited therapeutic options are currently available. Notwithstanding significant efforts, very little innovation has occurred in advanced pancreatic cancer. Chemotherapy remains the main treatment modality. Approximately 40-50% of the patients treated with chemotherapy are eligible for second-line treatment.

About ERYTECH and eryaspase

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. An investigator sponsored Phase 2 trial in acute lymphoblastic leukemia recently reported positive results, and an investigator sponsored Phase 1 trial in first-line pancreatic is ongoing.

The U.S. Food and Drug Administration (FDA) and the European Medicines Agency granted eryaspase orphan drug status for the treatment of pancreatic cancer and ALL. Eryaspase received Fast Track designation from the FDA for the treatment of second line pancreatic cancer.

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 GMP manufacturing site in Princeton, New Jersey, USA. Eryaspase is not an approved medicine.

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.

For more information, please visit www.erytech.com

Forward-looking information

This press release contains forward-looking statements including but not limited to statements with respect to the clinical development plans of eryaspase; the clinical trials of the Company's product candidates, including the timeline for patient enrollment as well as expected timing of the availability of results and interim superiority analysis; potential impacts of the ongoing coronavirus (COVID-19) pandemic on the Company's clinical trials, including TRYbeCA-1 clinical trial; the possible sales of ADSs pursuant to the ATM program; and the Company's anticipated cash runway as extended by its convertible bond financing and ATM facility. 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. 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 and timeline 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 2019 Document d'Enregistrement Universel filed with the AMF on March 18, 2020 and in the Company's Annual Report on Form 20-F filed with the SEC on March 18, 2020 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. In addition, the COVID-19 pandemic and the associated containment efforts have had a serious adverse impact on the economy, the severity and duration of which are uncertain. Government stabilization efforts will only partially mitigate the consequences. The extent and duration of the impact on the Company's business and operations is highly uncertain, and that impact includes effects on its clinical trial operations and supply chain. Factors that will influence the impact on the Company's business and operations include the duration and extent of the pandemic, the extent of imposed or recommended containment and mitigation measures, and the general economic consequences of the pandemic. The pandemic could have a material adverse impact on the Company's business, operations and financial results for an extended period of time.

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