



ERYTECH Completes Enrollment in TRYbeCA-1 Phase 3 Trial in Second-Line Pancreatic Cancer

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- **A total of 510 patients enrolled**
- **Events required to trigger interim superiority analysis accrued**
- **Interim superiority analysis expected in Q1 2021; final analysis in Q4 2021**

LYON, France and CAMBRIDGE, Mass., Dec. 14, 2020 (GLOBE NEWSWIRE) -- ERYTECH Pharma (Nasdaq & Euronext: ERYP), a clinical-stage biopharmaceutical company developing innovative therapies by encapsulating therapeutic drug substances inside red blood cells, today announced the completion of enrollment in the TRYbeCA-1 Phase 3 trial in second-line pancreatic cancer.

TRYbeCA-1, the pivotal Phase 3 clinical trial evaluating ERYTECH's lead product candidate, eryaspase, in second-line metastatic pancreatic cancer, has completed patient enrollment. A total of 510 patients participated in the trial, slightly above the target enrollment of 482 patients.

The trial recently accrued the required number of events for the planned interim superiority analysis, to be performed by an Independent Data Monitoring Committee. The results from the interim superiority analysis are expected to be reported in the first quarter of 2021. Since the interim analysis does not include an evaluation for futility, there will be two possible outcomes: the trial will either: (1) continue toward a final analysis, expected in the fourth quarter of 2021, or (2) be concluded early if compelling improvement in overall survival is demonstrated, in which case the Company expects to file for regulatory approval in the United States and in Europe in the second half of 2021.

Earlier this year, the U.S. Food and Drug Administration granted eryaspase Fast Track Designation as a potential second-line treatment for patients with metastatic pancreatic cancer. Eryaspase also benefits from Orphan Drug status in pancreatic cancer in both the United States and Europe.

"We are extremely pleased that the TRYbeCA-1 trial enrollement has continued to progress on schedule despite the challenges caused by the COVID-19 global pandemic," said Dr. Iman El Hariry, Chief Medical Officer of ERYTECH. *"This achievement is only possible because of the hard work of the study investigators, hospital staff at the trial sites, patients and their families. We look forward to the outcome of the planned interim analysis for superiority early next year."*

"Patients with advanced pancreatic cancer need new treatment options, particularly in the second line setting after failure of gemcitabine-nab-paclitaxel or FOLFIRINOX combinations," added Dr Jean-Philippe Metges, medical oncologist at the University Hospital in Brest (France) and the national coordinator of the TRYbeCA-1 trial for France. *"TRYbeCA-1 is one of the largest clinical trials currently open in second-line metastatic pancreatic cancer. If successful, this will lead to a treatment paradigm shift in this disease."*

About TRYbeCA-1

TRYbeCA-1 is a randomized controlled Phase 3 clinical trial evaluating ERYTECH's lead product candidate, eryaspase, in second-line metastatic pancreatic cancer. Target enrollment was 482 patients. Five-hundred and ten patients were enrolled in the trial in close to 90 clinical sites in the United States and 11 countries in Europe and 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 (OS). The trial was designed to detect an OS hazard ratio (HR) of 0.725 with close to 90% power at a single-sided alpha level of 2.5%. An interim superiority analysis, to be performed by an independent data monitoring committee (IDMC), is foreseen on two-thirds of total OS events. Demonstration of improved OS with a single-sided p-value below 0.006 will be considered compelling evidence of survival benefit at this interim analysis and can form the basis for the IDMC to recommend early conclusion of the trial for superiority.

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 185,000 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 below 10%. It is currently the fourth leading cause of cancer death in 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. Approximately 50% of patients 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. Eryaspase is not approved in any country.

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.

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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