ERYTECH Announces First Patient Enrolled in a Phase 1 Investigator Sponsored Trial of Eryaspase in First-Line Pancreatic Cancer

- Trial to evaluate safety of eryaspase in combination with FOLFIRINOX for the first-line treatment of pancreatic cancer
- Trial in Progress (TiP) poster accepted for presentation at the American Society of Clinical Oncology – Gastrointestinal Cancers Symposium (ASCO GI)

Lyon (France) and Cambridge, MA (U.S.), January 14th, 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 the first patient enrolled in a Phase 1 investigator sponsored trial (IST), named rESPECT, of its lead product eryaspase for the first-line treatment of pancreatic cancer.

The rESPECT Phase 1 IST (NCT04292743) will be conducted by Dr Marcus Noel (Associate Professor of Medicine at Georgetown University, Washington DC, USA). The trial will enroll approximately 18 patients who have received no prior chemotherapy for the treatment of locally advanced or metastatic pancreatic cancer. The dose of eryaspase will be escalated and added to modified FOLFIRINOX to assess the safety and tolerability of the combination. FOLFIRINOX is one of the most commonly utilized first-line chemotherapy regimens for the treatment of pancreatic cancer.

The study has been accepted for poster presentation at the forthcoming Virtual ASCO GI meeting (abstract #TPS453). The TiP poster will be available on ASCO GI’s website starting at 8:00 a.m. ET/1:00 p.m. GMT on Friday 15th January 2021.

Poster is available to view online at the ASCO Virtual meeting website: https://meetinglibrary.asco.org/record/194379/slide

Dr Marcus Noel commented that: “First-line pancreatic cancer remains a challenging disease to treat with few treatment options. Our aim for this study is to demonstrate that eryaspase can be added to existing standard therapy, mFOLFIRINOX. I look forward to sharing the full study rationale and design at the Virtual ASCO GI.”

Dr Iman E-Hariry, Erytech’s Chief Medical Officer, added: “We are delighted to be working alongside Dr Noel at the University of Georgetown. We are grateful to Dr Noel for providing his expertise and leadership in developing and initiating the study protocol. The initiation of this trial represents an important milestone for the program, as we begin to evaluate the potential of eryaspase in first-line pancreatic cancer and anticipate top-line results from the Phase 3 TRYbeCA-1 trial in second-line pancreatic cancer in 2021.”

About rESPECT

rESPECT is a single-arm, multi-center, open-label Phase 1 trial, initiated and sponsored by Georgetown University, Washington DC, USA. A standard 3+3 dose escalation design will be used to determine the maximum tolerated dose (MTD) from 4 possible dose levels of Eryaspase in combination with mFOLFIRINOX. The trial is designed to demonstrate the addition of eryaspase to mFOLFIRINOX (5-fluorouracil [5-FU], leucovorin, irinotecan, and oxaliplatin) will be safe and show preliminary signs of efficacy in patients with advanced pancreatic cancer. Safety assessments include adverse events, physical examination abnormalities, vital signs, and clinical laboratory tests.
About Pancreatic Cancer

Pancreatic cancer is a disease in which malignant (cancer) cells are found in the tissues of the pancreas. 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. Every year, there are approximately 185,000 new cases of pancreatic cancer diagnosed in Europe and the United States. Approximately half of patients are diagnosed with metastatic disease and approximately 30% of patients are diagnosed with locally advanced disease. Advanced pancreatic cancer is a particularly aggressive cancer, with a five-year survival rate below 10%. 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

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.

ERYTECH produces its product candidates for treatment of patients in Europe at its GMP 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: ERY) and on the Euronext regulated market in Paris (ISIN code: FR0011471135, ticker: ERY). 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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