

## **ERYTECH Announces Maximum Tolerated Dose Declared in a Phase 1 Investigator Sponsored Trial of Eryaspase in First-Line Pancreatic Cancer**

- **No dose-limiting toxicity (DLT) reported in first two dose cohorts, leading to declaration of the maximum tolerated dose (MTD) at 100 U/kg**
- **Encouraging clinical activity observed in first patients**

**Lyon (France) and Cambridge, MA (U.S.), October 4, 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 MTD has been declared in a Phase 1 investigator sponsored clinical trial (IST), named rESPECT, of its lead product candidate eryaspase for the first-line treatment of pancreatic cancer, defining the recommended dose for future clinical trials in this indication at 100 U/kg.

The rESPECT IST (NCT04292743) is a single arm, dose escalating Phase 1 clinical trial to evaluate the safety of eryaspase in combination with modified FOLFIRINOX. The trial is conducted by Dr Marcus Noel, Associate Professor of Medicine at Georgetown University, Washington DC, USA, and includes pancreatic cancer patients who have received no prior chemotherapy for the treatment of locally advanced or metastatic pancreatic cancer. FOLFIRINOX is one of the most commonly utilized first-line chemotherapy regimens for the treatment of pancreatic cancer, despite its toxicity. Patients were treated across two dose cohorts of 75 U/kg and 100 U/kg eryaspase, with three and six patients included, respectively.

After review of the safety data, the dose escalation committee concluded that the novel combination of mFOLFIRINOX plus eryaspase was well tolerated with no DLT. Consequently, the MTD has been declared at a dose of 100 U/kg eryaspase. Interestingly, all six patients evaluated for response achieved disease control, four patients with objective response and two with stable disease.

The trial will continue to enroll additional patients at the 100 U/kg dose level to further assess the safety and clinical activity. The declared MTD of 100 U/kg eryaspase corresponds with the dose currently being used in clinical trial in second-line patients and it can now be taken forward into future late-stage clinical studies in first-line pancreatic patients.

Full disclosure of both safety and efficacy information will be made at a future medical congress.

**Dr Marcus Noel, Associate Professor of Medicine at Georgetown University, Washington DC, USA,** commented: *“As an oncologist, one of my biggest challenges is the ability to add treatments to existing backbone chemotherapies, such as mFOLFIRINOX, which are already difficult for patients to tolerate. It is highly encouraging that this study has demonstrated the possibility to add a novel treatment, eryaspase, to mFOLFIRINOX without observing DLT. Furthermore, whilst the trial is not designed to answer if eryaspase is efficacious, partial responses in four out of the six patients with imaging are clearly encouraging.”*

**Dr Iman El-Hariry, ERYTECH’s Chief Medical Officer,** added: *“We are delighted to be working alongside Dr Noel at the University of Georgetown and reaching the important milestone of declaring the MTD of eryaspase in first-line pancreatic patients. We look forward to discussing future study designs with Dr Noel and other Key Opinion Leaders so that we can bring this potentially valuable therapy to first-line pancreatic patients at the earliest opportunity. In the fourth quarter of this year, we also expect top-line results from the TRYbeCA-1 Phase 3 clinical trial in second-line pancreatic cancer. If that trial confirms the survival benefit we*

*observed in the earlier Phase 2 trial, we will plan to launch a pivotal trial in first-line pancreatic cancer and potentially other settings such as locally advanced pancreatic cancer.”*

### 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 a Phase 3 clinical development for the treatment of second-line pancreatic cancer, which is fully enrolled and expected to read out top-line results in Q4 2021, and in an ongoing Phase 2 for the treatment of triple-negative breast cancer. An investigator sponsored Phase 2 trial (IST) in acute lymphoblastic leukemia recently reported positive results, and a Phase 1 IST in 1L advanced pancreatic cancer is ongoing.

Eryaspase received Fast Track designation from the U.S. Food and Drug Administration (FDA) for the treatment of advanced pancreatic cancer and treatment of acute lymphoblastic leukemia (ALL) patients who have developed hypersensitivity reactions to E. coli-derived pegylated asparaginase (PEG-ASNase). The FDA and the European Medicines Agency have granted eryaspase orphan drug status for the treatment of pancreatic cancer and ALL.

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](http://www.erytech.com)*

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### Forward-looking Information

This press release contains forward-looking statements including, but not limited to, statements with respect to the clinical development and regulatory plans of eryaspase including the timing of results from the TRYbeCA-1 trial, the Company’s ability to attend a pre-BLA meeting with the FDA and start a rolling BLA submission of eryaspase in the second half of 2021, the timing of potential BLA submissions to the FDA for the treatment of second-line pancreatic cancer and acute lymphoblastic leukemia, the timing of a potential submission to the EMA for the treatment of second-line pancreatic cancer, the Company’s ability to obtain

regulatory approval for the treatment of patients with acute lymphoblastic leukemia who developed hypersensitivity reactions to PEG-asparaginase, the Company's ability to extend the indication scope of eryaspase, the Company's ability for additional funding under the OCABSA financing agreement, and the Company's anticipated cash runway. 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 2020 Document d'Enregistrement Universel filed with the AMF on March 8, 2021 and in the Company's Annual Report on Form 20-F filed with the SEC on March 8, 2021 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