PRESS RELEASE

# ERYTECH Announces Completion of First Cohort in a Phase 1 Investigator Sponsored Trial of Eryaspase in First-Line Pancreatic Cancer

- **No dose-limiting toxicity reported in the first dose cohort**
- **Encouraging clinical activity observed in first patients**
- **Trial will be escalated to the next dose**

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**Lyon (France) and Cambridge, MA (U.S.), April 19, 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 completion of enrollment of the first treatment cohort and the escalation to the next and potentially final dose level 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.**

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 will enroll approximately 18 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.

The trial was launched at the end of last year and has now enrolled the first cohort of three patients. After review of the safety data, the Dose Escalation Committee concluded that no dose-limiting toxicity (DLT) had been observed in the first cohort treated at a therapeutic dose of 75 U/kg eryaspase, and as of the date of this press release, treatment was observed to be well tolerated in the cohort.

Interestingly, two of the three patients treated had a partial response and significantly decreased levels of CA19-9, a pancreatic cancer tumor marker, and the third patient had stable disease after the first cycle of treatment. The trial will now be escalated to the next cohort, where the dose level will be increased to 100 U/kg eryaspase. This will be the highest dose level cohort in the trial and the presumed maximum tolerable dose (MTD) assuming no dose limiting toxicity is observed.

Dr Marcus Noel commented that: *"It has been a highly encouraging start to the clinical trial with eryaspase observed to be well tolerated in combination with mFOLFIRINOX in the initial, therapeutically relevant dose cohort. It is early days and, whilst the trial is not designed to answer if eryaspase is efficacious, the observed reductions in CA19-9 and the partial responses in two out of three patients are clearly encouraging."*

Dr Iman E-Hariry, ERYTECH's Chief Medical Officer, added: *"We are delighted to be working alongside Dr Noel at the University of Georgetown and are pleased with the successful start to the trial. We look forward to treating patients in the next dose cohort and hope to determine the MTD in the coming months. 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 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.

ERYTECH'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: 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)*

## 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 including the Phase 1 Investigator Sponsored Trial in first-line pancreatic cancer and the determination of the maximum tolerable dose. 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.

**CONTACTS**


**ERYTECH**
**Eric Soyer**
CFO & COO

+33 4 78 74 44 38
investors@erytech.com

**LifeSci Advisors, LLC**
Investor Relations
**Corey Davis, Ph.D.**

+1 (212) 915 - 2577
cdavis@lifesciadvisors.com

**NewCap**
**Mathilde Bohin /**
**Louis-Victor Delouvrier**
Investor relations
**Nicolas Merigeau**
Media relations

+33 1 44 71 94 94
erytech@newcap.eu