

# ERYTECH Announces Positive Results from Eryaspase Phase 2 Trial in Acute Lymphoblastic Leukemia Presented at the American Society of Hematology Annual Meeting

Webcast today, Monday, December 7 at 4:00 pm CET/10:00 am ET

 The study confirms the potential of eryaspase as an attractive treatment option for ALL patients with hypersensitivity to PEG-asparaginase

Lyon (France) and Cambridge, MA (U.S.), December 7, 2020 – ERYTECH Pharma (Nasdaq & Euronext: ERYP), a clinical-stage biopharmaceutical company developing innovative therapies by encapsulating therapeutic drug substances inside red blood cells, today announces results from the NOPHO sponsored Phase 2 trial of eryaspase in ALL patients, which were presented by Dr. Line Stensig Lynggaard at the 62<sup>nd</sup> American Society of Hematology (ASH) Annual Meeting yesterday. In a webcast later today, Dr. Birgitte Klug Albertsen, Associate Professor at Aarhus University Hospital, Denmark, and Principal Investigator of the trial, will comment on the data and be available for Q&A.

The Phase 2 NOR-GRASPALL-2016 trial evaluated the safety and pharmacological profile of eryaspase in ALL patients who had previously experienced hypersensitivity reactions to pegylated asparaginase therapy. The trial was conducted by the Nordic Society of Pediatric Hematology and Oncology (NOPHO) at 21 clinical sites in the Nordic and Baltic countries of Europe and enrolled 55 patients. Primary objectives of the trial were asparaginase enzyme activity and safety. Both endpoints were met.

Eryaspase demonstrated sustained asparaginase enzyme activity above the threshold of >100 U/L at trough levels, 14 days after first infusion in 54 of the 55 patients treated.

Eryaspase was generally well tolerated when added to chemotherapy and almost all patients were able to receive the intended courses of asparaginase (median of 5 doses per patient). Of the 55 patients, only 2 patients had severe allergic reaction and withdrew eryaspase treatment.

Dr Line Stensig Lynggaard, the study leader for NOPHO, commented: "Maintaining adequate asparaginase treatment following hypersensitivity to PEG-asparaginase remains an important goal when treating patients with ALL. A global shortage of supply Erwinia-derived asparaginase, which is the current alternative treatment option to PEG-asparaginase, highlights the need for new alternative treatment options. Our study has demonstrated that eryaspase, given as a convenient schedule every two weeks, provides a sustained asparaginase enzyme activity level, few hypersentivity reactions and is generally well tolerated in combination with chemotherapy. We conclude that eryaspase is an attractive treatment alternative for ALL patients with hypersensitivity to PEG-asparaginase."

"We are proud to be working with the NOPHO group in conducting this study in ALL and very grateful to them for presenting the findings at ASH this year. The full study results provide the possibility of an alternative treatment for ALL patients with hypersensitivity to PEG-asparaginase" said Dr. Iman El-Hariry, ERYTECH's Chief Medical Officer. "We look forward to discussing further the potential path forward for eryaspase in ALL with regulatory authorities, including the FDA".

A related eryaspase poster will be presented by Dr. Frank Hoke (ERYTECH's Head of Clinical Pharmacology) on Monday 7<sup>th</sup> December 2020 from 8am PST / 11am EST / 5pm CET.

<u>Abstract #2799</u>: Population Pharmacokinetics of Eryaspase in Patients with Acute Lymphoblastic Leukemia or Pancreatic Adenocarcinoma

The analysis shows the extended circulation time of eryaspase, provides information on patient factors that influence the exposure of eryaspase, and evaluates patient population (pancreatic cancer vs ALL) and formulation (native vs recombinant asparaginase). Specifically, the simulations demonstrate that 100 U/kg dosed every two weeks would achieve the clinical AEA target levels of 100 U/L at trough in approximately 95% of patients.

The abstract (#2799) can be found at: https://ash.confex.com/ash/2020/webprogram/Paper134377.html

## **Webcast Details**

ERYTECH will hold a webcast later today, Monday, December 7, at 4:00 pm CET / 10:00am ET.

Dr. Birgitte Klug Albertsen, Associate Professor at Aarhus University Hospital, Denmark, and Principal Investigator of the trial, Dr. Iman El-Hariry, Chief Medical Officier of ERYTECH Pharma, and Gil Beyen, Chief Executive Officer of ERYTECH Pharma, will comment on the data and be available for Q&A.

The webcast can be followed live online via the link: <a href="https://edge.media-server.com/mmc/p/yp9nynh6">https://edge.media-server.com/mmc/p/yp9nynh6</a>

Conference ID#: 2272914#

### **About Acute Lymphoblastic Leukemia**

Acute lymphoblastic leukemia (ALL) is a cancer of the blood and bone marrow that is the most common type of cancer in children in the US and Europe. More than 13,000 cases are diagnosed in the US and Europe each year with the majority of patients diagnosed before age 20. Asparaginase has been an integral component of ALL treatment for several years but is associated with treatment-limiting hypersensitivity in up to 30% of patients. Discontinuation of asparaginase therapy in ALL patients has been associated with inferior event free survival highlighting the need for additional asparaginase based treatment options.

### **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 cell's 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 first-line triple-negative breast cancer. An investigator-sponsored Phase 2 study in acute lymphoblastic leukemia was recently completed in the Nordic countries of Europe. 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 <a href="https://www.erytech.com">www.erytech.com</a>

# 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 potential indications for and benefits of eryaspase; statements relating to the TRYbeCA-1 clinical trial, including the timeline for patient enrollment as well as expected timing of the availability of results and interim superiority analysis; potential impacts on the Company's clinical trials, including TRYbeCA-1 clinical trial, due to the coronavirus (COVID-19) pandemic such as delays in regulatory review, manufacturing and supply chain interruptions; and the overall impact of the COVID-19 pandemic on the global healthcare system as well as the Company's business, financial condition and results of operations. 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.

### **CONTACTS**

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