



ERYTECH Announces Publication of Positive Results from Eryaspase Phase 2 Trial in Hypersensitive ALL in the British Journal of Haematology

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- **The study confirms the potential of eryaspase (GRASPA®) as an attractive treatment option for acute lymphoblastic leukemia (ALL) patients with hypersensitivity to PEG-asparaginase**

Cambridge, MA (U.S.) and Lyon (France), April 06, 2022 – ERYTECH Pharma (Nasdaq & Euronext: ERYP), a clinical-stage biopharmaceutical company developing innovative therapies by encapsulating therapeutic drug substances inside red blood cells, today announces the results from the NOPHO sponsored Phase 2 trial of eryaspase in ALL patients are now published in the *British Journal of Haematology*.

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 Haematology 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 92.5% of patients. 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.

The Principal Investigator, Dr. Birgitte Klug Albertsen, Associate Professor at Aarhus University Hospital, Denmark, commented, "I am grateful that the editors of the British Journal of Haematology selected our study for publication. The study demonstrated that eryaspase, given as a convenient schedule every two weeks, provides a sustained asparaginase enzyme activity level above the recommended threshold for other Asparaginase treatments, few hypersensitivity reactions and is generally well tolerated in combination with chemotherapy. We conclude that eryaspase seems to be a promising 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 hopeful that 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 have an ongoing dialogue with the U.S. FDA regarding a potential regulatory approval in this indication based on the NOPHO-sponsored trial."*

The paper: **"Asparaginase Encapsulated in Erythrocytes as Second-line Treatment in Hypersensitive Patients with Acute Lymphoblastic Leukaemia"** by Line Stensig Lynggaard, Goda Vaitkeviciene, Cecilia Langenskiöld, Anne Kristine Lehmann, Päivi M. Lähteenmäki, Kristi Lepik, Iman El Hariry, Kjeld Schmiegelow, and Birgitte Klug Albertsen, can be viewed online at <https://doi.org/10.1111/bjh.18152>, appearing in ***British Journal of Haematology*, 2022;00:1– 10, published by Wiley.**

For additional information and copies of the paper, please contact Wiley at <https://wolsupport.wiley.com/s/>

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 (GRASPA®)

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. The proof of concept of eryaspase as a cancer metabolism agent was established in different trials in acute lymphoblastic leukemia (ALL) and pancreatic cancer. An investigator sponsored Phase 2 trial (IST) evaluating the use of eryaspase in ALL patients who developed hypersensitivity reactions to pegylated asparaginase recently reported positive results, based on which the Company intends to request approval in the United States and potentially other territories. The Company is also pursuing a Phase 1 investigator-sponsored clinical trial in first-line pancreatic cancer.

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. 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

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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 a potential BLA submission to the FDA for the treatment of acute lymphoblastic leukemia, 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 or other financing attempts, 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.

Attachment

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