



## ERYTECH Provides Update on Phase 2 Investigator Sponsored Trial of Eryaspase in Second-Line Acute Lymphoblastic Leukemia

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- Patient enrollment completed; 50 patients in the trial
- Encouraging preliminary results based on interim data
- Unmet medical need confirmed by FDA

LYON, France and CAMBRIDGE, Mass., June 09, 2020 (GLOBE NEWSWIRE) -- **ERYTECH Pharma (Nasdaq & Euronext: ERYP)**, a clinical-stage biopharmaceutical company developing innovative therapies by encapsulating therapeutic drug substances inside red blood cells, today provided an update on the ongoing Phase 2 trial, sponsored by the Nordic Society of Paediatric Haematology and Oncology (NOPHO) of eryaspase in second-line acute lymphoblastic leukemia (ALL) patients.

The NOR-GRASPALL-2016 trial is evaluating the safety and activity of eryaspase in primarily pediatric acute lymphoblastic leukemia (ALL) patients who developed hypersensitivity reactions to pegylated asparaginase. The trial which is being conducted at 22 clinical sites in the Nordic and Baltic countries of Europe has reached its target enrollment of 50 patients.

Preliminary findings of the study suggest that eryaspase achieved the target level and duration of asparaginase activity in these patients. Additionally, the addition of eryaspase to the combination chemotherapy was associated with an acceptable tolerability profile, enabling the majority of these patients to receive their fully intended courses of asparaginase. Recent data have confirmed that discontinuation of asparaginase therapy in ALL patients has been associated with inferior disease free survival<sup>1</sup>.

*"Hypersensitivity to asparaginase remains an important concern in the treatment of ALL patients,"* said Dr Birgitte Klug Albertsen, Associate Professor at Aarhus University Hospital, Denmark, and Principal Investigator of the trial. *"Based on the results we have observed thus far, eryaspase appears to have promise as a novel approach to continue asparaginase-based therapy for patients who develop hypersensitivity to pegylated asparaginase. We look forward to sharing the full results of the trial at a future medical congress."*

*"Initial feedback obtained from FDA has confirmed that ALL patients experiencing hypersensitivity to pegylated asparaginase represents an unmet medical need given the limited available treatment choices for these patients,"* said Dr Iman El Hariry, Chief Medical Officer of ERYTECH Pharma. *"The encouraging evidence of activity in the NOPHO trial could provide support that eryaspase may serve as an additional potential therapeutic option in this patient population. We plan to further discuss these data with FDA as they mature to determine the appropriate next steps and assess a potential path forward for eryaspase in this setting."*

### 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.<sup>2,3</sup> More than 13,000 cases are diagnosed in the US and Europe each year with the majority of patients diagnosed before age 20.<sup>4-6</sup> 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<sup>7</sup>. Discontinuation of asparaginase therapy in ALL patients has been associated with inferior event free survival highlighting the need for additional asparaginase based treatment options.

1. J Clin Oncol 2020 Apr 10;JCO1903024. doi: 10.1200/JCO.19.03024. [Epub ahead of print]
2. American Cancer Society, Key Statistics for Childhood Leukemia. Available at <https://www.cancer.org/cancer/leukemia-in-children/about/key-statistics.html>
3. World Health Organization, Incidence of Childhood Leukemia. Available at [http://www.euro.who.int/\\_data/assets/pdf\\_file/0005/97016/4.1.-Incidence-of-childhood-leukaemia-EDITED\\_layouted.pdf?ua=1](http://www.euro.who.int/_data/assets/pdf_file/0005/97016/4.1.-Incidence-of-childhood-leukaemia-EDITED_layouted.pdf?ua=1)
4. Surveillance, Epidemiology and End Results Program, available at <https://seer.cancer.gov/statfacts/html/alyl.html>
5. Eur J Cancer 2011 Nov;47(17): 2493-2511
6. Lancet 2013 Jun 1; 381 (9881): 1943-1955
7. J Pharmacol Pharmacother. 2016 Apr-Jun; 7(2): 62-71

### 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 second-line acute lymphoblastic leukemia is ongoing in the Nordic countries of Europe.

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 [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 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.

PDF available at: <http://ml.globenewswire.com/Resource/Download/78b29581-c536-4224-b85e-bdc8b03b9321>