



ERYTECH Granted U.S. FDA Fast Track Designation for Eryaspase in Hypersensitive ALL

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- **Fast Track designation for eryaspase underscores the need for new treatment options for patients who developed hypersensitivity reactions to pegylated asparaginase**

Cambridge, MA (U.S.) and Lyon (France), July 29, 2021 – ERYTECH Pharma (Nasdaq & Euronext: ERYP), a clinical-stage biopharmaceutical company, leader in red blood-cell based cancer therapeutics, announced today that the U.S. Food and Drug Administration (FDA) has granted eryaspase Fast Track designation for the treatment of acute lymphocytic leukemia (ALL) patients who have developed hypersensitivity reactions to E. coli-derived pegylated asparaginase (PEG-ASNase).

"This is yet another significant milestone and meaningful inflection point in advancing our lead product candidate eryaspase, further supporting our recently announced intention to submit a BLA for eryaspase in hypersensitive ALL patients," said Gil Beyen, CEO of ERYTECH. *"We believe that the FDA's Fast Track designation for eryaspase underscores its potential to address this high unmet medical need."*

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.

In December 2020, positive results from a Phase 2 trial evaluating the safety and enzyme activity of eryaspase in primarily pediatric ALL patients who developed hypersensitivity reactions to pegylated asparaginase were presented by the Nordic Society of Pediatric Hematology and Oncology at the 2020 American Society of Hematology annual meeting. This data demonstrated that eryaspase, in combination with chemotherapy, administered every two weeks, provided a sustained asparaginase enzyme activity level, and was generally well tolerated with few hypersensitivity reactions.

The Company recently confirmed its intention to submit a Biologics License Application (BLA) for eryaspase in this indication in the fourth quarter of 2021 pending successful completion of remaining steps.

Fast Track is a program designed to facilitate the expedited development and review of a new drug, alone or in combination with other drugs, to treat serious or life-threatening conditions for which there is a demonstration of the potential to address an unmet medical need. The purpose is to advance new drugs earlier for patients who need them.

In April 2020, eryaspase was also granted Fast Track designation for the development of a second-line treatment of patients with metastatic pancreatic cancer. A Phase 3 trial in this indication completed enrollment in January 2021 and final results are expected in the fourth quarter of 2021.

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 FDA Fast Track Designation

Fast Track is a program designed to facilitate the expedited development and review of a new drug alone or in combination with other drugs to treat serious or life-threatening conditions for which there is a demonstration of the potential to address an unmet medical need. The purpose is to advance new drugs earlier for patients who need them. Fast Track addresses a broad range of serious conditions. A drug that receives Fast Track designation is eligible for some or all of the following:

- More frequent meetings and interactions with the review team at the FDA to discuss the drug's development and ensure collection of appropriate data needed to support drug approval as well as to discuss accelerated approval, the structure and content of an NDA, and other critical issues.
- More frequent written communications from FDA about such things as the design of the proposed clinical trials and use of biomarkers.
- Eligibility for Accelerated Approval and Priority Review, if relevant criteria are met.
- Rolling Review, which means that a drug company can submit completed sections of its Biologic License Application (BLA) or New Drug Application (NDA) for review by FDA, rather than waiting until every section of the marketing application is completed before the entire application can be reviewed. BLA or NDA review usually does not begin until the drug company has submitted the entire application to the FDA.

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 final 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 lymphocytic 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

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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 Company's anticipated timing of filing a BLA, the Company's ability to obtain regulatory approval for the treatment of patients with acute lymphoblastic leukemia who developed hypersensitivity reactions to PEG-asparaginase, and the Company's expectations regarding alternative markets for hypersensitive ALL patients. 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

Attachment

- [ERYTECH PR FDA FastTrack ALL EN vf](#)