

ERYTECH Confirms Plans To Submit BLA for Eryaspase in Hypersensitive ALL Patients

- Meeting with the U.S. FDA clarified steps and requirements for the submission of a Biologics License Application (BLA) for eryaspase for the treatment of ALL patients who developed hypersensitivity reactions to prior asparaginase therapy, supported by the NOPHO¹-sponsored Phase 2 trial data, previously presented at the ASH 2020 Annual Meeting
- The Company expects to submit the BLA before the end of the year

Cambridge, MA (U.S.) and Lyon (France), July 21, 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 its intention to move forward towards the submission of a BLA to the US Food and Drug Administration (FDA) for eryaspase in hypersensitive acute lymphoblastic leukemia (ALL) patients following feedback from the agency in a pre-BLA meeting.

The purpose for the meeting was to discuss clinical, non-clinical and quality content and expectations for the Company’s potential BLA submission. Based on the discussion and the totality of the available information to the Company to date, ERYTECH believes its regulatory package can potentially support an approval of eryaspase in hypersensitive ALL patients. Pending successful completion of remaining steps, the Company anticipates submitting a BLA in the fourth quarter of 2021.

“We are encouraged by the interactive dialogue with the agency, and grateful for the feedback and guidance we received on a potential path to approval,” said Gil Beyen, CEO of ERYTECH. “This is an important milestone for ERYTECH as it advances our lead product candidate eryaspase as an alternative treatment for ALL patients with hypersensitivity to PEG-asparaginase, while our Phase 3 trial in second line pancreatic cancer is nearing completion. If all goes well, we could be in a position to make this product candidate available to ALL and pancreatic cancer patients in the course of next year.”

In December 2020, positive Phase 2 clinical results were presented by the Nordic Society of Pediatric Hematology and Oncology, at the 2020 American Society of Hematology annual meeting. 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.

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 cells’ altered asparagine and glutamine metabolism. Eryaspase is in Phase 3 clinical development for the

¹ Nordic Society of Pediatric Hematology and Oncology

treatment of second-line pancreatic cancer and in 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. 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

CONTACTS

ERYTECH
Eric Soyer
CFO & COO

LifeSci Advisors, LLC
Corey Davis, Ph.D.
Investor relations

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

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

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

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



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 results for an extended period of time.