ERYTECH Provides Regulatory Update

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- **ERYTECH to stop further plans to pursue a BLA submission seeking an approval for Graspa® in hypersensitive ALL**
- **Evaluation of strategic partnering options ongoing**

Cambridge, MA (U.S.) and Lyon (France), August 24, 2022 – ERYTECH Pharma (Nasdaq & Euronext: ERYP), a clinical-stage biopharmaceutical company developing innovative therapies by encapsulating therapeutic drug substances inside red blood cells, today provided a regulatory update, announcing that it is no longer seeking approval for Graspa® in hypersensitive acute lymphoblastic leukemia (ALL) following feedback from the U.S. Food and Drug Administration (FDA).

"*We are obviously disappointed to stop the process of seeking approval for Graspa in ALL after all the work done and clinical promise observed in this indication,*" **said Gil Beyen, Chief Executive Officer of ERYTECH.** "*In multiple clinical trials, Graspa showed promising results for patients, and we were encouraged by the dialogue with the FDA and the Fast Track designation that we received for this indication last year. However, the changing competitive landscape, combined with new FDA's requests for additional clinical data that would require significant additional resources on our part, led to the difficult decision to stop the development of Graspa in ALL. We are now focusing our resources on our most promising preclinical programs, while pursuing strategic partnering options to maximize value for our shareholders and employees.*"

Following positive results of a Phase 2 trial, sponsored by the Nordic Organization for Paediatric Haematology and Oncology (NOPHO), presented at the 2020 American Society of Hematology annual meeting, ERYTECH has been in discussions with the FDA for the approval of Graspa to treat ALL patients who had previously experienced hypersensitivity reactions to pegylated asparaginase therapy.

A meeting to discuss the submission of a Biologics License Application (BLA) took place in June 2021, after which the Company confirmed its intention to submit a BLA, subject to the submission of additional requested information to the FDA and agreement on an Initial Pediatric Study Plan (iPSP).

The Company recently received feedback from the FDA on its iPSP, submitted in July 2022. After thorough evaluation of this feedback, which included a new request for additional data, and taking into account the changing competitive landscape in the treatment of hypersensitive ALL, the Company has determined that it is in the best interests of the Company and its shareholders to no longer seek approval for Graspa in ALL and to focus its resources on its preclinical programs and strategic partnering activities.

Following the sale of its production facility in Princeton, New Jersey, for $44.5 million in April 2022, the Company appointed a specialized advisor to evaluate strategic options to leverage its ERYCAPS® platform with complementary assets and/or a broader corporate transaction. Multiple options are under review, and the Company expects to give further updates on these strategic initiatives in the fourth quarter of this year.

About ERYTECH

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 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 through a long-term supply agreement with Catalent, operating from ERYTECH's former GMP facility 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

CONTACTS

ERYTECH
Eric Soyer
CFO & COO

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

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

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

Forward-looking information

This press release contains forward-looking statements, forecasts and estimates with respect to the clinical results from and the development plans of eryaspase, business and regulatory strategy and anticipated future performance of ERYTECH and of the market in which it operates. 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. All statements contained in this press release other than statements of historical facts are forward-looking statements, including, without limitation, statements regarding ERYTECH’s business and regulatory strategy and its evaluation of potential strategic transactions. 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. Therefore, actual results may turn out to be materially different from the anticipated future results, performance or achievements expressed or implied by such statements, forecasts and estimates. Important factors that could cause actual results and outcomes to differ materially from those indicated in the forward-looking statements include, among others, the following: (1) the failure to achieve certain regulatory and commercial milestones; (2) the inability to maintain the listing of ERYTECH’s shares on the Nasdaq Global Select market and the Euronext regulated market; (3) changes in applicable laws or regulations; (4) the possibility that ERYTECH may be adversely affected by other economic, business and/or competitive factors; (5) the inability to agree to terms on a long-term supply agreement with Catalent; and (6) other risks and uncertainties indicated from time to time in ERYTECH’s regulatory filings. 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 2021 Universal Registration Document (*Document d’Enregistrement Universel*) filed with the AMF on April 27, 2022 and in the Company’s Annual Report on Form 20-F filed with the SEC on April 28, 2022 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.

Attachment

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