

# **ERYTECH Reports Top-line Results of Phase 2b Study of Eryaspase for the Treatment of AML**

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Conference call and webcast to take place Monday, December 11th at 10:00 a.m. EST

LYON, France--(BUSINESS WIRE)--Dec. 8, 2017-- Regulatory News:

ERYTECH Pharma (Euronext Paris: ERYP) (Nasdaq: ERYP) ("ERYTECH"), a clinical-stage biopharmaceutical company developing innovative therapies by encapsulating therapeutic drug substances inside red blood cells, today announced topline results from its Phase 2b clinical study evaluating eryaspase (GRASPA®) for the treatment of acute myeloid leukemia (AML).

The open-label, randomized, multi-center clinical study, evaluated eryaspase in newly diagnosed AML patients over the age of 65 and unfit for intensive chemotherapy. The study enrolled a total of 123 patients at 30 European sites. The median age of the patients was 78 years. Patients were randomized two-to-one to receive eryaspase in combination with low-dose cytarabine (LDAC) versus LDAC alone. The primary endpoint in this proof-of concept study was overall survival (OS). The key secondary endpoints included progression free survival, overall response and toxicity. The study was performed in collaboration with Orphan Europe (Recordati Group), ERYTECH's partner for the anticipated commercialization of GRASPA® for the treatment of ALL and AML in Europe.

The study did not meet its primary endpoint of overall survival (OS). The OS Hazard Ratio (HR) was 1.06 (95% CI; 0.70, 1.61). When adjusting for minor imbalances in the main prognostic factors at baseline (age, karyotype and FAB status), the OS HR was 0.98 (95% CI; 0.64, 1.50). The median number of months on treatment was less then 2 months in both treatment arms. The toxicity profile was acceptable and consistent with previously reported data for eryaspase.

"These data reflect the complexity of this disease, particularly in the older age group." commented Iman El-Hariry, MD, PhD, Chief Medical Officer of ERYTECH. "While we are disappointed with the outcome, we are reassured with the safety profile of eryaspase in these very frail and elderly patients."

Gil Beyen, Chairman and CEO of ERYTECH, added, "Although clearly disappointing, these results do not change our commitment to the development of the eryaspase product candidate. Eryaspase has shown positive safety and efficacy results in the treatment of pancreatic cancer and acute lymphoblastic leukemia and we remain committed to bringing this treatment option to patients in these and potential other indications."

ERYTECH will hold a conference call and webcast on Monday, December 11<sup>th</sup> at 10:00 am EST to discuss the results of this study. The full dataset will be discussed at a scientific congress in 2018.

Investors and analysts wishing to participate can access the call via the following teleconferencing numbers:

**USA:** +1 833 8186807 **United-Kingdom:** +080 00323836

 Switzerland: +080 0561782
 Germany: +080 01815287

 France: +080 5081485
 Belgium: +080 073308

 Sweden: +020 798505
 Finland: +080 0412874

Netherlands: +080 00200089

**Password**: 6983889

The webcast can be followed live online via the following link:

Webcast Link: https://edge.media-server.com/m6/p/o2fziqc6

An archive of the webcast will be available for 90 days on the "Webcast" section of the Company's investor relations site at <a href="https://www.erytech.com">www.erytech.com</a>.

Additionally, a replay of the call will be available for 7 days. To listen to the replay, please dial:

USA: +1 404 537 3406

Participant Password: 6983889

#### About acute myeloid leukemia (AML)

AML is a form of acute leukemia or blood cancer that results from the improper maturation of myeloid stem cells leading to the production of myeloblasts. The increasing numbers of abnormal blasts crowd out healthy cells in bone marrow (resulting in infection, anemia, and bleeding) and can spread to other parts of body. With about 40,000 new patients per year in Europe and the United States, AML is the most common type of acute leukemia. Affecting mainly the adult and senior patient population, the median age of patients diagnosed with AML is approximately 67 years, and AML represents one of the highest mortality rates among all type of cancers and an important unmet medical need.

## About ERYTECH and eryaspase (GRASPA®): www.erytech.com

Founded in Lyon, France in 2004, ERYTECH is a clinical-stage biopharmaceutical company developing innovative therapies for rare forms of cancer and orphan diseases. Leveraging its proprietary ERYCAPS platform, which uses a novel technology to encapsulate therapeutic drug substances inside red blood cells, ERYTECH has developed a pipeline of product candidates targeting markets with high unmet medical needs. ERYTECH's initial focus is on the development of products that target the amino acid metabolism of cancer, depriving them of nutrients necessary for their survival.

The Company's lead product, eryaspase, also known under the trade name GRASPA®, consists of an enzyme, L-asparaginase, encapsulated inside donor-derived red blood cells. L-asparaginase depletes asparagine, a naturally occurring amino acid essential for the survival and proliferation of cancer cells. L-asparaginase has been a standard component of multi-agent chemotherapy for the treatment of acute lymphoblastic leukemia (ALL), but side effects limit treatment compliance, especially in adults and patients with weak performance status. Eryaspase aims to provide L-asparaginase to patients who cannot tolerate current non-encapsulated asparaginases.

In addition to eryaspase, ERYTECH is developing two other product candidates, erymethionase and eryminase, that focus on using encapsulated enzymes to target cancer metabolism and induce tumor starvation. ERYTECH is also exploring the use of its ERYCAPS platform for developing cancer immunotherapies (ERYMMUNE) and enzyme replacement therapies (ERYZYME).

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.

#### 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. They include all matters that are not historical facts. 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 may turn out to be materially different from the anticipated future results, performance or achievements expressed or implied by such statements, forecasts and estimates. Documents filed by ERYTECH Pharma with the French Autorité des Marchés Financiers (<a href="https://www.amf-france.org">www.amf-france.org</a>), also available on ERYTECH's website (<a href="https://www.amf-france.org">www.erytech.com</a>) describe such risks and uncertainties. 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 estima

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