



ERYTECH to Present Pharmacodynamic Data from Phase 2/3 Trial of Eryaspase in ALL at ASCO 2018

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LYON, France, June 04, 2018 (GLOBE NEWSWIRE) -- **ERYTECH Pharma**(Euronext:ERYP) (Nasdaq:ERYP), a clinical-stage biopharmaceutical company developing innovative therapies by encapsulating therapeutic drug substances inside red blood cells, today announced that it will present pharmacodynamic characterization data from its Phase 2/3 trial of eryaspase (GRASPA®) in combination with chemotherapy for the treatment of relapsed acute lymphoblastic leukemia (ALL) at the American Society of Clinical Oncology (ASCO) Annual Meeting, being held June 1-5, 2018 in Chicago, Illinois.

The European Phase 2/3 trial pharmacodynamic data will be presented during the poster session of the Hematologic Malignancies by Dr. Iman El-Hariry, Chief Medical Officer of ERYTECH and Dr. Philip Lorenzi, Co-Director of the proteomics and metabolomics core facility at MD Andersen Cancer Center.

Poster Session: Pharmacodynamic Characterization of eryaspase (L-asparaginase Encapsulated in Red Blood Cells) in Combination with Chemotherapy in a Phase 2/3 Trial in Patients with Relapsed Acute Lymphoblastic Leukemia (NCT01518517).

Poster: 7049
Lead Author: Dr. Iman El Hariry
Poster Session: Hematologic Malignancies—Leukemia, Myelodysplastic Syndromes, and Allotransplant
Location: Hall A
Date: Monday, June 4
Time: 8:00 a.m. – 11:30 a.m.

This randomized Phase 2/3 study enrolled patients with relapsed ALL (n=80, age: 1-55 years), randomized to eryaspase or native ASNase in combination with chemotherapy. The study demonstrated prolonged asparaginase activity and marked reduction in allergic reactions with eryaspase, when compared with control native asparaginase. In addition, the study demonstrated an overall favorable safety profile as well as a higher complete remission (CR) rate with eryaspase.

The duration of asparagine (ASN) depletion was also evaluated in the study, and was inferior in the eryaspase arm, compared to control. These results are largely confounded by the lack of a reliable assay to measure ASN due to *ex vivo* depletion of ASN before the enzyme can be quenched. This can lead to over-estimation of ASN depletion with a free asparaginase enzyme, less so with an encapsulated enzyme. Importantly, ASN depletion $\leq 2 \mu\text{M}$ was maintained for approximately 7 days in 70% and 75% of patients, in the eryaspase and control arms, respectively. Of interest, correlation with complete remission rate suggests ASN depletion $\leq 2 \mu\text{M}$ may not be needed with eryaspase; rather, a level $\leq 7.55 \mu\text{M}$ at Day 6 may be sufficient.

The abstract is available on the [ASCO website](#). The poster will be available on [ERYTECH's website](#) at the start of the poster session.

About ERYTECH: 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 altered amino acid metabolism of cancer cells, 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 pediatric acute lymphoblastic leukemia (ALL), but side effects limit treatment compliance, especially in adults and patients with weak performance status.

Eryaspase demonstrated positive efficacy and safety results in various clinical trials in ALL, including in a Phase 2 study in patients over 55 years of age and in a Phase 2/3 trial in relapsed or refractory ALL patients, as well as in pancreatic cancer, where it achieved positive results in a Phase 2b trial of second-line treatment of patients with metastatic pancreatic cancer. ERYTECH is preparing for the launch of a pivotal Phase 3 clinical trial in second line pancreatic cancer and Phase 2 trials in first line pancreatic cancer and triple-negative breast cancer.

ERYTECH produces eryaspase at its own GMP-approved and operational manufacturing site in Lyon (France), and at a site for clinical production in Philadelphia (USA). ERYTECH has entered into licensing and distribution partnership agreements for eryaspase for ALL and AML in Europe with Orphan Europe (Recordati Group), and for ALL in Israel with TEVA, which will market the product under the GRASPA® brand name. The European Medicines Agency (EMA) and the U.S. Food and Drug Administration (FDA) have granted orphan drug designations for eryaspase for the treatment of ALL, AML and pancreatic cancer.

In addition to eryaspase, ERYTECH is developing erymethionase, methionine- γ -lyase encapsulated in red blood cells, to target cancer cells' amino acid 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.

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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 the potential of ERYTECH's product pipeline, its clinical development and regulatory plans for eryaspase, the timing of ERYTECH's clinical studies and trials and announcements of data from those studies and trials, and the contents and timing of decisions by the FDA and EMA regarding ERYTECH's product candidates. 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. 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 2017 Document de Référence filed with the AMF in April 2018 and in the Company's Annual Report on Form 20-F filed with the SEC on April 24, 2018 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.



Source: Erytech Pharma S.A.