PRESS RELEASE

ERYTECH reports positive top-line Phase III results from clinical study with GRASPA® in Acute Lymphoblastic Leukemia

- **GRASPA® meets primary endpoints compared to native L-asparaginase:**
  - **Statistically significant reduction of allergic reactions**
  - **Statistically significant increase in duration of asparaginase activity**
- **Secondary endpoints confirm the favorable clinical efficacy of GRASPA®**
- **GRASPA® well tolerated by patients with previous allergies to L-asparaginase**
- **Submission of European marketing authorization application targeted for 1H 2015**
- **Important validation of ERYTECH's technology forming strong basis for further leveraging the product and platform in other oncology indications**

Lyon (France), September 30, 2014 – ERYTECH (Euronext Paris: FR0011471135 - ERYP), the French biopharmaceutical company that develops innovative 'tumor starvation' treatments for acute leukemia and other oncology indications with unmet medical needs, reports positive Phase III results from its pivotal study with GRASPA® in Acute Lymphoblastic Leukemia.

Analysis of the primary and first secondary efficacy endpoints of the GRASPALL clinical trial with one year follow up shows that the GRASPIVOTALL (GRASPALL2009-06) clinical trial convincingly meets both of its primary endpoints, and that the secondary efficacy endpoints analyzed so far confirm the favorable clinical efficacy profile of GRASPA®. The study also shows favorable results in patients with prior allergies to L-asparaginase.

The GRASPIVOTALL study is a controlled, multicenter Phase II/III trial with 80 children and adults suffering from relapsing or refractory Acute Lymphoblastic Leukemia (ALL) with three arms. The first two arms compare GRASPA® to native *E. Coli* L-asparaginase, both in combination with standard chemotherapy (COOPRALL), in a 1-to-1 randomization in patients without prior allergies to L-asparaginase. The third arm is an open label assessment of GRASPA® for patients who have experienced allergic reactions related to asparaginase in their first line treatment.

The primary endpoint of the study consisted of two objectives, in accordance with CHMP[1] advice: a) superior safety, expressed as a significant reduction of the incidence of allergic reactions with GRASPA® compared to the control group, and b) non-inferior duration of asparaginase activity above the threshold of 100 IU/l during the induction phase in the non-allergic patients. Both endpoints needed to be met for the study to be considered positive. The main secondary efficacy endpoints included the assessment of clinical parameters such as complete remission (CR), minimal residual disease (MRD), event-free survival (EFS) and overall survival (OS).

Primary endpoints met

- Statistically significant reduction of allergic reactions: none of the 26 patients in the GRASPA® arm experienced an allergic reaction versus 12 of the 28 (42.9%) patients treated with reference L-asparaginase in the control group (p<001).

[1] Based on Scientific Advice obtained from the Scientific Advice Working Party (SAWP) of the Commission for Human Medicinal Products (CHMP) at the European Medicines Agency (EMA)

- Statistically significant increase in duration of circulating asparaginase activity: in the GRASPA® group, asparaginase levels were maintained above 100 IU/l for an average of 20.5 days with up to 2 injections during the first month of treatment (induction phase) versus 9.2 days in the control group with up to 8 injections of reference L-asparaginase (p<001).

Secondary endpoints confirm the favorable clinical efficacy of GRASPA®

- At the end of the induction phase, 15 patients (71.4%) in the GRASPA® arm show complete remission versus 11 patients (42.3%) in the control arm.

GRASPA® well tolerated by patients with previous allergies to L-asparaginase

- A favorable clinical profile was seen in patients with prior allergies to L-asparaginase with only 2 patients experiencing mild allergic reactions.

"The results of this study are an important step forward for the treatment of ALL patients that are at risk to receive L-asparaginase, which remains an important unmet medical need. The virtual absence of allergic reactions, also in patients with prior allergies to L-asparaginase, is very encouraging." comments Professor Yves Betrand, hemato-oncologist at IHOP (Institute for Pediatric Hematology and Oncology) in Lyon (France) and principal investigator of the GRASPALL study.

These results confirm earlier observations with GRASPA® in a Phase I/II randomized dose escalation study in 24 relapsing ALL patients, and a Phase II study in first line ALL patients over 55 years of age.

Further analysis of additional secondary and exploratory endpoints is ongoing. Results will be available later this year and are planned to be presented at an upcoming scientific conference.

Based on the results of the GRASPALL study and the earlier studies performed with GRASPA®, ERYTECH intends to submit its application dossier for European Marketing Authorization in the first half of 2015.

"We are very pleased and encouraged by the positive results of this Phase III study. They validate the potential of our red cell bioreactor technology platform to increase the therapeutic index and tolerability of certain drugs. With GRASPA®, the enzyme activity is protected by the red cell membrane, preventing neutralisation by circulating antibodies. I wish to take this opportunity to thank all people who contributed to this study, patients, physicians and the Erytech team and collaborators, for their efforts and dedication.", said Yann Godfrin, co-founder and Chief Scientific Officer of ERYTECH Pharma.

"The positive Phase III results mark the start of an exciting new period for ERYTECH", adds Gil Beyen, Chairman and Chief Executive Office. *"Not only will they form the basis for our filing for European Marketing Authorization in ALL, they also strengthen the case for GRASPA®/ERY-ASP in other hematological indications, such as AML and lymphomas, and in a broad range of solid tumors, where the toxicity has been a limiting factor for the use of asparaginase. Next to focusing on making the product available to ALL patients throughout Europe together with our partner Orphan Europe (Recordati Group), we will continue and even accellerate the developments in other indications and with other active ingredients."*

A Phase IIb study with GRASPA® in Acute Myeloid Leukemia (AML) is progressing well with more than half of the patients enrolled and a Phase II study in pancreatic cancer has been launched earlier this year. Building on these positive results with GRASPA® in ALL, the company plans to accelerate the development in ALL in the US and to launch Phase II clinical trials in additional oncology indications with high unmet medical need.

About Acute Lymphoblastic Leukemia (ALL)

Acute Lymphoblastic Leukemia (ALL) is an aggressive form of leukemia (blood or bone marrow cancer) that is characterized by a rapid and abnormal proliferation of lymphoid precursor cells. ALL usually progresses quickly and, if not treated, can be fatal within a few months. Every year about 10,000 people are diagnosed with ALL in Europe (EU27) and about 6,000 in the US. About 60% of these are children, 20% adults and 20% seniors (above 55 years of age). Thanks to the development of new therapies and medicines, notably asparaginase, the prognosis for children affected by ALL has increased considerably with 5 year survival rates having increase from 30% in the 1960s to around 90% today. For older patients (adults and seniors) and patients in relapse, who often don't tolerate existing asparaginase based therapies, overall long-term survival remains among the lowest in the field of cancer (10% to 30%), leaving an important unmet medical need.

About ERYTECH and ERY-ASP/GRASPA®: www.erytech.com

Created in Lyon in 2004, ERYTECH is a French biopharmaceutical company providing new prospects for cancer patients, particularly those with acute leukemia and selected solid tumors.

By encapsulating the asparaginase enzyme in red blood cells, ERYTECH has developed ERY-ASP/GRASPA®[2], an original treatment that targets cancer cells through "tumor starvation" while significantly reducing the side effects for patients. ERY-ASP/GRASPA® is currently completing Phase III clinical development in Acute Lymphoblastic Leukemia (ALL) and is in Phase IIb clinical trial in Acute Myeloid Leukemia (AML) in Europe. The product is also in Phase I/II clinical development in ALL in the USA.

Every year about 50,000 patients are diagnosed with Acute Lymphoblastic Leukemia (ALL) or Acute Myeloid Leukemia (AML), the two forms of acute leukemia. Today, for about 80% of these patients, mainly adults and relapsing patients, current forms of asparaginase cannot be used due to their toxicity. With a presumed improved safety profile, ERY-ASP/GRASPA® is being developed to allow all leukemia patients to be treated, even the most fragile ones, representing a market opportunity of more than EUR 1 billion.

The company is also developing other indications in solid tumors and certain orphan indications outside oncology. A Phase II study in pancreas cancer is ongoing and the company is exploring other solid tumor indications for ERY-ASP.

ERYTECH has obtained orphan drug designations for ERY-ASP/GRASPA® in ALL, AML and pancreas cancer, both in Europe and the USA, and has its own GMP-approved and operational manufacturing site in Lyon (France), and a site for clinical production in Philadelphia (USA).

The company has concluded licensing and distribution partnership agreements for ALL and AML in Europe with Orphan Europe (Recordati Group), and for ALL with TEVA in Israel.

ERYTECH is listed on Euronext regulated market in Paris. (ISIN code: FR0011471135, ticker: ERYP) and is part of the CAC Healthcare, CAC Pharm. & Bio and Next Biotech indexes.

Forward-looking information

This document may contain forward-looking statements and estimates with respect to the financial situation, the results of operations, the strategy, the project and to the 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 the Company's control. There can be no guarantees with respect to pipeline products that the products will receive the necessary regulatory approvals or that they will prove to be commercially successful. Therefore, actual results, the financial condition, performance or achievements of ERYTECH, or industry results, may turn out to be materially different from any 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 (www.amf-france.org), also available on our website (www.erytech.com) 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 the publication of this document. ERYTECH disclaims any obligation to update any such forward-looking statement. Readers are cautioned not to place undue reliance on any of these forward-looking statements. forecast or estimates to reflect any change in the Company'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 French law.

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[2] Also known as ERY-ASP. GRASPA is the intended tradename of the product for use in ALL and AML in Europe and has been licensed to ERYTECH's commercial partner Orphan Europe (Recordati Group). ERY-ASP is the codename used outside Europe and in other indications.