ERYTECH announces positive DSMB review of its Phase IIb study in Acute Myeloid Leukemia

November 12, 2013 9:43 AM ET

ERYTECH Announces Positive DSMB Review of its Phase IIb Study in Acute Myeloid Leukemia

- **Review of safety data of first 30 patients treated**
- **Unanimous recommendation to pursue study without modification**
- **First large scale study with an asparaginase product in this patient population**

November 12, 2013 12:00 PM Eastern Standard Time

LYON, France--(BUSINESS WIRE)--Regulatory News:

ERYTECH Pharma (Paris:ERYP) (NYSE Euronext Paris: FR0011471135 - ERYP), a French biopharmaceutical company that develops innovative treatments for acute leukemia and other oncology indications with unmet medical needs, announces that an independent Data and Safety Monitoring Board (DSMB) completed its first assessment of the company's Phase IIb study in Acute Myeloid Leukemia (AML) study and unanimously recommended continuation of the trial without modification.

The GRASPA-ML study is a multicentre, randomized, controlled Phase IIb trial evaluating efficacy and tolerability of GRASPA® in the treatment of newly diagnosed AML patients over 65 years old that are unfit for intensive chemotherapy. In this 123 patients study, one-third of the patients receive the current standard treatment (low-dose cytarabine) and two-thirds receive low-dose cytarabine plus GRASPA®. The study was initiated in March 2013 and is performed in collaboration with Orphan Europe (Recordati Group), ERYTECH's partner for the commercialization of GRASPA® in 38 pays European countries.

A DSMB is an external committee of independent clinical research experts who review data in ongoing clinical trials with particular attention to safety. The DSMB assessment was based on a pre-planned safety analysis on the first 30 patients included in the study and with a minimum of 1 month follow-up. A second DSMB review is planned when 60 patients will be treated in the study.

"We are very pleased to see that our first trial in AML is progressing on track, with this first DSMB review confirming the safety profile of the product. This trial will be a landmark in the field of AML as it will be the first time that a large group of AML patients is receiving repeated doses of an asparaginase-based product. The use of asparaginase has to date been very limited in this indication due to the toxicity of the current forms. Thanks to the encapsulation in the red blood cells we are enabling the use of asparaginase in the treatment of these very fragile patients", comments Yann Godfrin, co-founder and CSO of ERYTECH Pharma.

"The study, if positive, will broaden the scope of use of our GRASPA product to AML, the most common type of acute leukemia and about 3 to 4 times larger than our first indication in Acute Lymphoblastic Leukemia. The rapid enrollment we are observing in the study, with in the meantime close to a third of the patients enrolled in the study, is a good indication of the important unmet medical need in this very severe indication", adds Gil Beyen, Chairman & CEO of ERYTECH.

About Acute Myeloid Leukemia
Acute Myeloid Leukemia (AML) is an aggressive form of leukemia (blood or bone marrow cancer) that is characterized by a rapid and abnormal proliferation of myeloid precursor cells. AML usually progresses quickly and, if not treated, can be fatal within a few months. With about 34 000 new patients per year in Europe and the US, AML is the most common type of acute leukemia. Affecting mainly the adult and senior patient population that often cannot tolerate the existing

forms of asparaginase products, AML represents one of the highest mortality rates among all type of cancers and an important unmet medical need. The median age of patients affected by AML is 67 years.

About ERYTECH and 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. 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, there is no adequate solution due to the toxicity of existing treatments, representing a market opportunity of more than EUR 1 billion. By encapsulating the asparaginase enzyme in red blood cells, ERYTECH has developed GRASPA®, an original and effective treatment that targets leukemia cells through "starvation" while significantly reducing the side effects for patients, and allowing all patients to be treated, even the most fragile ones. 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). ERYTECH has concluded distribution partnership agreements for Europe with Orphan Europe (Recordati Group), and with TEVA for Israel. In the United States, ERYTECH is launching a Phase Ib clinical trial in ALL, after having received approval from the US FDA. GRASPA® benefits from the orphan drug status both in ALL and in AML.
The company is also developing other indications in solid tumors and certain orphan indications outside oncology. ERYTECH has its own GMP-approved and operational manufacturing site.

ERYTECH is listed on NYSE 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. 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, 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.

Contacts

ERYTECH
Gil Beyen
Chairman and CEO
Pierre-Olivier Goineau
Vice President and COO
Tel: +33 4 78 74 44 38

investors@erytech.com
or
*New***Cap.**
Julien Perez / Emmanuel Huynh
Investor and press relations
Tel: +33 1 44 71 98 52
erytech@newcap.fr