

## **ERYTECH announces clinical trial authorizations in Finland and Spain for its European Phase IIb study in AML**

- **More than one third of patients enrolled and 18 investigation centers opened to date**
- **Authorizations to perform clinical trials in Finland and Spain internationalizes the study and is expected to further accelerate patient recruitment**

**Lyon (France), January 15<sup>th</sup>, 2014** – ERYTECH Pharma (Euronext Paris: FR0011471135 - ERYP), a French biopharmaceutical company that develops innovative treatments for acute leukemia and other oncology indications with unmet medical needs, announces it received authorizations for its Phase IIb GRASPA-ML clinical trial in Acute Myeloid Leukemia (AML) in Finland and Spain.

The study was first launched in France in March 2013, where to-date more than one third of the patients (out of a total of 123 patients to be recruited to complete the study) have been enrolled. The opening of centers in additional countries is adding international credibility and visibility to the study and is expected to further accelerate the pace of patient recruitment. Next to France, Spain and Finland, additional countries are expected to be authorized in the coming months.

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 November 2013, an independent Data and Safety Monitoring Board (DSMB) completed its first assessment of the study and unanimously recommended continuation of the trial as planned.

The study is performed in collaboration with Orphan Europe (Recordati Group), ERYTECH's partner for the commercialization of GRASPA® in 38 pays European countries, under a licensing and distribution agreement that was signed at the end of 2012.

*"We are pleased with the good progress of our Phase IIb study in Acute Myeloid Leukemia. Patient enrollment is in line with our expectations and the opening of foreign centers will further strengthen the study. If positive, the study will broaden the scope of use of our GRASPA® product to AML, the most common type of acute leukemia in adults",* comments Yann Godfrin, Co-founder and CSO of ERYTECH.

### **About Acute Myeloid Leukemia (AML)**

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](http://www.erytech.com)

Founded 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.

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. 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, representing a market opportunity of more than EUR 1 billion. 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 received FDA clearance to start clinical development in ALL in the USA. ERYTECH has concluded distribution partnership agreements for Europe with Orphan Europe (Recordati Group), and with TEVA for Israel.

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 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](http://www.amf-france.org)), also available on our website ([www.erytech.com](http://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.

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