ERYTECH Pharma announces fast take-off of its Phase IIb study in Acute Myeloid Leukemia

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ERYTECH Announces Fast Take-off of Its Phase IIb Study in Acute Myeloid Leukemia

- **100% Of French Sites Authorized to Participate in the Study, More Than 50% of Which Are Open for Patient Enrollment**
- **Already 10% of Patients Enrolled in the Study**
- **Opening of Additional European Centers Forthcoming to Further Accelerate Patient Recruitment**

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

ERYTECH (NYSE Euronext Paris : FR0011471135 - ERYP) (Paris:ERYP), a French biopharmaceutical company that develops innovative treatments for acute leukemia and other oncology indications with unmet medical needs, announces a fast take-off of its Phase IIb study in Acute Myeloid Leukemia (AML).

The study, a multicentre, open, randomized, controlled Phase IIb trial evaluating efficacy and tolerability of GRASPA® in the treatment of newly diagnosed acute myeloid leukemia (AML) patients, over 65 years, unfit for intensive chemotherapy, was initiated in March 2013.

In the mean time and in line with the planning, all 21 French investigation sites have been authorized to participate in the study. With 13 of these sites having been initiated and opened so far, already 12 out of a total of 123 patients have been enrolled in the study. The current pace of inclusion shall enable ERYTECH to recruit the last patient in the study before the end of 2014. In parallel to the patient recruitments realized in France, it is foreseen to open other specialized centers in different European countries in view of internationalizing the study and further accelerating patient enrollment.

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.

In February 2013, the European Medicines Agency (EMA) granted GRASPA® the orphan drug status for the treatment of AML. The orphan drug status provides certain advantages for the sponsor such as reduced procedure costs and ten years of commercial exclusivity.

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.

To address this challenge, ERYTECH can build on its solid experience in Acute Lymphoblastic Leukemia (ALL) where GRASPA®, currently in Phase III of clinical development, has already demonstrated convincing clinical results both in terms of safety and efficacy in fragile adult and senior patients. In ALL, GRASPA® benefits from the orphan drug status both in Europe and in the US.

« We are very pleased with the fast take-off of this study and by the adoption of GRASPA® by the clinicians, confirming their need for new therapies enabling them to treat adult and senior acute leukemia patients efficiently. The increased tolerability

profile obtained through the encapsulation of asparaginase in the red blood cells opens perspectives to treat all patients suffering from acute leukemia, even the most fragile ones, not only the children. » comments Yann Godfrin, co-founder and CSO of ERYTECH.

« Much in line with this Phase IIb study in which patient recruitment is happening at a fast pace, we are pursuing the execution of our clinical development plan we announced during our initial public offering in April. The next steps will concern our studies in ALL in Europe and the US, as well as in solid tumors. » concludes Gil Beyen, Chairman and CEO of ERYTECH.

Next updates :

- **Financial highlights for the 2nd quarter 2013 :** Thursday, 18 July 2013 (after closing)
- **Business and financial update of the 1st semester 2013 :** Wednesday, 31 August 2013 (after closing)

About ERYTECH: www.erytech.com

Created in Lyon in 2004, ERYTECH is a French biopharmaceuticals company that opens new prospects for cancer patients, particularly those with acute leukaemia. By encapsulating the asparaginase enzyme in red blood cells, ERYTECH has developed GRASPA®, an original and effective treatment that targets leukaemia cells through “starvation” while significantly reducing the side effects for patients. 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 the Recordati -Orphan Europe group, and with TEVA for Israël. In the United States, ERYTECH is launching a Phase Ib clinical trial in ALL, after having received approval from the US FDA. The company has its own GMP approved and operational manufacturing site.

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

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