

ERYTECH announces presentation of additional data at the American Society of Hematology 57th Annual Meeting

Lyon (France), December 8th 2015 – ERYTECH Pharma (Euronext Paris: ERYP & OTC US: EYRY), the French biopharmaceutical company that develops innovative ‘tumor starvation’ treatments for acute leukemia and other malignancies with unmet medical needs, announces that investigators presented additional results from the pivotal Phase 2/3 clinical trial with GRASPA that add to the body of data supporting the potential benefit of GRASPA in combination with chemotherapy in the treatment of Acute Lymphoblastic Leukemia (ALL).

These results, which were presented at the 57th Annual Meeting of the American Society of Hematology (ASH) in Orlando, included an update on the clinical activity of GRASPA versus native L-asparaginase after two years of patient follow-up, a further characterization of the pharmacokinetic and pharmacodynamics properties of both products, and an analysis of the impact of neutralizing antibodies on the efficacy and safety of GRASPA versus native L-asparaginase in a randomized Phase 2/3 study in patients with relapsed or refractory ALL.

Professor André Baruchel, Head of Pediatric Hemato-Immunology at Paris Hôpital Robert Debré (APHP) and a trial investigator, presented a poster entitled *“Updated Clinical Activity of GRASPA Versus Native L-Asparaginase in Combination with COOPRALL Regimen in a Phase 3 Randomized Trial in Patients with Relapsed Acute Lymphoblastic Leukemia”*. The presentation included earlier reported safety and efficacy data, with additional two-year follow-up on event-free survival (EFS) and overall survival (OS). The two-year survival data confirm the favorable trend that had been observed after one year of follow-up. Median EFS was 11.8 months in the native L-asparaginase group and has not been reached yet in the GRASPA arm after two years of follow-up. Median OS was not reached in either of the treatment arms. The main conclusion of the presentation was that the favorable efficacy and safety profile of GRASPA offers an effective alternative option for patients who have received prior asparaginase therapy.

Dr. Xavier Thomas, hemato-oncologist at the Lyon University Hospital and a trial investigator, presented a poster entitled *“Pharmacokinetic and Pharmacodynamic Characterization of GRASPA Versus Native L-Asparaginase in Combination with COOPRALL Chemotherapy in a Phase 3 Randomized Trial for the Treatment of Patients with Relapsed Acute Lymphoblastic Leukemia (NCT01518517)”*. The mean duration of asparaginase activity above the threshold of 100IU/l during the induction phase was 20.5 days (\pm : 5.2 days) in the GRASPA arm versus 9.4 days (\pm : 7.4 days) in the patients treated with native L-asparaginase ($p < 0.001$). Also in patients who had experienced prior allergies to L-asparaginase, the duration of L-asparaginase was maintained for 18.6 days (\pm : 6.3 days). Prolonged asparaginase activity with GRASPA was maintained across several subpopulations (age groups, risk groups, presence or absence of prior allergic reactions to asparaginase). The difference between GRASPA and native L-asparaginase was most pronounced in adults and high risk patients, where mean duration of asparaginase activity was respectively 3.2 days and 6.3 days with native L-asparaginase versus 19.3 and 20.9 with GRASPA.

Professor Yves Bertrand, Head of the Pediatric Hematology and Oncology Institute at the Lyon University Hospital and Principal Investigator/Coordinator of the trial, presented a poster entitled “Evaluation of the Impact of the Presence of Neutralizing L-Asparaginase Antibodies on the Efficacy and Safety of GRASPA in a Phase 3 Randomized Trial Versus Native L-Asparaginase in Patients with Relapsed Acute Lymphoblastic Leukemia”. All 80 patients enrolled and treated in the Phase 2/3 study had been treated with L-asparaginase during their first line of treatment. One third of the patients had experienced prior allergic reactions to L-asparaginase. 58% of these patients had positive antibody status at baseline. Of the other two thirds of patients, about 25% had positive antibody status at baseline. GRASPA consistently demonstrated superior duration of asparaginase activity and lower hypersensitivity regardless of antibody status. Five out of seven (71%) patients with positive antibody status, treated with native L-asparaginase, developed allergic reactions versus one out of 21 (5%) of the patients with positive antibody status in the GRASPA group. Positive antibodies appeared to attenuate the clinical activity in all treatment arms. This provides additional rationale for investigating GRASPA in patients with ALL in first line setting.

The posters can be viewed online on ERYTECH’s website via <http://www.erytech.com>

“The clinical data that were presented at this year’s ASH meeting provide further insight into the results obtained in our pivotal Phase 2/3 study with GRASPA and add to understanding of the potential benefit of the product in the treatment of ALL,” comments Iman El-Hariry, Chief Medical Officer of ERYTECH, *“The combination of superior sustained asparaginase activity with lower incidence of allergic reactions and a generally favorable safety profile in the GRASPA arm was associated with improvement in CR rate and encouraging EFS and OS rates at 2-year follow-up. The current study provides a rationale for investigating the activity of GRASPA in patients with ALL in first line setting.”*

About ERYTECH and ERY-ASP (GRASPA®): 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 treatment of blood cancers, including acute lymphoblastic leukemia (ALL) and acute myeloid leukemia (AML), by depriving tumors of nutrients necessary for their survival. ERYTECH has recently announced positive efficacy and safety results from its completed Phase 2/3 pivotal clinical trial in Europe with its lead product candidate, ERY-ASP, also known under the trade name GRASPA®, in children and adults with relapsed or refractory ALL. ERYTECH also has an ongoing Phase 1 clinical trial of ERY-ASP in the United States in adults with newly diagnosed ALL, and a Phase 2 clinical trial in Europe evaluating GRASPA as a first-line therapy for the treatment of elderly patients with AML, each in combination with chemotherapy.

ERY-ASP 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, from circulating blood plasma.

Every year over 50,000 patients in Europe and the United States are diagnosed with ALL or AML. For about 80% of these patients, mainly adults and relapsing patients, current forms of L-asparaginase cannot be used due to their toxicity or as a result of allergic reactions. ERYTECH believes that the safety and efficacy profile of ERY-ASP/GRASPA®, as observed in its Phase 2/3 pivotal clinical trial, offers an attractive alternative option for the treatment of leukemia patients.

ERYTECH believes that ERY-ASP has the potential as a treatment approach in solid tumors and is conducting a Phase 2 clinical trial in Europe in patients with metastatic pancreatic cancer. In addition to its current product candidates that focus on using encapsulated enzymes to induce tumor starvation, ERYTECH is exploring the use of its platform for developing cancer vaccines and enzyme replacement therapies.

The EMA and the U.S. Food and Drug Administration (FDA) have granted orphan drug designations for ERY-ASP/GRASPA for the treatment of ALL, AML and pancreatic cancer. ERYTECH produces ERY-ASP 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 ERY-ASP 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.

ERYTECH is listed on Euronext regulated market in Paris (ISIN code: FR0011471135, ticker: ERYP) and is part of the CAC Healthcare, CAC Pharma & Bio, CAC Mid & Small, CAC All Tradable, EnterNext PEA-PME 150 and Next Biotech indexes. ERYTECH is also listed in the U.S. under an ADR level 1 program (OTC, ticker EYRY).

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