ERYTECH REPORTS ADDITIONAL POSITIVE PHASE III RESULTS FROM CLINICAL STUDY WITH ERY-ASP/GRASPA® IN ACUTE LYMPHOBLASTIC LEUKEMIA

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Complete results of the Phase III study were presented and discussed at an investigator meeting held in connection with the annual meeting of the American Society of Hematology (ASH) in San Francisco
Additional analysis confirms clinical benefit of ERY-ASP/GRASPA® versus native asparaginase
In addition to achieving the primary endpoints, a statistically significant improvement of complete remission rate, a trend towards improved survival and a better overall safety profile was demonstrated

Lyon (France), December 8, 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 additional positive Phase III results from the pivotal study with ERY-ASP/GRASPA® in Acute Lymphoblastic Leukemia.

Positive top-line data of the study were made available end of September, and demonstrated that the Phase III GRASPIVOTALL clinical trial met both of its primary endpoints. A significant reduction of clinical hypersensitivity was observed with ERY-ASP/GRASPA® (development name: ERY001)while maintaining asparaginase activity longer than with native L-asparaginase (L-ASP) in the control arm. The study also showed favorable results in patients with prior allergies to asparaginase, both in terms of hypersensitivities and asparaginase activity.

Additional study results based on the pre-specified key secondary endpoints were presented and discussed at an investigator meeting in connection with the annual meeting of the American Society of Hematology (ASH) in San Francisco. It is worth noting that the study was not powered to demonstrate statistical significance on any of the secondary parameters.

These additional results show:

- a significantly improved complete remission (CR) rate and a trend towards increased overall and event-free survival (OS and EFS) with ERY001 compared to native L-asparaginase (L-ASP). Median OS and EFS have not been reached;
- a better overall safety profile, notably with improved clotting parameters (coagulation disorders), in addition to lower hypersensitivity reactions (no allergic reactions with ERY001 versus 43% with L-ASP, with 25% Grade 3 or above);
- neither the risk status nor the age of the patients (children versus adults) had an influence on the study outcome;
- favorable results also in the patients with prior hypersensitivities to asparaginase (exploratory 'HypSen' arm) who could not be randomized to native asparaginase.

The table below summarizes the main results of the GRASPIVOTALL clinical study with ERY001 after one year follow-up.

	Randomized arms		**HypSen arm**
	ERY001	**L-ASP**	**ERY001**
	N=26	N=28	N=26
Primary Endpoints			

Duration of asparaginase activity >100IU/l (days)*	20.5±5.2	9.4±7.4	p<0.001	18.6±6.3
Asparaginase related hypersensitivity All Grades	0 (0%)	12 (43%)	p<0.001	3 (12%)
With Grade≥3	0 (0%)	7 (25%)		0 (0%)
Main Secondary Endpoints				
CR**	17 (65%)	11 (39%)	p=0.026	14 (54%)
Excluding missing values	17/23 (74%)	11/26 (42%)		14/24 (58%)
MRD $<10^{-3}$ **	9 (35%)	7 (25%)	p=0.605	6 (23%)
6 months OS	92.3%	78.6%	HR=0.35 (95% CI:0.09-1.39)	73.1%
12 months OS	76.9%	67.9%	HR=0.63 (95%CI:0.23-1.74)	50.0%
12 months EFS	64.9%	48.6%	HR=0.54 (95%CI:0.23-1.26)	50.3%
Patients with at least 1 AE***	19 (73%)	28 (100%)		17 (65%)
Antithrombin III decrease	4 (15%)	20 (71%)	p<0.05	6 (23%)
Hypofibrigenemia	8 (31%)	19 (68%)	p<0.05	7 (27%)

*measured in whole blood ** at the end of induction ***study drug-related adverse events during induction period.

The most common adverse events of key interest in the two randomised arms over the one year follow-up period, regardless of relationship to study drug or grade, were as follows: elevated alanine aminotransferase: 54% versus 32%; elevated aspartate aminotransferase: 31% versus 21%; elevated bilirubin levels: 8% versus 29%; hypofibrinogenaemia: 31% versus 68%; hypoalbuminemia: 19% versus 39%; decreased antithrombin III 15% versus 71%; and: elevated amylase: 31% versus 29%; elevated lipase: 27% versus 36%, in ERY001 and L-ASP groups, respectively.

"Based on these results, I believe ERY001 is a suitable option for patients with relapsed ALL, maintaining asparaginase efficacy with improved tolerability. In addition, the results of this study are an important step forward for the treatment of ALL patients who are at risk of hypersensitivity reactions with L-asparaginase, which remains an unmet medical need." comments Professor Yves Bertrand, hemato-oncologist at IHOP (Institute for Pediatric Hematology and Oncology) in Lyon (France) and principal investigator of the study.

"What we learned from the additional analysis of the Phase III data – significance on complete remission, a trend towards increased survival, and significant improvement on some of the key safety concerns – is exceeding the original expectations and objectives of this study. The Phase III results will support the company's plans for a regulatory filing for GRASPA® in the European Union in the first half of 2015 and for accelerating the clinical development in the United States." adds Gil Beyen, Chairman & CEO of ERYTECH.

About the GRASPIVOTALL study

The GRASPIVOTALL study was 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 compared ERY001 (ERYASP/GRASPA®) to native *E. Coli* L-asparaginase (L-ASP), both in combination with the recommended chemotherapy (COOPRALL), in a 1-to-1 randomization in patients without prior allergies to L-asparaginase. The third arm was an exploratory arm that assessed ERY001 in patients who have experienced allergic reactions related to asparaginase in their first line treatment (HypSen arm).

The study co-primary endpoints were: a) superior safety, expressed as a significant reduction of the incidence of allergic reactions with ERY001 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 endpoints included the assessment of clinical parameters such as complete remission (CR), minimal residual disease (MRD), overall and event free survival (OS and EFS), and safety. The study was not powered to demonstrate statistical significance on any of the secondary parameters.

Eighty patients were treated from December 2009 to August 2013 in 27 centers in France and Belgium, 26 in the ERY001 arm (21 children, 5 adults), 28 in the L-ASP arm (21 children, 7 adults) and 26 in the HypSen arm (15 children, 11 adults). The study was also well balanced in terms of risk profile of the patients with 16 out of 26 patients receiving the normal risk treatment (F1/F2) in the ERY001 arm versus 15 out of 28 in the L-ASP arm. In the HypSen arm, 12 out of 26 patients were treated with F1/F2.

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 GRASPA® :www.erytech.com

By encapsulating the asparaginase enzyme in red blood cells, ERYTECH has developed ERY-ASP/GRASPA®, an innovative treatment that aims at destroying cancerous cells through "starvation" while significantly reducing side effects. ERY-ASP/GRASPA® has completed Phase III clinical development in Acute Lymphoblastic Leukemia (ALL) and is in Phase IIb in Acute Myeloid Leukemia (AML) in Europe. The product is also in Phase I/II in ALL in the U.S.

Every year about 50,000 patients are diagnosed with ALL or AML in Europe and the U.S. Today, approximately 80% of these patients, mainly adults, seniors and relapsed children, cannot use the current forms of asparaginase due to their toxicity. ERY-ASP/GRASPA® is being developed with the goal of improving the tolerability profile in order to treat all patients diagnosed with acute leukemia, even the most fragile ones. The market segment addressed by ERYTECH represents a potential exceeding 1 billion euros.

ERYTECH is also developing treatments for solid tumors and some orphan indications outside oncology. It is currently conducting a Phase II study in pancreatic cancer in Europe and is examining other solid tumor indications for ERY-ASP.

ERYTECH has obtained orphan drug designations for ERY-ASP/GRASPA® in ALL, AML and pancreatic cancer in Europe and the U.S. The company has its own operational manufacturing sites in Lyon, France and Philadelphia, U.S.

ERYTECH has concluded two distribution partnership agreements in the field of acute leukemia, one in Europe with Orphan Europe (Recordati Group), and one in Israel with TEVA.

ERYTECH is listed on the Euronext regulated market in Paris (ISIN code: FR0011471135, ticker code: ERYP) and is part of the CAC All Shares, CAC Healthcare, CAC Pharma & Bio, CAC Small, CAC Mid&Small, CAC All Tradable, EnterNext PEA-PME 150 and Next Biotech indexes. ERYTECH shares are eligible to PEA-PME (French share savings plan for SMEs).

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.