

ERYTECH announces granting of new patent in the United States

- Patent that can strengthen positioning of ERY-ASP/GRASPA® by detecting the presence of neutralizing antibodies to asparaginase
- Patent delivered in the USA with patent term until 2029
- Patent already granted in Europe, Australia and Singapore

Lyon (France), le 20 octobre 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, announces the granting of a new patent in the field of asparaginase in the United States.

The patent ‘*Test for predicting neutralization of asparaginase activity*’ (WO 2010/052315 A1) protects the process and methods for the detection of factors neutralizing the activity of asparaginase in patients, notably anti-asparaginase antibodies. A large percentage of patients treated with current forms of asparaginases are known to develop neutralizing antibodies to asparaginase, which drastically reduces its activity and treatment efficacy. In addition, these patients have a higher chance to develop hypersensitivity reactions, some of which can be severe. Detecting the presence of these neutralizing factors before the administration of asparaginase can reduce the risk of treatment inefficacy and allergic reactions by enabling to propose the product with the best risk profile in these conditions.

In the clinical studies with ERY-ASP/GRASPA®, a very significant reduction of allergic reactions and a sustained asparaginase activity have been observed, even in the presence of antibodies, and this thanks to the encapsulation of the asparaginase in red blood cells. Recent analysis of the top-line Phase III results of the GRASPIVOTALL (GRASPALL2009-06) study in relapsing Acute Lymphoblastic Leukemia (ALL) has shown favorable results, also in patients who had prior allergies to L-asparaginase. In patients without history of allergic reactions, none of the patients developed allergies to GRASPA® versus 43% for the native L-asparaginase. Only two of twenty-six patients with prior allergies to L-asparaginase developed allergies to GRASPA® and these have been of mild nature. In these patients the average duration of asparaginase activity observed was similar to the duration observed in non-allergic patients (18.6 days of asparaginase activity above 100IU/l versus 20.3 days in the non-allergic patients). These results seem to confirm the hypothesis that the encapsulated asparaginase is not ‘visible’ to the circulating antibodies, which allows it to continue its activity without the formation of immunogenic complexes.

The interest for ERYTECH would be to make available a test to clinicians allowing to detect neutralizing antibodies earlier and to switch to other forms of asparaginase, like ERY-ASP/GRASPA®, faster and before clinical symptoms of allergies or inactivation occur.

The patent application was filed in 2009. The patent has in the meantime been granted in Europe, Australia and Singapore, and now also in the United States. According to American law, the patent will be valid until mid 2029.

ERYTECH’s patent portfolio consists of 13 patent families worldwide, covering its technologies, its products and their therapeutic usages.

« The granting of this new patent in the United States is an additional tool to favor the future adoption of ERY-ASP/GRASPA® by physicians. The test based on this patented technology will be developed in

collaboration with a specialized industrial partner in view of making it available at the time of European Marketing Authorization, aimed by mid 2016 », comments Pierre-Olivier Goineau, co-founder and COO of ERYTECH Pharma.

About ERYTECH and ERY-ASP/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 and selected solid tumors.

By encapsulating the asparaginase enzyme in red blood cells, ERYTECH has developed ERY-ASP/GRASPA®, an original treatment that targets cancer cells through “tumor starvation” while significantly reducing the side effects for patients. ERY-ASP/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 is also in Phase I/II clinical development in ALL in the USA.

Every year about 50,000 patients are diagnosed with ALL or AML, the two forms of acute leukemia. Today, for about 80% of these patients, mainly adults and relapsing patients, current forms of asparaginase cannot be used due to their toxicity. With a presumed improved safety profile, ERY-ASP/GRASPA® is being developed to allow all leukemia patients to be treated, even the most fragile ones, representing a market opportunity of more than EUR 1 billion.

The company is also developing other indications in solid tumors and certain orphan indications outside oncology. The company is currently launching a Phase II study in pancreas cancer and is exploring other solid tumor indications.

ERYTECH has obtained orphan drug designations for ERY-ASP/GRASPA® in ALL, AML and pancreas cancer, both in Europe and the USA, and has its own GMP-approved and operational manufacturing site in Lyon (France), and a site for clinical production in Philadelphia (USA).

The company has concluded licensing and distribution partnership agreements for ALL and AML in Europe with Orphan Europe (Recordati Group), and for ALL with TEVA in Israel.

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), 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.

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