

ERYTECH announces positive DSMB annual review of its Expanded Access Program in ALL

- Independent experts have reviewed the safety data of the first 7 patients treated under the Expanded Access Program (EAP) with GRASPA® in Acute Lymphoblastic Leukemia (ALL)
- GRASPA® well tolerated in patients with prior hypersensitivity reactions to *E.Coli* and to *Erwinia* derived asparaginases
- 12 patients treated to-date

Lyon (France), May 5, 2015 – ERYTECH Pharma (Euronext Paris - ERYP; OTC US - EYRY), the French biopharmaceutical company that develops innovative ‘tumor starvation’ treatments for acute leukemia and other oncology indications with unmet medical needs, announces that an independent Data and Safety Monitoring Board (DSMB) completed its first safety assessment of the company’s Expanded Access Program (EAP) in Acute Lymphoblastic Leukemia (ALL) and recommended continuation of the program without modification.

The EAP (#NCT02197650) was set up to provide access to GRASPA® to patients with ALL, in first line or relapse, who are at risk to receive currently-marketed asparaginase products.

A DSMB is an independent external committee of clinical research experts who review data in ongoing clinical trials with particular attention to safety. This protocol of the EAP specifies a yearly safety assessment by a DSMB.

The first DSMB reviewed the safety data of the first 7 patients treated in the program with 3 months of follow-up. Prior to their inclusion in the program, all 7 patients, 3 children and 4 adults, had experienced hypersensitivity reactions to both *E. Coli* and *Erwinia* derived asparaginases. All patients received multiple doses of GRASPA® (range 2 to 7 doses; average 3.4). Following the review of the safety data, the DSMB recommended to continue the enrollment of patients in the EAP without changes to the protocol.

To date, 12 patients, 6 patients in first line and 6 patients in relapse, have been enrolled in the EAP.

Gil Beyen, Chairman and CEO of ERYTECH, comments: *“We are very pleased with the early indication of the favorable tolerability of GRASPA® in these ‘double allergic’ patients, which is very encouraging. It brings additional confirmation of GRASPA®’s reduced immunotoxicity and paves the way for its use in first line treatment. In the recently completed Phase II/III study, a favorable tolerability of the product had already been observed in relapsed ALL patients, including a number of patients allergic to E.coli asparaginase.”*

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® has recently announced positive Phase III data 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 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, 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. A Phase II study in pancreas cancer is ongoing and the company is exploring other solid tumor indications for ERY-ASP.

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 Pharma & Bio, CAC Mid & Small, CAC All Tradable, EnterNext PEA-PME 150 and Next Biotech indexes. ERYTECH is also listed in the US under an ADR level 1 program (OTC, ticker EYRY).

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