

ERYTECH announces two positive DSMB reviews

- Dose escalation to next dose level and acceleration of patient enrollment recommended in US Phase I study with ERY-ASP in Acute Lymphoblastic Leukemia (ALL)
- Continuation of enrollment recommended in the ERY-ASP/Folfox treatment arm in Phase II pancreatic cancer study

Lyon (France), June 22, 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 positive safety reviews after the completion of the first cohort in the company’s US Phase I study with ERY-ASP in Acute Lymphoblastic Leukemia (ALL), and following the treatment of the first three patients with ERY-ASP in combination with Folfox in its Phase II study in pancreatic cancer.

US Phase I study in ALL

ERYTECH’s first clinical study with ERY-ASP¹ in the United States is a Phase I dose escalation study in newly diagnosed ALL patients over 40 years of age. The study foresees a safety review after each cohort of patients treated and requires FDA approval for moving to the next dose.

The safety data of the first cohort of patients (at dose 50 IU/kg) has now been reviewed by a steering committee (SC) consisting of the DSMB² members and investigators in the study. No safety concerns have been identified and the SC recommends escalating ERY-ASP dose to the next dose level of 100 IU/kg. There is a strong commitment from the investigators on the study to complete the trial in a speedy manner.

GRASPA¹, the European version of the ERY-ASP product, recently announced positive Phase III data in relapsed ALL patients.

EU Phase II study in pancreas cancer

The ERY-ASP pancreatic cancer Phase II study is a multicenter, randomized trial for the second-line treatment of patients with progressive metastatic pancreatic cancer. In a study of approximately 90 patients, conducted in France, ERY-ASP in addition to the standard of care (Gemcitabine or Folfox) is being compared to the standard of care alone in a 2-to-1 randomization. The primary endpoint is progression-free survival (PFS) at 4 months.

The study foresees a DSMB review on the safety of the combination of ERY-ASP with the standard treatments (Gemcitabine and Folfox). An earlier DSMB had already cleared the combination of ERY-ASP plus Gemcitabine. A second DSMB assessment on the first 3 patients treated with ERY-ASP in combination with Folfox, took place recently. No safety concerns were identified and the enrollment in this treatment group has been re-initiated. A third safety review on the first 24 patients in the study is expected soon.

¹ ERY-ASP and GRASPA both refer to asparaginase encapsulated in red blood cells. GRASPA is the invented name for the product in ALL and AML in Europe and has been licensed to ERYTECH’s commercial partner Orphan Europe (Recordati Group). ERY-ASP is refers to the product used outside Europe and outside acute leukemia.

² A DSMB (Data Safety Monitoring Board) is an independent external committee of clinical research experts who review data in ongoing clinical trials with particular attention to safety.

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 or 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 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 pancreatic 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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