



## ERYTECH Reports Positive Phase 2b Data for eryaspase for the Treatment of Metastatic Pancreatic Cancer

Mar 27, 2017 | Press Releases

Conference call and webcast on Tuesday, March 28<sup>th</sup> at 14:30 pm CET/08:30 am EDT

- **Primary progression-free survival (PFS) and overall survival (OS) endpoints met in patients with low asparagine synthetase (ASNS)**
- **Statistically significant improvement of OS and PFS in the entire patient population**

LYON, France--(BUSINESS WIRE)--Mar. 27, 2017-- Regulatory News:

**ERYTECH Pharma (Paris:ERYP) (ADR:EYRY) (Euronext Paris - ERYP), a French clinical-stage biopharmaceutical company developing innovative therapies by encapsulating therapeutic drug substances inside red blood cells, today announced positive topline results from its Phase 2b clinical study evaluating its product candidate, eryaspase (GRASPA®), in combination with chemotherapy for the treatment of second-line metastatic pancreatic cancer. The multicenter, randomized Phase 2b study met its prespecified co-primary endpoints, and showed significant improvement in both progression-free survival (PFS) and overall survival (OS) in patients treated with eryaspase combined with chemotherapy compared to chemotherapy alone.**

The Phase 2b study evaluated eryaspase, L-asparaginase encapsulated in red blood cells, as a second-line treatment in combination with chemotherapy in patients with metastatic pancreatic cancer. In this 140-patient study, conducted in France, eryaspase was added to the standard of care (gemcitabine or FOLFOX) and compared to the standard of care alone in a 2-to-1 randomization.

Asparagine synthetase (ASNS) expression status in several tumor types, such as leukemia, lymphoma and pancreatic cancer, is believed to play an important role in determining sensitivity to asparaginase treatment. The primary objective of the study was to evaluate the effect of eryaspase on PFS or OS in patients with low ASNS, about 70% of the study population, with a prespecified Hazard Ratio (HR) below 0.85 for either PFS or OS. This endpoint was met showing a HR of 0.73 for PFS and 0.62 for OS.

The effect of eryaspase was furthermore demonstrated regardless of ASNS expression. In the entire patient population, the study achieved a HR of 0.57 for OS (95% CI: 0.38, 0.85) ( $p=0.034$ ) with a median OS of 26.1 weeks (95% CI: 21.0, 28.9) for the eryaspase arm versus 19.0 weeks (95% CI: 12.3, 21.7) for the standard of care arm. Similar results were observed for PFS. ASNS expression does not appear to be predictive, but seems to be a prognostic factor. The role of ASNS will be further explored in future clinical studies.

The treatment was generally well tolerated.

Complete data will be presented at an upcoming medical conference, and will be submitted for publication.

Prof Pascal Hammel, MD, PhD, gastroenterologist-oncologist at Beaujon Hospital in Paris and principal investigator of the study, commented, *"These results generated by eryaspase in combination with the standard of care are highly encouraging and compare favorably to gemcitabine or FOLFOX treatment administered alone. The results of this study support eryaspase as a potential treatment option for patients with metastatic pancreatic cancer in the second-line setting."*

*"Pancreatic adenocarcinoma is a dismal disease with poor survival outcome," commented Iman El-Hariry, MD, PhD, Chief Medical Officer of ERYTECH. "We believe this is the first Phase 2b study of an asparaginase product in pancreatic adenocarcinoma, yet it demonstrated a significant 43% reduction in risk of death in a very difficult-to-treat disease with few treatment options. The study had well balanced demographic and baseline patient characteristics. The improvement in OS and PFS was consistent across subgroups. The adverse events observed in this study were consistent with the known safety profile of eryaspase. We would like to thank all of our participating clinical sites for their hard work and commitment to the study."*

Gil Beyen, Chairman and CEO of ERYTECH, added, *"We have been studying the metabolic pathways for the past decade with the aim to develop effective treatments for patients with metabolically-driven tumors. We are very excited by these new positive data. They provide further important clinical proof of concept supporting the development of eryaspase as a potential treatment in one of the most aggressive tumor types. We will now explore the path forward with clinicians and regulators to bring eryaspase to patients with metastatic pancreatic cancer as soon as possible. The results of this study not only reinforce the role of eryaspase in the treatment of this disease, they also provide further rationale for its evaluation in other tumor types."*

ERYTECH will hold a conference call and webcast on Tuesday, March 28<sup>th</sup> at 2:30 pm CET / 8:30 am EDT, to discuss the results of its Phase 2b clinical study.

Investors and analysts wishing to participate can access the call via the following teleconferencing numbers:

<b>USA:</b> +1 6467224907	<b>United-Kingdom:</b> +44 2030432440
<b>Switzerland:</b> +41 225809022	<b>Germany:</b> +49 69222229031
<b>France:</b> +33 172001510	<b>Belgium:</b> +32 24029640
<b>Sweden:</b> +46 850334664	<b>Finland :</b> +358 942599700
<b>Netherlands:</b> +31 107138194	

Confirmation Code: **43037159#**

The webcast can be followed live online via the link:

<http://www.anywhereconference.com?UserAudioMode=DATA&Name=&Conference=135307755&PIN=43037159>

Following the live call, a replay will be available for 90 days. To listen to the replay, please dial:

**USA:** +1 877 64 230 18

**United-Kingdom:** +44(0) 2033679460

**France:** +33(0)1 72 00 15 00

Confirmation Code: **307755#**

Additionally, an archive of the webcast will be available on the "Webcast" section of the Company's investor relations site at [www.erytech.com](http://www.erytech.com)

#### **About pancreatic cancer:**

Pancreatic cancer is a disease in which malignant (cancer) cells are found in the tissues of the pancreas. Every year there are about 150,000 new cases of pancreatic cancer diagnosed in Europe and the United States. Pancreatic cancer is a particularly aggressive cancer, with a five-year survival rate of less than 10% and is currently the fourth most common cause of cancer death in the EU for men and women.

#### **About ERYTECH and eryaspase (GRASPA®):** [www.erytech.com](http://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 plans to pursue regulatory approvals for its lead product candidate, eryaspase, also known as ERY-ASP or under the trade name GRASPA®, having achieved positive efficacy and safety results from its completed Phase 2/3 pivotal clinical trial in Europe in children and adults with relapsed or refractory ALL. ERYTECH also has an ongoing Phase 1 clinical trial of eryaspase in the United States in adults with newly diagnosed ALL, and a Phase 2b clinical trial in Europe in elderly patients with newly diagnosed AML, each in combination with chemotherapy. ERYTECH believes that eryaspase also has potential as a treatment approach in solid tumors. ERYTECH has successfully completed a Phase 1 study and a 140-patient Phase 2 clinical trial in France, evaluating eryaspase in patients with second line metastatic pancreatic cancer.

Eryaspase 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. ERYTECH produces eryaspase 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 eryaspase 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. The European Medicines Agency (EMA) and the U.S. Food and Drug Administration (FDA) have granted orphan drug designations for eryaspase for the treatment of ALL, AML and pancreatic cancer.

In addition to eryaspase, ERYTECH is developing two other product candidates that focus on using encapsulated enzymes to induce tumor starvation. The company is also exploring the use of its ERYCAPS platform for developing cancer immunotherapies and enzyme replacement therapies.

*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).*

#### **Forward-looking information**

This press release contains forward-looking statements, forecasts and estimates with respect to the clinical development plans, business and regulatory strategy, and 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 ERYTECH's control. There can be no guarantees with respect to pipeline product candidates that the candidates will receive the necessary regulatory approvals or that they will prove to be commercially successful. Therefore, actual results may turn out to be materially different from the anticipated 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](http://www.amf-france.org)), also available on ERYTECH's website ([www.erytech.com](http://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 this press release. Readers are cautioned not to place undue reliance on any of these forward-looking statements. ERYTECH disclaims any obligation to update any such forward-looking statement, forecasts or estimates to reflect any change in ERYTECH'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 law.

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