



## ERYTECH Selects Triple Negative Breast Cancer as Next Indication for Eryaspase

Feb 13, 2018 | Press Releases

- **Set-up activities for Phase 2 clinical study ongoing and patient enrollment expected to start Q3 2018**

LYON, France--(BUSINESS WIRE)--Feb. 13, 2018-- Regulatory News:

**ERYTECH Pharma (Euronext: ERYP- Nasdaq: ERYP), a clinical-stage biopharmaceutical company developing innovative therapies by encapsulating therapeutic drug substances inside red blood cells, today announced the selection of Triple Negative Breast Cancer as the next target indication for broadening the scope of eryaspase (GRASPA®) development in solid tumors.**

L-asparaginase is a cornerstone treatment in acute lymphoblastic leukemia (ALL), especially for pediatric patients, but the excessive toxicity of conventional L-asparaginase formulations has limited its use in other indications.

The positive Phase 2b result of eryaspase (L-asparaginase encapsulated in red blood cells) in metastatic pancreatic cancer, reported in 2017, represents, to our knowledge, the first-ever evidence of clinical benefit of an asparaginase-based product in a solid tumor indication. In this 141-patient randomized Phase 2b study, eryaspase in combination with chemotherapy demonstrated a 40% reduction in risk of death rate (HR=0.60; p=0.009) compared to chemotherapy alone.

Following these very encouraging results, ERYTECH conducted a comprehensive evaluation to determine other potential solid-tumor indications for developing eryaspase. Metastatic Triple-Negative Breast Cancer (TNBC) has now been selected as the next indication to expand the potential use of eryaspase in solid tumors. TNBC is an aggressive and metabolically active form of breast cancer with high rates of symptomatic metastases. A recent publication in *Nature*<sup>1</sup> supports the hypothesis that restricting availability of asparagine can reduce metastatic progression of cancer cells in breast cancer. One of the most striking observations from our Phase 2b trial in pancreatic cancer was the 40% reduction of new lesions in the eryaspase arm compared to the control arm.

*"TNBC is a heterogenous subgroup of breast cancer associated with poor patient outcome and high risk of recurrence compared to other breast cancer subtypes. Aside from BRCA1/2 mutation status, treatment options for TNBC remain limited," commented Iman El-Hariry, MD, PhD, Chief Medical Officer of ERYTECH. "There is growing evidence of altered metabolism in TNBC. The evaluation of eryaspase in metastatic TNBC provides a promising new therapeutic approach, which capitalizes on reprogramming of the metabolic pathways in this disease."*

Gil Beyen, Chairman and CEO of ERYTECH, added, *"The selection of TNBC as the second solid tumor indication for evaluating eryaspase anti-tumor activity brings hope for improving the health of these women. The safety profile of eryaspase provides additional rationale for combination with currently existing therapies to increase treatment options in TNBC."*

The development in TNBC complements ERYTECH's pipeline of programs, which focus on the development of therapies that target amino acid metabolism of tumor cells. Set-up activities of a Phase 2 proof-of-concept clinical study have started and ERYTECH expects to enroll the first patient in Q3 2018.

### About Triple-Negative Breast Cancer (TNBC)

Breast cancer is the most commonly diagnosed cancer in women globally with nearly 1.8 million new cases diagnosed annually<sup>2</sup>. It is estimated that over 600,000 women each year are diagnosed with breast cancer in the United States and Europe in aggregate<sup>3</sup>. Approximately 10-20% of breast cancers are TNBC, a form of breast cancer that lacks expression of estrogen receptor (ER), progesterone receptor (PR) and does not overexpress HER2<sup>4</sup>. TNBC is associated with a poorer prognosis when compared to other breast cancer subtypes. As commonly utilized hormone therapy and HER2 targeting agents are not treatment options for women with TNBC, there is significant unmet need for novel therapeutic approaches in this subtype of breast cancer.

### 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 development of products that target the altered amino acid metabolism of cancer cells, depriving them of nutrients necessary for their survival.

The Company's lead product, eryaspase, also known under the trade name GRASPA®, 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. L-asparaginase has been a standard component of multi-agent chemotherapy for the treatment of pediatric acute lymphoblastic leukemia (ALL), but side effects limit treatment compliance, especially in adults and patients with weak performance status.

Eryaspase demonstrated positive efficacy and safety results in various clinical trials in ALL, including in a Phase 2 study in patients over 55 years of age and in a Phase 2/3 study in relapsed or refractory ALL patients, as well as in pancreatic cancer, where it achieved positive results in a Phase 2b study of second-line treatment of patients with metastatic pancreatic cancer.

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, erymethionase and eryminase, that focus on using encapsulated enzymes to target cancer metabolism and induce tumor starvation. ERYTECH is also exploring the use of its ERYCAPS platform for developing cancer immunotherapies (ERYMMUNE) and enzyme replacement therapies (ERYZYME).

*ERYTECH is listed on the Nasdaq Global Select Market in the United States (ticker: ERYP). ERYTECH and on the Euronext regulated market in Paris (ISIN code: FR0011471135, ticker: ERYP). ERYTECH is part of the CAC Healthcare, CAC Pharma & Bio, CAC Mid & Small, CAC All Tradable, EnterNext PEA-PME 150 and Next Biotech indexes.*

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

This press release contains forward-looking statements, forecasts and estimates with respect to the clinical results from and the development plans of eryaspase, 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, forecast 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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<sup>1</sup> Knott et al., Nature, Februari 2018

<sup>2</sup> World Health Organization (International Agency for Research on Cancer), Globocan 2012

<sup>3</sup> Cancer Facts and Figures, 2018 (American Cancer Society)

<sup>4</sup> Yam C et al., The Oncologist, September 2017

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Source: ERYTECH Pharma

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