



ERYTECH Announces Publication of its Phase 2b Trial of Eryaspase in Metastatic Pancreatic Cancer in the European Journal of Cancer

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First asparaginase-based therapy to demonstrate clinical efficacy and safety in solid tumors

LYON, France and CAMBRIDGE, Mass., Nov. 25, 2019 (GLOBE NEWSWIRE) -- **ERYTECH Pharma (Nasdaq and Euronext: ERYP), a clinical-stage biopharmaceutical company developing innovative therapies by encapsulating therapeutic drug substances inside red blood cells, today announced that the full results from its Phase 2b trial evaluating eryaspase in metastatic pancreatic cancer are now published online in the *European Journal of Cancer*.**

The Phase 2b trial evaluated eryaspase, L-asparaginase encapsulated in red blood cells, as a second-line treatment in combination with chemotherapy in 141 patients with metastatic pancreatic cancer. In this trial, conducted in France, eryaspase was added to gemcitabine or mFOLFOX chemotherapy and compared to the chemotherapy alone in a 2-to-1 randomization.

Eryaspase in combination with chemotherapy significantly prolonged both Overall Survival (OS) and Progression Free Survival (PFS) in the entire patient population, with a 40% reduction in the risk of death (OS HR, 0.60; $P=0.008$), and a 44% reduction in risk of disease progression on average over time (PFS HR, 0.56; $P=0.005$). No unexpected safety findings were reported and eryaspase did not add substantially to the toxicity of chemotherapy. The results of the trial were first presented at ESMO 2017¹.

Principal Investigator Professor Pascal Hammel, gastroenterologist-oncologist and head of the Oncology Unit at Beaujon Hospital in Paris, said, *"I am grateful that the editors of the European Journal of Cancer selected our study for publication. To our knowledge, this is the only Phase 2b study investigating the role of an asparaginase in pancreatic cancer. We look forward to confirming these results in the ongoing Phase 3 study (TRYbeCA1) which is now well underway internationally."*

Dr. Iman El-Hariry, Chief Medical Officer of ERYTECH, said, *"Despite intense research efforts, limited progress has been made toward increased overall survival and metastatic pancreatic cancer remains a high unmet medical need. Therefore, we are very encouraged by the support from the medical community and their active participation in the TRYbeCA1 study, which builds on the Phase 2b study results published today in the European Journal of Cancer."*

Copies of the paper: **"Erythrocyte-encapsulated asparaginase (eryaspase) combined with chemotherapy in second-line treatment of advanced pancreatic cancer: an open-label, randomized Phase IIb trial"** by Pascal Hammel, Portales Fabienne, Laurent Mineur, Jean-Philippe Metges, Thierry Andre, Christelle De La Fouchardiere, Christophe Louvet, Farid El Hajbi, Roger Faroux, Rosine Guimbaud, David Tougeron, Olivier Bouche, Thierry Lecomte, Christine Rebischung, Christophe Tournigand, Jerome Cros, Richard Kay, Adam Hamm, Anu Gupta, Jean-Baptiste Bachet, Iman El Hariry.

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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 approximately 185,000² 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 below 10%³. It is currently the third leading cause of cancer death in the United States and is projected to rise to the second leading cause by 2030⁴. Limited therapeutic options are currently available for this indication, thereby reinforcing the need to develop new therapeutic strategies and rational drug combinations with the aim of improving overall patient outcomes and quality of life.

About the European Journal of Cancer:

The European Journal of Cancer (EJC) integrates preclinical, translational, and clinical research in cancer, from epidemiology, carcinogenesis and biology through to innovations in cancer treatment and patient care. The journal publishes original research, reviews, previews, editorial comments and correspondence. The EJC is the official journal of the [European Organisation for Research and Treatment of Cancer \(EORTC\)](#) and the [European Society of Breast Cancer Specialists \(EUSOMA\)](#).

<https://www.journals.elsevier.com/european-journal-of-cancer>

About ERYTECH and eryaspase: www.erytech.com

ERYTECH is a clinical-stage biopharmaceutical company developing innovative red blood cell-based therapeutics for severe forms of cancer and orphan diseases. Leveraging its proprietary ERYCAPS platform, which uses a novel technology to encapsulate drug substances inside red blood cells, ERYTECH is developing a pipeline of product candidates for patients with high unmet medical needs. ERYTECH's primary focus is on the development of product candidates that target the altered metabolism of cancer cells by depriving them of amino acids necessary for their growth and survival.

The Company's lead product candidate, eryaspase, which consists of L-asparaginase encapsulated inside donor-derived red blood cells, targets the cancer cell's altered asparagine and glutamine metabolism. Eryaspase is in Phase 3 clinical development for the treatment of second-line pancreatic cancer and in Phase 2 for the treatment of first-line triple-negative breast cancer. An investigator-sponsored Phase 2 study in second-line acute lymphoblastic leukemia is ongoing in the Nordic countries of Europe.

ERYTECH produces its product candidates for treatment of patients in Europe at its GMP-approved manufacturing site in Lyon, France, and for patients in the United States at its recently opened GMP manufacturing site in Princeton, New Jersey, USA.

ERYTECH is listed on the Nasdaq Global Select Market in the United States (ticker: ERYP) 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.

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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, expansion of manufacturing capacity 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. All statements contained in this press release other than statements of historical facts are forward-looking statements, including, without limitation, statements regarding the ERYTECH's business strategy including its clinical development of eryaspase; the status of the TRYbeCA1 trial including the timeline for patient enrollment, expansion of trial into the United States and intended activities with respect to the interim analysis; the potential of ERYTECH's product pipeline; the timing of ERYTECH's preclinical studies and clinical trials and announcements of data from those studies and trials; ERYTECH's anticipated manufacturing capacity and ability to meet future demand and ERYTECH's anticipated cash runway and sufficiency of cash resources. 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. Further description of these risks, uncertainties and other risks can be found in the Company's regulatory filings with the French Autorité des Marchés Financiers (AMF), the Company's Securities and Exchange Commission (SEC) filings and reports, including in the Company's 2018 Document de Référence filed with the AMF in March 2019 and in the Company's Annual Report on Form 20-F filed with the SEC on March 29, 2019 and future filings and reports by the Company. 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.

¹ References: *Annals of Oncology* (2017) 28 (suppl_5): v209-v268. 10.1093/annonc/mdx369

² WHO, *Cancer Today* (gco.iarc.fr)

³ Siegel et al., *Cancer Statistics 2016* (8%, US data)

⁴ Rahib et al., *Cancer Research*, 2014

PDF available at: <http://ml.globenewswire.com/Resource/Download/01872fda-a26e-4601-8963-96c86819c1ce>



Source: Erytech Pharma S.A.