



## ERYTECH Granted U.S. FDA Fast Track Designation for eryaspase in Second-Line Pancreatic Cancer

Apr 28, 2020 | Press Releases

- **Fast Track designation for eryaspase underscores the urgent need for potential new treatment options for patients with second line metastatic pancreatic cancer**

LYON, France and CAMBRIDGE, Mass., April 28, 2020 (GLOBE NEWSWIRE) -- **ERYTECH Pharma (Nasdaq & Euronext: ERYP)**, a clinical-stage biopharmaceutical company developing innovative therapies by encapsulating therapeutic drug substances inside red blood cells, announced today that the U.S. Food and Drug Administration (FDA) has granted eryaspase Fast Track Designation for the development of a second-line treatment of patients with metastatic pancreatic cancer.

*"This is yet another significant milestone and meaningful validation of our technology as we continue our TRYbeCA-1 Phase 3 trial evaluating eryaspase in second-line metastatic pancreatic cancer,"* said Gil Beyen, CEO of ERYTECH. *"We believe that the FDA's Fast Track designation for eryaspase underscores its potential to address this high unmet medical need."*

ERYTECH's lead product candidate, eryaspase, is being evaluated in a Phase 3 trial (TRYbeCA-1) in second-line metastatic pancreatic cancer in 11 countries in Europe and the United States. More than 75% of the approximately 500 patients to be enrolled in the trial have been randomized. An interim superiority analysis, to be conducted by an independent data monitoring committee (IDMC) when two-thirds of the events have occurred, is currently expected to take place around year-end 2020 and the final analysis in the second half of 2021.

In a previous Phase 2b trial, eryaspase demonstrated significant improvement in both overall survival (OS) and progression-free survival (PFS) with a Hazard Ratio (HR) of 0.60 and 0.59 respectively. Overall, eryaspase was well tolerated and showed a safety profile comparable to that of standard chemotherapy.

Fast Track is a program designed to facilitate the expedited development and review of a new drug, alone or in combination with other drugs, to treat serious or life-threatening conditions for which there is a demonstration of the potential to address an unmet medical need. The purpose is to advance new drugs earlier for patients who need them.

### 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 150,000 new cases of pancreatic cancer diagnosed in Europe and the United States. Advanced pancreatic cancer is a particularly aggressive cancer, with a five-year survival rate of less than 10%. It is currently the fourth leading cause of cancer death in Europe and the United States and is projected to rise to the second leading cause by 2030. 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 TRYbeCA-1

TRYbeCA-1 is a randomized, controlled Phase 3 clinical trial evaluating eryaspase in second-line metastatic pancreatic cancer. The trial is planned to enroll approximately 500 patients at approximately 100 clinical sites in Europe and the United States. Eligible patients are randomized 1-to-1 to receive eryaspase in combination with standard chemotherapy (gemcitabine/nab-paclitaxel or an irinotecan-based regimen) or chemotherapy alone. The primary endpoint of TRYbeCA-1 is overall survival. An interim superiority analysis will be conducted when approximately two-thirds of the events will have occurred.

### About FDA Fast Track Designation

Fast Track is a program designed to facilitate the expedited development and review of a new drug alone or in combination with other drugs to treat serious or life-threatening conditions for which there is a demonstration of the potential to address an unmet medical need. The purpose is to advance new drugs earlier for patients who need them. Fast Track addresses a broad range of serious conditions.

A drug that receives Fast Track designation is eligible for some or all of the following:

- More frequent meetings and interactions with the review team at the FDA to discuss the drug's development and ensure collection of appropriate data needed to support drug approval as well as to discuss accelerated approval, the structure and content of an NDA, and other critical issues.
- More frequent written communications from FDA about such things as the design of the proposed clinical trials and use of biomarkers.
- Eligibility for Accelerated Approval and Priority Review, if relevant criteria are met.
- Rolling Review, which means that a drug company can submit completed sections of its Biologic License Application (BLA) or New Drug Application (NDA) for review by FDA, rather than waiting until every section of the marketing application is completed before the entire application can be reviewed. BLA or NDA review usually does not begin until the drug company has submitted the entire application to the FDA.

### About ERYTECH and eryaspase: [www.erytech.com](http://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 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.*

## Forward-looking information

This press release contains forward-looking statements including but not limited to statements with respect to the clinical development plans of eryaspase; the potential indications for and benefits of eryaspase; statements relating to the TRYbeCA-1 clinical trial, including the timeline for patient enrollment as well as expected timing of the availability of results and interim superiority analysis; potential impacts on the Company's clinical trials, including TRYbeCA-1 clinical trial, due to the coronavirus (COVID-19) pandemic such as delays in regulatory review, manufacturing and supply chain interruptions; and the overall impact of the COVID-19 pandemic on the global healthcare system as well as the Company's business, financial condition and results of operations. 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. 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 and timeline 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 2019 Document d'Enregistrement Universel filed with the AMF on March 18, 2020 and in the Company's Annual Report on Form 20-F filed with the SEC on March 18, 2020 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. In addition, the COVID-19 pandemic and the associated containment efforts have had a serious adverse impact on the economy, the severity and duration of which are uncertain. Government stabilization efforts will only partially mitigate the consequences. The extent and duration of the impact on the Company's business and operations is highly uncertain, and that impact includes effects on its clinical trial operations and supply chain. Factors that will influence the impact on the Company's business and operations include the duration and extent of the pandemic, the extent of imposed or recommended containment and mitigation measures, and the general economic consequences of the pandemic. The pandemic could have a material adverse impact on the Company's business, operations and financial results for an extended period of time.

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Source: Erytech Pharma S.A.