

ERYTECH Presents TRYbeCA-1 Trial-in-Progress Poster at the 2019 ASCO GI Annual Meeting

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LYON, France and CAMBRIDGE, Mass., Jan. 18, 2019 (GLOBE NEWSWIRE) -- ERYTECH Pharma (Euronext Paris: ERYP - Nasdaq: ERYP), a clinical-stage biopharmaceutical company developing innovative therapies by encapsulating drug substances inside red blood cells, announced that a poster entitled "TRYbeCA-1: A randomized, phase 3 study of eryaspase in combination with chemotherapy versus chemotherapy alone as second-line treatment in patients with pancreatic adenocarcinoma (NCT03665441)" will be presented today at the 2019 American Society of Clinical Oncology (ASCO) Annual Meeting in San Francisco. The poster (Abstract # TPS471) will be available at www.erytech.com/after-presentation at the conference.

In September 2018, the TRYbeCA-1 trial was initiated. The Trial-in-Progress poster will provide an update on the study progress with investigators sites that have been initiated in multiple countries and actively recruiting patients. The trial is planned to enroll approximately 500 patients with second line metastatic pancreatic cancer in 120-130 clinical sites in 12 European countries and the United states. Currently the trial is approved for patients participation in eight selected European countries, and enrolling patients in 21 clinical sites.

Patients who meet the eligibility criteria are randomized 1-to-1 to receive eryaspase in combination with standard chemotherapy (gemcitabine/abraxane or irinotecan-based regimen) or chemotherapy alone until disease progression. The primary endpoint is overall survival. An interim analysis is foreseen when approximately two-thirds of events have occurred.

The launch of the Trybeca-1 Phase 3 trial follows the positive Phase 2b results in the same patient population, that were reported in September 2017¹. This open-label, multi-center, 2-to-1 randomized study in 141 patients demonstrated significant improvement in both overall survival and progression-free survival. Overall, eryaspase was well tolerated and did not appear to increase the toxicity of the chemotherapy.

"Patients with advanced pancreatic cancer need new treatment options. As global co-Principal Investigator, I am delighted with the rapid set-up of the study. The Trial-in-Progress poster demonstrates that we are making excellent progress toward the initiation of over 100 centers for TRYbeCA-1," commented Dr. Manuel Hidalgo-Medina, medical oncologist at Beth Israel Deaconess Medical Center in Boston and professor of medicine at Harvard Medical School.

"The results from our landmark Phase 2b study are highly promising and underscore the importance of targeting tumor metabolism pathways in pancreatic cancer. We are hopeful to provide a novel treatment modality for this highly unmet medical need. We are very pleased that the Phase 3 study is making excellent progress and patient enrollment continues as planned. Our enrolled patients mark the initiation of the trial in Europe. We expect investigator sites in the United States will begin enrolling this quarter," commented Iman El-Hariry, Chief Medical Officer.

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 ERYTECH and eryaspase (GRASPA®): www.erytech.com

ERYTECH is a clinical-stage biopharmaceutical company developing innovative red blood cell-based therapeutics for cancer and orphan diseases. Leveraging its proprietary ERYCAPS platform, a novel technology to encapsulate drug substances inside red blood cells, ERYTECH is developing a pipeline of product candidates to address markets 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 preparations to enter Phase 2 clinical development for the treatment of triplenegative breast cancer. ERYTECH's next product candidate erymethionase, which consists of methionine-gamma-lyase encapsulated in red blood cells to target methionine-dependent cancers, has demonstrated promising preclinical results and is in preparations to enter Phase 1 clinical development.

ERYTECH is also exploring the use of its ERYCAPS platform for developing cancer immunotherapies (ERYMMUNE) and enzyme therapies (ERYZYME).

ERYTECH produces product candidates at its GMP-approved manufacturing site in Lyon, France, and at the American Red Cross in Philadelphia, USA. A large-scale GMP manufacturing facility is under construction in 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 potential of ERYTECH's product pipeline, its clinical development and regulatory plans for eryaspase, the timing of ERYTECH's clinical studies and trials and announcements of data from those studies and trials, and the contents and timing of decisions by the FDA and EMA regarding ERYTECH's product candidates. 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 2017 Document de Référence filed with the AMF in April 2018 and in the Company's Annual Report on Form 20-F filed with the SEC on April 24, 2018 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.

¹Hammel et al, Annals of Oncology (2017) 28 (suppl 5): v209-v268



Source: Erytech Pharma S.A.