ERYTECH Announces Enrollment of First Patient in Phase 2 Clinical Trial Evaluating Eryaspase in TNBC

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LYON, France and CAMBRIDGE, Mass., June 26, 2019 (GLOBE NEWSWIRE) -- **ERYTECH Pharma (Euronext: ERYP - Nasdaq: ERYP), a clinical-stage biopharmaceutical company developing innovative therapies by encapsulating drug substances inside red blood cells, today announced that the first patient has been enrolled in its Phase 2 clinical trial, named TRYbeCA2, evaluating its lead product candidate eryaspase for the treatment of first line triple negative breast cancer (TNBC).**

Following the positive Phase 2 results with eryaspase in second-line metastatic pancreatic cancer, ERYTECH selected triple-negative breast cancer 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 Phase 2/3 clinical trial in first-line metastatic TNBC, named TRYbeCA2, was designed and the Phase 2 part of the trial was launched in Spain, Belgium, Hungary and the United Kingdom. The trial is evaluating eryaspase in combination with gemcitabine and carboplatin chemotherapy, compared to chemotherapy alone. Target enrollment in the Phase 2 part of the trial is approximately 64 patients. The primary endpoint is objective response rate.

"Most women with triple negative breast cancer have very limited treatment options." stated Iman El Hariry, MD, PhD, Chief Medical Officer of ERYTECH. *"Based on accumulated preclinical research of targeting metabolic pathways in TNBC, we believe that the combination of eryaspase with chemotherapy may offer a potential treatment option to these patients. The trial reinforces our strategy to develop medicines that may benefit patients with challenging diseases."*

"I am very pleased that eryaspase, an innovative and promising approach, is evaluated in this Phase 2/3 study in TNBC patients and hopeful that it may provide a novel treatment modality for this highly unmet medical need," commented Prof. Awada, Head of the Medical Oncology Clinic at Jules Bordet Cancer Institute Brussels, Belgium.

About Triple-Negative Breast Cancer (TNBC)

Breast cancer is the most commonly diagnosed cancer in women globally with nearly 2.0 million new cases diagnosed annually[1]. It is estimated that approximately 800,000 women each year are diagnosed with breast cancer in the United States and Europe in aggregate[1,2]. 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[3]. 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.

[1] World Health Organization (International Agency for Research on Cancer), Globocan 2018
[2] Cancer Facts and Figures, 2018 (American Cancer Society)
[3] Yam C et al., The Oncologist, September 2017

About ERYTECH: 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 triple-negative breast cancer. ERYTECH is also developing erymethionase, which consists of methionine-gamma-lyase encapsulated in red blood cells to target methionine-dependent cancers.

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 has recently opened for operations in Princeton, New Jersey, USA and will begin manufacturing later this year.

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 of eryaspase, and the timing of ERYTECH's preclinical studies and clinical trials and announcements of data from those studies and trials. 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 on March 29, 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.

Source: Erytech Pharma S.A.