

ERYTECH Announces Opening of Operations at its New Princeton, NJ GMP Manufacturing Facility

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■ Inauguration event held last week to officially open 30,000 sq. ft GMP manufacturing facility constructed in Princeton, NJ to produce lead product candidate ervaspase in the United States

PRINCETON, N.J. and CAMBRIDGE, Mass. and LYON, France, June 24, 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, announced today the opening of its new Princeton, NJ GMP manufacturing facility.

The facility will support production capacity needs for eryaspase, the Company's lead product candidate for patients in the United States. Eryaspase is in Phase 3 clinical development for the treatment of second-line pancreatic cancer. The Phase 3 clinical trial, which is referred to as the Trybeca-1 trial is expected to enroll approximately 500 patients with second-line metastatic pancreatic cancer at approximately 120 clinical sites in Europe and the United States. The trial started enrolling patients in Europe in September 2018 and is now actively enrolling patients in several European countries. The Princeton facility is targeted to begin manufacturing eryaspase in the fourth quarter of this year to ensure supply for US participants in the Trybeca-1 trial.

The Princeton facility is equipped with multiple clean rooms, with flexibility designed into its configuration and staffing for further scale-up, in view of supplying eryaspase for this Phase 3 and other clinical trials, as well as for the initial expected commercial demand in the United States, if approved.

"The official inauguration of the Princeton, NJ facility last week represents our strong commitment to the United States and the technologic transferability of our ERYCAPS platform", said Gil Beyen, CEO of Erytech. "The investment we see coming to fruition today signals the company's growth and ushers in hope for the numerous cancer patients we are dedicated to serve."

Speakers at the site inauguration included Pancreatic Cancer Expert Physician Marcus Noel, MD, and Kerry McKean Kelly, founder of Kelly's Heroes patient advocacy group. Comments were also shared by the local Mayor, Hemant Marathe, ERYTECH's Facility Project Leader, Siera Talbott, and CFO/COO, Eric Soyer.

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: 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 as well as ERYTECH's business and regulatory strategy and expansion of ERYTECH's manufacturing capacity and ability to meet clinical supply demand. 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, its manufacturing capacity and the timing of ERYTECH's preclinical studies and clinical 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.