



ERYTECH Confirms Strategic Focus of Eryaspase on Solid Tumors and Ceases Development in Acute Lymphoblastic Leukemia

Jun 24, 2018 | Press Releases

(GLOBE NEWSWIRE via COMTEX) --- Focuses development efforts on solid tumor indications

- Confirms planned launch of company-sponsored randomized Phase 2 trial in first-line pancreatic cancer, in addition to ongoing launch of Phase 3 trial in second-line pancreatic cancer.
- Expands eryaspase production capacity in the United States and France
- Plans to cease development in acute lymphoblastic leukemia (ALL), including withdrawal of European Marketing Authorization Application (MAA)

LYON, France and CAMBRIDGE Mass., June 24, 2018 (GLOBE NEWSWIRE) -- ERYTECH Pharma (Euronext:ERYP) (Nasdaq:ERYP), a clinical-stage biopharmaceutical company developing innovative therapies by encapsulating therapeutic drug substances inside red blood cells, today announced that it will focus its development efforts for its product candidate eryaspase on the potential treatment of selected solid tumor indications. The company also announced that it plans to cease its development program for eryaspase in acute lymphoblastic leukemia (ALL), including the withdrawal of its previously submitted MAA for eryaspase for the treatment of relapsed and refractory ALL.

In 2017, ERYTECH announced positive results from a Phase 2b clinical trial of eryaspase combined with chemotherapy in patients suffering from second-line metastatic pancreatic cancer, as well as the intended launch of a pivotal Phase 3 clinical trial in this indication. Set-up activities are on track and the Phase 3 trial is expected to begin enrollment in the third quarter of 2018. ERYTECH now confirms that it intends to sponsor a Phase 2 proof-of-concept clinical trial of eryaspase later this year in first-line pancreatic cancer, with enrollment expected to commence in the first half of 2019.

In 2018, following the positive results in second-line metastatic pancreatic cancer, ERYTECH also evaluated other potential solid tumor indications and selected metastatic triple-negative breast cancer (TNBC) as the next indication for which to pursue clinical development of eryaspase. ERYTECH is preparing for a Phase 2 proof-of-concept clinical trial in this indication, with the first patient expected to be enrolled in the fourth quarter of 2018. ERYTECH is also evaluating development options in other pancreatic cancer settings and in additional solid tumor indications with high unmet medical need.

In order to ensure adequate supply of eryaspase for its planned clinical trials, as well as the potential commercialization of eryaspase, if approved, the Company is constructing a large-scale manufacturing facility in the United States (Princeton, New Jersey) and is also expanding its manufacturing capacity in Lyon, France. ERYTECH expects both facilities to be operational for clinical production at the expanded capacity in the first quarter of 2019.

Despite having observed favorable efficacy results and safety profile in multiple clinical trials of eryaspase in patients with ALL, ERYTECH now believes, based on recent feedback from the regulatory agencies in Europe and the United States, that significant additional investment would be required in order to seek regulatory approval of eryaspase for the treatment of ALL. In the context of the rapidly changing and increasingly competitive landscape with newly-approved treatment options for ALL, the regulatory requirements and what ERYTECH observes to be a limited market opportunity for eryaspase in ALL, ERYTECH has elected to cease further clinical development efforts in ALL and to withdraw its European MAA. The resources that will become available as a result of this strategic decision will be allocated to what ERYTECH estimates is a significantly larger unmet medical needs and market opportunity for the potential treatment of solid tumors.

ERYTECH's preclinical development efforts are not affected by this strategic decision. The next product candidate, erymethionase, methionine-g-lyase encapsulated in red blood cells, and the ERYMMUNE (immuno-therapy) research program are also targeting solid tumor indications. ERYTECH intends to initiate a Phase 1 clinical trial of erymethionase later this year, with enrollment expected to commence in the first half of 2019.

Conference Call Details

ERYTECH management will hold a conference call on Monday, June 25, 2018 at 02:30pm CET / 08:30am EDT. Gil Beyen, Chairman and CEO, Eric Soyer, CFO and COO and Iman El-Hariry, CMO will be available for a Q&A session.

The call is accessible via the below teleconferencing numbers, followed by the Conference ID#: 6590689#:

USA/Canada: +1 833 818 6807	France: +33 176748988
Belgium: +32 24003547	Switzerland: +41 445802606
Spain: +34 914142503	Germany: +49 6922224728
Finland: +358 972519310	United-Kingdom: +44 2031070289
Sweden: +46 856619361	Netherlands: +31 207075547

An archived replay of the call will be available for 7 days by dialing + 1 855 859 2056, Conference ID: 6590689#.

About ERYTECH: www.erytech.com

Founded in Lyon, France in 2004, ERYTECH is a clinical-stage biopharmaceutical company developing innovative therapies for rare forms of cancer and orphan diseases. Leveraging its proprietary ERYCAPS platform, which uses a novel technology to encapsulate therapeutic drug substances inside red blood cells, ERYTECH has developed a pipeline of product candidates targeting markets with high unmet medical needs. ERYTECH's initial focus is on the development of products that target the altered amino acid metabolism of cancer cells, depriving them of nutrients necessary for their survival.

The Company's lead product, eryaspase, also known under the trade name GRASPA®, consists of an enzyme, L-asparaginase, encapsulated inside donor-derived red blood cells. L-asparaginase depletes asparagine, a naturally occurring amino acid essential for the survival and proliferation of cancer cells. L-asparaginase has been a standard component of multi-agent chemotherapy for the treatment of pediatric acute lymphoblastic leukemia (ALL), but side effects limit treatment compliance, especially in adults and patients with weak performance status.

Eryaspase demonstrated promising efficacy and safety results in various clinical trials in ALL, as well as in a Phase 2b trial in second-line pancreatic cancer. ERYTECH is preparing for the launch of a pivotal Phase 3 clinical trial in second line pancreatic cancer and Phase 2 trials in first line pancreatic cancer and triple-negative breast cancer.

ERYTECH produces eryaspase at its own GMP-approved and operational manufacturing site in Lyon (France), and at a site for clinical production in Philadelphia (USA). A large-scale manufacturing facility is under construction in New Jersey (USA).

In addition to eryaspase, ERYTECH is developing erymethionase, methionine-γ-lyase encapsulated in red blood cells, to target cancer cells' amino acid metabolism and induce tumor cell starvation. ERYTECH is also exploring the use of its ERYCAPS platform for developing cancer immunotherapies (ERYMMUNE) and enzyme replacement therapies (ERYZYME).

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 development plans of eryaspase and erymethionase, including the expected timing for the commencement of clinical trials, as well as ERYTECH's business and regulatory strategy, and the 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. They include all matters that are not historical facts. 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, including in the Company's Document de Référence filed on April 24, 2018, the Company's Securities and Exchange Commission filings and reports, including in the Company's Annual Report on Form 20-F filed on April 24, 2018 and amended on May 23, 2018, and future filings and reports made by the Company from time to time. 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.

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