РНАХІАМ

ERYTECH Provides Update on the TRYbeCA-1 Phase 3 Clinical Trial of Eryaspase in Second Line Pancreatic Cancer

Apr 20, 2020 | Press Releases

- More than 75% of the planned ~500 patients enrolled in the trial
- Trial to continue as planned after third safety review by independent data monitoring committee
- Interim superiority analysis expected around year-end; final analysis in second half of 2021

LYON, France, April 20, 2020 (GLOBE NEWSWIRE) -- ERYTECH Pharma (Nasdaq & Euronext: ERYP), a clinical-stage biopharmaceutical company developing red blood cell-based cancer therapeutics, today provided an update on the pivotal Phase 3 clinical trial for advanced metastatic pancreatic cancer (TRYbeCA-1), which is evaluating the efficacy and safety of ERYTECH's lead product candidate eryaspase in combination with chemotherapy as second-line therapy.

"We are pleased that the TRYbeCA-1 trial has continued to progress well despite the challenges caused by the COVID-19 global pandemic," said Gil Beyen, CEO of ERYTECH. "The third independent safety review has once again confirmed the favorable safety profile of our lead product candidate eryaspase, and the trial has now surpassed 75% of the planned target enrollment. While prioritizing the safety of patients, health care providers and our employees, we have successfully deployed measures to safeguard the integrity of the trial by ensuring patients' continued access to treatment and appropriate follow-up. The enrollment of new patients is also continuing, but at a slower pace than over the past few weeks. We currently anticipate a limited delay in completing patient enrollment of 3 to 4 months from previous plans. In addition, and unrelated to COVID-19, the average time to events appears longer than originally expected. We now expect the interim superiority analysis around the end of this year and final results in the second half of 2021."

The independent data monitoring committee (IDMC) has reviewed the safety data for the first 320 patients enrolled and treated in the TRYbeCA-1 trial. In line with the two earlier safety reviews, no safety issues were identified and the IDMC recommended to continue the trial as planned.

To date, more than 75% of the approximately 500 patients to be enrolled in the trial have been randomized. Various measures have been put in place to facilitate compliance with the study schedule and to preserve study data integrity.

Through March 2020, new patient enrollment continued as planned notwithstanding the increasing difficulties experienced by the hospitals to organize the proper treatment and follow-up. Over the past two weeks, ERYTECH has observed a reduction in enrollment rate due to the COVID-19 pandemic and now believes new patient enrollment will be below plan in the coming months. The Company currently expects a delay of 3 to 4 months in completion of patient enrollment, bringing the time of complete enrollment to the fourth quarter of this year.

With more than 75% of the patients enrolled in the trial, the Company believes that the planned interim superiority analysis, to be conducted by an IDMC when two-thirds of the total death events have been reached, will not be significantly affected by the expected delay in enrollment. However, based on recent tracking of the total death events in the trial, the average time to event appears longer than originally anticipated. As a result, the Company now expects to report the interim analysis around year-end 2020 and the final analysis in the second half of 2021.

About TRYbeCA-1

TRYbeCA-1 is a randomized, controlled Phase 3 clinical trial evaluating eryaspase in second-line metastatic pancreatic cancer. The trial is designed 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 have occurred.

About ERYTECH and eryaspase: 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 development for the treatment of first-line triple-negative breast cancer. An investigator-sponsored Phase 2 trial 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.

CONTACTS

ERYTECH Eric Soyer CFO & COO LifeSci Advisors, LLC Investor Relations Corey Davis, Ph.D.

Mathilde Bohin / Louis-Victor Delouvrier Investor relations Nicolas Merigeau Media relations

NewCap

+33 4 78 74 44 38 investors@ERYTECH.com +1 (212) 915 - 2577 cdavis@lifesciadvisors.com +33 1 44 71 94 94 <u>ERYTECH@newcap.eu</u>

PDF available at: http://ml.globenewswire.com/Resource/Download/078b2476-57fd-4091-8a72-0807e6a764e2



Source: Erytech Pharma S.A.