



## ERYTECH Announces Results from TRYbeCA-1 Phase 3 Trial of Eryaspase in Patients with Second-line Advanced Pancreatic Cancer

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Management to host Conference Call on Monday, October 25,  
at 8:30am EDT/ 2:30pm CEST

- **The trial did not meet its primary endpoint of overall survival**
- **The prespecified subgroup of patients treated with eryaspase and an irinotecan-based chemotherapy demonstrated an interesting trend of survival benefit, which merits further investigation**
- **Patients treated with eryaspase demonstrated superior disease control compared to patients treated with chemotherapy only. Other secondary endpoints showed nominal improvement**
- **The safety profile of eryaspase was consistent with earlier clinical trials results and safety reviews**
- **ERYTECH will now focus on its late-stage program in hypersensitive ALL and confirms its intention to submit a BLA before the end of the year**
- **ERYTECH will review strategic and partnering alternatives, including for the further development and commercialization of eryaspase**

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Cambridge, MA (U.S.) and Lyon (France), October 25, 2021 – ERYTECH Pharma (Nasdaq & Euronext: ERYP), a clinical-stage biopharmaceutical company developing innovative therapies by encapsulating therapeutic drug substances inside red blood cells, today announced top-line results from its Phase 3 TRYbeCA-1 clinical trial evaluating eryaspase as second-line treatment in 512 patients with metastatic pancreatic cancer. The trial did not meet its primary endpoint of overall survival (OS).

In the TRYbeCA-1 trial, eryaspase demonstrated an improvement in the primary endpoint of OS compared to chemotherapy alone with a hazard ratio (HR) of 0.92 (95% confidence interval (CI), 0.76-1.11) in the intent-to-treat population, and the difference was not statistically significant (p-value 0.375). The median OS for patients treated with eryaspase plus chemotherapy was 7.5 months (95% CI, 6.5-8.3), compared to 6.7 months (95% CI, 5.4-7.5) for chemotherapy alone.

Interestingly, while the patients treated with gemcitabine plus nabpaclitaxel did not experience a survival benefit from the addition of eryaspase, patients treated with eryaspase and an irinotecan-based chemotherapy regimen showed nominal survival benefit with a HR of 0.77 (95% CI, 5.7-1.05) over those treated with chemotherapy alone. This prespecified subgroup had a median OS of 8.0 months in the eryaspase-treated arm versus 5.7 months in the control arm (per protocol population).

Key secondary endpoints of the trial, including progression-free survival, disease control rate and objective response rate, showed benefit in favor of eryaspase.

The safety profile of eryaspase observed in the TRYbeCA-1 trial was consistent with earlier observations and previous safety reviews by the trial's independent data monitoring committee (IDMC).

Further analysis of the data will be performed, and full results will be presented at an upcoming medical conference.

ERYTECH will now focus on its late-stage program in acute lymphoblastic leukemia (ALL) and pursue a path to approval in hypersensitive ALL based on positive results of NOPHO-sponsored Phase 2 trial. The Company reiterates its intention to submit a BLA before the end of the year.

*"While the results are disappointing, we congratulate the company for a very well managed trial in this difficult disease. With a median survival of 7.5 months, ERYTECH has created a new reference standard for clinical evaluation in second line pancreatic cancer", said Prof. Pascal Hammel, MD, PhD, gastroenterologist-oncologist at Beaujon Hospital in Paris and co-principal investigator of the TRYbeCA-1 trial.*

*"I agree with Prof Hammel, and want to add that the results in the subgroup of fluoropyrimidine-based treatments are, with a median survival of 8 months, really remarkable and merit further investigation. Especially since this was also the better subgroup in the Phase 2b trial", said Prof. Manuel Hidalgo, M.D., Ph.D., Weill Cornell Medicine/NewYork-Presbyterian Hospital, and co-principal investigator of the study.*

*"Pancreatic cancer is a very challenging, heterogeneous disease, and the results of the TRYbeCA-1 Phase 3 trial have now also encountered this significant hurdle." said Dr Iman El Hariry, Chief Medical Officer of ERYTECH. "It is very disappointing that the clinical benefit eryaspase demonstrated in the Phase 2 trial was not confirmed; however, the study has addressed important questions in the management of pancreatic cancer patients. I want to thank the patients, their families and healthcare providers, our vendors, as well as our colleagues at ERYTECH, who overcame many obstacles, including the COVID-19 pandemic, to execute this important trial. Targeting the altered asparagine and glutamine metabolism of cancer cells, well established in ALL, remains an important field of development, also for the field of solid tumors. The ERYTECH team along with its clinical advisors will review the full data analyses including the secondary and exploratory endpoints and provide a more detailed update on additional subgroup analysis after these are completed".*

*“These results are highly disappointing, not only for the ERYTECH team, but also for patients and healthcare providers as there continues to be a major unmet medical need in pancreatic cancer.” added Gil Beyen, CEO of ERYTECH. “We continue to believe in the potential of cancer metabolism and our ERYCAPS® platform to treat aggressive forms of cancer, and will, while evaluating the potential to continue the development in pancreatic cancer, now continue to focus on seeking approval of eryaspase for ALL patients who developed hypersensitivity to pegylated asparaginase. This is also an important medical need and a potentially attractive market opportunity for eryaspase. We confirm our previously announced intention to submit a BLA for this indication by year-end 2021. We will evaluate our strategic and partnering options in the coming weeks and will provide updated guidance on our global corporate strategy later in the year.”*

#### **TRYbeCA-1 Top-line Results and Analysis Conference Call Details**

ERYTECH management will hold a conference call and webcast on **October 25, at 8:30am EDT / 2:30 pm CEST** highlights the top-line results and plans for future approval and launch in 2022. Gil Beyen, CEO, Eric Soyer, CFO/COO, and Iman El-Hariry, CMO, will deliver a brief presentation, followed by a Q&A session.

- The audio call is accessible via the below registering link: <http://www.directeventreg.com/registration/event/2361482> (Conference ID : **2361482**). Once registered, participants will receive a unique access code and the call number details to join the teleconference.
- The webcast can be followed live online via the link: <https://edge.media-server.com/mmc/p/4cdxqddy>

An archive of the webcast will be available on ERYTECH's website, under the "Investors" section at [investors.erytech.com](http://investors.erytech.com)

An archived replay of the audio call will be available for 7 days by dialing + 1 855 859 2056, Conference ID: 2361482#.

#### **About ERYTECH and eryaspase**

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 cells' altered asparagine and glutamine metabolism. The proof of concept of eryaspase as a cancer metabolism agent was established in different trials in acute lymphoblastic leukemia (ALL) and pancreatic cancer. An investigator sponsored Phase 2 trial (IST) evaluating the use of eryaspase in ALL patients who developed hypersensitivity reactions to pegylated asparaginase recently reported positive results, based on which the Company intends to request approval in the United States and potentially other territories. The Company is also pursuing a Phase 1 investigator-sponsored clinical trial in first-line pancreatic cancer.

Eryaspase received Fast Track designation from the U.S. Food and Drug Administration (FDA) for this indication, and eryaspase benefits from orphan drug status for the treatment of ALL both in the United States and in 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. Eryaspase is not an approved medicine.

*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.*

For more information, please visit [www.erytech.com](http://www.erytech.com)

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#### **Forward-looking Information**

This press release contains forward-looking statements including, but not limited to, statements with respect to the clinical development and regulatory

plans of eryaspase including the Company's BLA submission of eryaspase by the end of 2021 as well as the pursuit for additional strategic alternatives, including seeking a partner for the further development and commercialization of eryaspase.

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 2020 Document d'Enregistrement Universel filed with the AMF on March 8, 2021 and in the Company's Annual Report on Form 20-F filed with the SEC on March 8, 2021 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.

**Attachment**

- [ERYTECH PR TRYbeCA-1 Top-Line\\_vf](#)