



ERYTECH Provides Business and Financial Update for the Third Quarter of 2021

Nov 15, 2021 | Press Releases

Conference call and webcast on Tuesday, November 16, 2021
at 8:30am EST / 2:30pm CET

- Progress towards seeking approval of eryaspase for the treatment of ALL patients who experienced hypersensitivity to pegylated asparaginase; Fast Track designation granted; submission of BLA intended around year-end
- Phase 3 trial in second-line pancreatic cancer did not meet its primary endpoint
 - Recommended Phase 2 dose determined from Phase 1 IST in first-line pancreatic cancer of eryaspase with mFOLFIRINOX
- Process to review strategic options and partnering alternatives launched
- Cash and cash equivalents of €38.0 million (\$43.9 million) at the end of September 2021

Cambridge, MA (U.S.) and Lyon (France), November 15, 2021 – ERYTECH Pharma (Nasdaq & Euronext: ERYP), a clinical-stage biopharmaceutical company developing innovative therapies by encapsulating therapeutic drug substances inside red blood cells, today provided a business update and an update on its cash position at the end of September 2021.

"While the outcome of our TRYbeCA-1 trial in second-line pancreatic cancer did not achieve its primary endpoint of overall survival, we remain encouraged by the observed improvement of overall survival in a subset of patients treated with FOLFIRI and will continue analyzing the sizeable TRYbeCA-1 data set in order to distill the reasons for this disappointing outcome," said Gil Beyen, CEO of ERYTECH. "We are also encouraged by the progress we are making towards seeking an approval for eryaspase for the treatment of ALL patients who experienced hypersensitivities to pegylated asparaginase. The dialogue with the FDA is continuing and we are hopeful we can submit our first BLA around year end. We were pleased with the granting of the Fast Track designation for this high unmet need indication in July."

Business Highlights

- Path to BLA in hypersensitive ALL, based on results of NOPHO-sponsored Phase 2 trial

The NOPHO trial evaluated the safety and pharmacological profile of eryaspase in acute lymphoblastic leukemia (ALL) patients who had previously experienced hypersensitivity reactions to pegylated asparaginase therapy. In December 2020, positive trial results were presented at the 2020 American Society of Hematology annual meeting.

Eryaspase in combination with chemotherapy, administered every two weeks, provided a sustained asparaginase enzyme activity level, and was generally well tolerated with few hypersensitivity reactions.

- The Company continued its interactions with the U.S. Food and Drug Administration (FDA) regarding a potential regulatory approval in this indication based on the NOPHO-sponsored trial. A pre-BLA meeting to discuss the submission of a Biologics License Application (BLA) took place in June after which the Company confirmed its intention to submit a BLA subject to successful completion of remaining activities.
- In July, the Company announced that the FDA had granted eryaspase Fast Track designation for the treatment of ALL patients who have developed hypersensitivity reactions to *E. coli*-derived pegylated asparaginase.

Subject to review of remaining information requests, the Company intends to submit a BLA around year-end.

- TRYbeCA-1, pivotal Phase 3 clinical trial in second-line advanced pancreatic cancer

As reported in late October, the Phase 3 TRYbeCA-1 trial did not meet the primary efficacy endpoint of overall survival (OS). The median OS for patients treated with eryaspase plus chemotherapy was 7.5 months, compared to 6.7 months for chemotherapy alone, with an OS hazard ratio (HR) of 0.92 in the intent-to-treat (ITT) population (p-value 0.375).

- The prespecified subgroup of patients treated with eryaspase and FOLFIRI, an irinotecan-based chemotherapy, demonstrated a nominal increase in median OS of 2.3 months, from 5.7 to 8 months (HR = 0.77; per protocol population), which the Company believes merits further investigation.
- Patients treated with eryaspase demonstrated improved 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.

Final data are being analyzed and will be presented at an upcoming medical conference.

■ **rESPECT, Phase 1 investigator-sponsored trial (IST) in first-line pancreatic cancer**

rESPECT is a Phase 1 trial, sponsored by the Georgetown Lombardi Comprehensive Cancer Center, evaluating the safety of eryaspase in combination with mFOLFIRINOX as a first-line treatment for locally advanced and metastatic pancreatic cancer in approximately 18 patients.

- Patient enrollment started in January 2021, and the first dose cohort (75 U/kg) of three patients was enrolled by the end of February. No dose-limiting toxicity (DLT) was observed, and the trial was escalated to the next dosing cohort (100 U/kg).
- After review of the safety data in the first two dose cohorts, the dose escalation committee concluded that the novel combination of mFOLFIRINOX plus eryaspase was well tolerated with no DLT. Consequently, the maximum tolerated dose (MTD) was determined at a dose of 100 U/kg eryaspase.
- Additionally, all six patients evaluated for response achieved disease control; three patients with objective response and three with stable disease.

The trial will continue enrolling up to approximately 18 patients. Reporting of final data is expected in the first half of 2022.

■ **TRYbeCA-2, randomized Phase 2 clinical trial in triple-negative breast cancer (TNBC)**

The TRYbeCA-2 trial is evaluating eryaspase in combination with gemcitabine and carboplatin chemotherapy, compared to chemotherapy alone, in metastatic TNBC. Target enrollment is approximately 64 patients. The primary end point of the trial is objective response rate.

- Following the disappointing results of eryaspase in combination with a gemcitabine-based chemotherapy in the TRYbeCA-1 trial in second-line pancreatic cancer, the Company has, in consultation with the trial's Steering Committee, decided to stop further enrollment in the TRYbeCA-2 trial.

The results of the patients enrolled in the TRYbeCA-2 trial to date are expected to be reported in the first half of 2022.

■ **Process to review strategic options and partnering alternatives launched**

The Company launched a process and appointed a specialized advisor to evaluate its strategic and partnering alternatives, including for the further development and commercialization of eryaspase. Gil Beyen, the CEO of ERYTECH, will lead these partnering efforts and take on the role of acting Chief Business Officer (CBO), as Jean-Sebastien Cleiftie, current CBO of ERYTECH will leave the Company at the end of this month.

Update on Q3 2021 Cash Position

- As of September 30, 2021, ERYTECH had cash and cash equivalents totaling €38.0 million (approximately \$43.9 million), compared with €44.4 million as of December 31, 2020 and €46.3 million on June 30, 2021. The €6.5 million decrease in cash position during the first nine months of 2021 was the result of a €7.8 million net cash utilization, which was mostly comprised of a €46.2 million net cash utilization in operating activities, €0.3 million used for investing activities and €38.8 million generated in financing activities, while the variation of the U.S. dollar against the euro led to a €1.3 million positive currency exchange impact.
- Financing activities in the first nine months of 2021 included a \$8 million placement in the United States through the Company's at-the-market (ATM) equity financing program for net proceeds of €6.4 million, a \$30 million Registered Direct offering for net proceeds of €22.4 million, and the drawdown of four tranches under the convertible notes (OCABSA) financing agreement signed with Alpha Blue Ocean, for net proceeds of €11.4 million.
- At the date of this press release, nine OCABSA tranches have been called since the initiation of the program in June 2020. During the last 12 months, the OCABSA converted notes, together with the shares issued under the ATM program, have resulted in the issuance of 4,690,904 new shares and 235,690 warrants, representing 17.6% of the Company's outstanding share capital.
- The Company believes that its current cash position can fund its planned operating expenses and current programs into the second quarter of 2022. Further, the Company has engaged in cash preservation measures and believes that these measures, together with further utilization of the OCABSA agreement, subject to the regulatory limit of 20% dilution, could

extend its cash horizon into the third quarter of 2022. The Company is currently exploring potential financing and partnering options to further extend its cash horizon beyond key 2022 development milestones.

- The release on October 25, 2021 of the TRYbeCA-1 Phase 3 trial in pancreatic cancer, which did not meet its primary endpoint, is considered a triggering event for impairment analysis, which will require the Company to test tangible and intangible assets for possible impairment. The Company is therefore not in a position to announce full financial results for the third quarter of 2021 until current uncertainties on business assumptions are clarified. The Company will conduct an impairment analysis in light of its new business situation, which may potentially lead to an impairment of some of its assets.

Key News Flow and Milestones Expected Over the Next 12 Months

- Planned BLA submission of eryaspase in hypersensitive ALL (around year end 2021)
- Results from the Phase 1 rESPECT Trial of eryaspase in combination with mFOLFIRINOX in first-line pancreatic cancer (1H 2022)
- Presentation of full dataset of TRYbeCA-1 trial at a medical meeting (1H 2022)
- Data from the randomized Phase 2 TRYbeCA-2 trial of eryaspase in TNBC (1H 2022)

Third Quarter 2021 Conference Call Details

ERYTECH management will hold a conference call and webcast on **Tuesday, November 16, 2021 at 8:30am EST / 2:30 pm CET** to discuss the recent business and financial updates. 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/6425429> (Conference ID : **6425429**)

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/uyoshe5q>.

An archived replay of the call will be available for 7 days by dialing + 1 855 859 2056, Conference ID: **6425429#**.

An archive of the webcast will be available on ERYTECH's website, under the "Investors" section at investors.erytech.com

Financial Calendar 2021

- **Business Update and Financial Highlights for the Fourth Quarter and Full Year 2021:** March 11, 2022 (after U.S. market close), followed by a conference call & webcast on March 14, 2022 (2:30pm CET/8:30am ET)

ERYTECH plans on attending the following upcoming investor conferences:

- Jefferies 2021 Global Healthcare Conference, November 16-19, London
- LifeSci Partners 11th Annual Corporate Access Event, January 5-7, 2022
- H.C. Wainwright, BioConnect Conference, January 10-13, 2022
- JPMorgan HealthCare Conference, January 10-13, 2022, San Francisco

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 the treatment of advanced pancreatic cancer and treatment of acute lymphoblastic leukemia (ALL) patients who have developed hypersensitivity reactions to E. coli-derived pegylated asparaginase.

The FDA and the European Medicines Agency have granted eryaspase orphan drug status for the treatment of pancreatic cancer and ALL.

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

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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 timing of a potential BLA submission to the FDA for the treatment of acute lymphoblastic leukemia, the Company's ability to obtain regulatory approval for the treatment of patients with acute lymphoblastic leukemia who developed hypersensitivity reactions to PEG-asparaginase, the Company's ability to extend the indication scope of eryaspase, the Company's ability for additional funding under the OCABSA financing agreement or other financing attempts, and the Company's anticipated cash runway. 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 Provides Business and Financial Update for the Third Quarter of 2021](#)