

## **ERYTECH Provides Business Update and Reports Financial Results for the First Half of 2021**

Conference call and webcast on Tuesday, September 21, 2021  
at 8:30am EDT / 2:30pm CET

- **TRYbeCA-1 Phase 3 trial of eryaspase in second-line metastatic pancreatic cancer fully enrolled since January 2021; on track for final results in Q4 2021**
- **Fast Track designation received for eryaspase in treatment of ALL patients who developed hypersensitivity reactions to pegylated asparaginase; working towards potential BLA submission in this indication before year-end**
- **Second dose cohort in Phase 1 Investigator Sponsored Trial (IST) in first-line pancreatic cancer enrolled; determination of Maximum Tolerable Dose (MTD) expected in 2H 2021; encouraging signs of clinical activity observed**
- **Closed a \$30 million registered direct financing with specialized healthcare investors in April**
- **Cash and cash equivalents of € 44.5 million (\$54.9million) at the end of June 2021**

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**Cambridge, MA (U.S.) and Lyon (France), September 20, 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 reported its financial results for the first half of 2021.

*“The first half of 2021 has again been one of great progress, setting the stage for a catalyst-rich remainder of the year,” said Gil Beyen, CEO of ERYTECH. “Our pivotal Phase 3 trial in second-line pancreatic cancer, TRYbeCA-1, has been fully enrolled since January and is on track to report top-line results in the fourth quarter. Subject to positive results, we expect to submit applications for approval in this indication in the United States and Europe in the first half of 2022. The second potentially pivotal track of eryaspase is for the treatment of ALL patients who have developed hypersensitivities to pegylated asparaginase. We recently confirmed our intention to submit a Biologics License Application (BLA) for this indication in the back half of this year. The recent granting of Fast Track designation underscores the need for new treatment options for these patients. Furthermore, the encouraging clinical activity observed in the first patients of the ongoing Phase 1 IST in first line pancreatic cancer adds to our conviction that eryaspase can be a meaningful contributor to helping cancer patients live longer, better.”*

### **Business Highlights**

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

TRYbeCA-1 is a randomized, controlled Phase 3 pivotal trial, evaluating eryaspase in second-line advanced pancreatic cancer at approximately 90 sites in the United States and in Europe. Eryaspase, in combination with standard chemotherapy (gemcitabine/nab paclitaxel or an irinotecan-based regimen), is compared with standard chemotherapy alone in a 1 to 1 randomization. The primary endpoint is overall survival (OS).

- ✓ Patient enrollment was completed in January 2021. A total of 512 patients were randomized in the trial, above the target enrollment of 482 patients.
- ✓ In February 2021, an interim efficacy and safety analysis was performed by an independent data monitoring committee (IDMC), which recommended the trial continue without modification to its final analysis. As with the three previous IDMC reviews, no safety issues have been identified and the Company remains blinded to the primary and secondary endpoint efficacy data.

Reporting of the top-line results from this trial is expected in the fourth quarter of 2021.

- **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 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 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 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 U.S. Food and Drug Administration (FDA) had granted eryaspase Fast Track designation for the treatment of acute lymphocytic leukemia (ALL) patients who have developed hypersensitivity reactions to E. coli-derived pegylated asparaginase (PEG-ASNase).

Subject to successful completion of remaining activities, the Company intends to submit a BLA in the fourth quarter of 2021.

- **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 a recommendation of the trial's investigators, the trial's inclusion criteria were modified in January 2021 to include second-line patients.
- ✓ The TRYbeCA-2 Steering Committee met in April 2021 and recommended the trial continue without modification after review of the safety data of the first 19 patients.

Initial (interim) data from the TRYbeCA-2 trial are expected to be reported in the first half of 2022.

- **rESPECT, Phase 1 investigator-sponsored trial 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 advanced and locally advanced 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) had been observed and the trial was escalated to the next dosing cohort (100 U/kg). This will be the highest dose level cohort in the trial and the presumed maximum tolerable dose (MTD) assuming no DLT is observed.

- ✓ Encouraging clinical activity has been observed in the first six evaluated patients in the trial. Three of the six patients had a partial response and the other three had stable disease.

Determination of the MTD is expected in the fourth quarter of 2021.

### First Half 2021 Financial Results

- Key financial figures for the first half of 2021 compared with the same period of the previous year are summarized below:

<i>In thousands of euros</i>	<b>1H 2021 (6 months)</b>	<b>1H 2020 (6 months)</b>
Revenues	—	—
Other income	2,270	1,849
<b>Operating income</b>	<b>2,270</b>	<b>1,849</b>
Research and development	(23,209)	(28,846)
General and administrative	(8,027)	(8,372)
<b>Operating expenses</b>	<b>(31,236)</b>	<b>(37,218)</b>
<b>Operating loss</b>	<b>(28,966)</b>	<b>(35,369)</b>
Financial income	2,807	672
Financial expenses	(1,791)	(265)
<b>Financial income (loss)</b>	<b>1,016</b>	<b>407</b>
Income tax	(2)	-
<b>Net loss</b>	<b>(27,952)</b>	<b>(34,962)</b>

- Net loss for the first half of 2021 was €28.0 million, down €7.0 million (-20%) year-over-year, with a €6.4 million decrease (-18%) in operating loss and a €0.6 million increase in financial income. The €6.4 million decrease in operating loss was attributable to the €5.6 million decrease in preclinical and clinical development expenses, concurrent with the completion of patient enrollment in the Company's Phase 3 clinical trial in pancreatic cancer, a €0.3 million decrease in general and administrative expenses, and a €0.4 million increase in other income, mostly related to R&D tax credits. The €0.6 million increase in financial result was mostly related to foreign currency gains on U.S. dollar.
- As of June 30, 2021, ERYTECH had cash and cash equivalents totaling €46.3 million (approximately \$54.9 million), compared with €44.4 million on December 31, 2020 and €37.4 million on March 31, 2021. The €1.9 million increase in cash position during the first half of 2021 was the result of a €1.2 million net cash generation, which was mostly comprised of a €32.6 million net cash utilization in operating activities, €0.3 million used for investing activities and €34.1 million generated in financing activities, while the variation of the U.S. dollar against the euro led to a €0.7 million positive currency exchange impact.
- Financing activities in the first half 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 €22.9 million, and the draw down of two tranches under the convertible notes (OCABSA) financing agreement signed with Alpha Blue Ocean, for net proceeds of €5.7 million.
- At the date of this press release, nine OCABSA tranches have been called since the initiation of the program in June 2020, including two tranches called after June 30, 2021, and all notes have been fully converted into shares. During the last 12 months, the OCABSA converted notes, together with the shares issued under the ATM program, have resulted in the issuance of 4,777,302 new shares and 235,690 warrants, representing 18.0% 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 believes that it would be able to fund operations into the third quarter of 2022 if it further utilizes the OCABSA agreement, assuming current market price and subject to the regulatory limit of 20% dilution.

### **Key News Flow and Milestones Expected Over the Next 12 Months**

- Top-line results from TRYbeCA-1 Phase-3 trial of eryaspase in 2L PAC (Q4 2021)
- Potential BLA filing of eryaspase in hypersensitive ALL (Q4 2021)
- Determination of the maximum tolerated dose in rESPECT, Phase 1 IST in 1L PAC (Q4 2021)
- Potential BLA filing of eryaspase in 2L pancreatic cancer (1H 2022)
- Initial (interim) data from the randomized Phase 2 TRYbeCA-2 trial of eryaspase in TNBC (1H 2022)

### **First Half 2021 Conference Call Details**

ERYTECH management will hold a conference call and webcast on **Tuesday, September 21, 2021 at 8:30am ET / 2:30 pm CET** on the business highlights and financial results for the half-year ended June 30, 2021. 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/6866536> (Conference ID : 6866536)

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/z2wjhmw4>.

An archived replay of the call will be available for 7 days by dialing + 1 855 859 2056, Conference ID: **6866536#**.

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

### **Financial Calendar 2021**

- Business Update and Financial Highlights for the Third Quarter of 2021: November 15, 2021 (after U.S. market close), followed by a conference call & webcast on November 16, 2021 (2:30pm CET/8:30am ET)

### **ERYTECH plans on attending the following upcoming investor conferences:**

- Healthtech Innovation Days (HTID), October 4-5, Paris (virtual)
- Jefferies 2021 Global Healthcare Conference, November 16-19, London
- Investir Day, November 23, Paris

### **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. Eryaspase is in a Phase 3 clinical development for the treatment of second-line pancreatic cancer, which is fully enrolled and expected to read out top-line results in Q4 2021, and in an ongoing Phase 2 for the treatment of triple-negative breast cancer. An investigator sponsored Phase 2 trial (IST) in acute lymphoblastic leukemia recently reported positive results, and a Phase 1 IST in 1L advanced pancreatic cancer is ongoing.

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 (PEG-ASNase). 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](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 timing of results from the TRYbeCA-1 trial, the Company's ability to attend a pre-BLA meeting with the FDA and start a rolling BLA submission of eryaspase in the second half of 2021, the timing of potential BLA submissions to the FDA for the treatment of second-line pancreatic cancer and acute lymphoblastic leukemia, the timing of a potential submission to the EMA for the treatment of second-line pancreatic cancer, 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, 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.