

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

Conference call and webcast on Wednesday, May 5, 2021  
at 8:30am EST/ 2:30pm CET

- **TRYbeCA-1, Phase 3 clinical trial in 2<sup>nd</sup> line pancreatic cancer, fully enrolled, and on track for final results in Q4 2021**
- **Pre-BLA meeting with FDA requested to discuss the potential submission of a Biologics License Application (BLA) for eryaspase in hypersensitive ALL in the second half of this year**
- **First dose cohort in Phase 1 Investigator Sponsored Trial (IST) in 1<sup>st</sup> line pancreatic cancer completed with no dose limiting toxicity; encouraging signs of clinical activity observed**
- **Cash and cash equivalents of €37.4 million (\$43.9 million) at the end of March 2021**
- **Successful registered direct round of \$ 30 million with specialized healthcare investors in April 2021**
- **Cash horizon extended to mid 2022, beyond anticipated key catalysts**

---

**Cambridge, MA (U.S.) and Lyon (France), May 4, 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 quarter of 2021.

*“The first quarter of 2021 has again been one of tremendous progress, and has further set the stage for a catalyst-rich second half of this year,” said Gil Beyen, CEO of ERYTECH. “All four of our clinical programs are expected to report significant defining events before the end of the year, two of which potentially supporting the application for regulatory approvals within the next twelve months. Our 512-patient pivotal Phase 3 trial in second-line pancreatic cancer, TRYbeCA-1, is on track for final results in the fourth quarter. Subject to positive results, we expect to submit our 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 developed hypersensitivities to pegylated asparaginase. We recently requested a pre-BLA meeting with the FDA to discuss the path to approval in this indication and we are targeting the potential submission of a Biologics License Application (BLA) in the second half of this year. We are also continuing work to further broaden the indication scope of eryaspase. The safety profile and encouraging clinical activity observed in the first dose cohort of the ongoing Phase 1 IST in first line pancreatic cancer add 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).

- ✓ 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 final results from this trial is expected in the fourth quarter of 2021.

- **Phase 2 trial in acute lymphoblastic leukemia (ALL), sponsored by the Nordic Society of Pediatric Hematology and Oncology (NOPHO)**

The NOPHO trial evaluated the safety and pharmacological profile of eryaspase in ALL patients who had previously experienced hypersensitivity reactions to pegylated asparaginase therapy. The primary objective of the trial was to assess asparaginase enzymatic activity. 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. In April 2021, ERYTECH requested a pre-BLA meeting to discuss the submission of a Biologics License Application.

Subject to the feedback from this meeting, the Company plans to potentially submit the BLA in the second half 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 data from the TRYbeCA-2 trial are expected to be reported in the fourth quarter of 2021.

- **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 of three patients was enrolled by the end of February.
- ✓ After review of the safety data, the Dose Escalation Committee concluded that no dose-limiting toxicity (DLT) had been observed in the first cohort treated at a therapeutic dose of 75 U/kg eryaspase, and that the treatment was well tolerated in the cohort thus far.

- ✓ After the first dose cycle of treatment, two of the three patients had a partial response and significantly decreased levels of CA19-9, a pancreatic cancer tumor marker; the third patient had stable disease after the first cycle of treatment.
- ✓ The trial has been escalated to the next dosing cohort, where the dose level will be increased to 100 U/kg (the same dose as in TRYbeCA-1) eryaspase. This will be the highest dose level cohort in the trial and the presumed maximum tolerable dose (MTD) assuming no dose limiting toxicity is observed.

Determination of the MTD is expected in the second half of 2021.

### First Quarter 2021 Financial Results and Cash Guidance

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

<i>In thousands of euros</i>	<b>Q1 2021</b>	<b>Q1 2020</b>
Revenues	—	—
Other income	1,440	747
<b>Operating income</b>	<b>1,440</b>	<b>747</b>
Research and development	(10,512)	(15,350)
General and administrative	(4,173)	(4,488)
<b>Operating expenses</b>	<b>(14,685)</b>	<b>(19,838)</b>
<b>Operating loss</b>	<b>(13,245)</b>	<b>(19,091)</b>
Financial income	2,047	1,623
Financial expenses	(747)	(121)
<b>Financial income (loss)</b>	<b>1,300</b>	<b>1,502</b>
Income tax	-	-
<b>Net loss</b>	<b>(11,945)</b>	<b>(17,589)</b>

- Net loss for the first quarter of 2021 was €11.9 million, down €5.6 million (-32%) year-over-year, with a €5.8 million decrease (-31%) in operating loss and a €0.2 million decrease in financial income. The €5.8 million decrease in operating loss was attributable to the €4.8 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 €0.7 million increase in other income, mostly related to R&D tax credits. The €0.2 million decrease in financial result was mostly related to the IFRS accounting of the convertible notes.
- As of March 31, 2021, ERYTECH had cash and cash equivalents totaling €37.4 million (approximately \$43.9 million), compared with €44.4 million on December 31, 2020. The €7.0 million decrease in cash position during the first quarter of 2021 was the result of a 3-month €7.6 million net cash utilization, which was mostly comprised of a €16.3 million net cash utilization in operating activities, €0.1 million used for investing activities and €8.8 million generated in financing activities, while the variation of the U.S. dollar against the euro led to a €0.6 million positive currency exchange impact.
- Financing activities in the first quarter of 2021 included the placement of 744,186 newly issued ordinary shares underlying American Depositary Shares (ADSs) in the United States through the Company's at-the-market (ATM) equity financing program for net proceeds of €6.4 million, and the draw down of one tranche under the convertible notes (OCABSA) financing agreement signed with Alpha Blue Ocean, for net proceeds of €2.9 million.

- As of the date of this press release, all notes of the six OCABSA tranches called to date have been converted and, together with the shares issued under the ATM program, have resulted in the issuance of 3,677,676 new shares and 202,020 warrants, representing 18.3% of the Company's outstanding share capital to date.

### **Financing Round of \$30 million on April 29, 2021**

- On April 29, 2021, the Company announced that it has entered into definitive agreements with several health-care focused institutional and accredited investors for the purchase and sale of 1,034,483 units ("Units"), each Unit consisting of four ordinary shares in the form of ADSs and three warrants, each to purchase one ordinary share, in a registered direct offering to specified categories of investors.
- The subscription price for one Unit is corresponding to \$7.25 (€6.01) per ADS and associated 0.75 warrant. The warrants have an exercise price of €7.50 (\$9.05) per share, will be immediately exercisable upon issuance and will expire two years from the issuance date.
- The aggregate gross proceeds to the Company from the sale of the Units, excluding any exercise of the warrants, is expected to be approximately \$30.0 million. The Company intends to use the net proceeds from this offering to fund further development of its products candidates, including through the completion of the Phase 3 TRYbeCA-1 trial and the costs to prepare the associated regulatory filings, and for associated working capital and other general corporate purposes.
- The Company believes that its current cash position and the net proceeds from the April 29, 2021 offering can fund its planned operating expenses and current programs into the first quarter of 2022. Further, the Company believes that it would be able to fund operations into the third quarter of 2022 if it utilizes the OCABSA agreement, subject to the regulatory limit of 20% dilution.

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

- Final results from TRYbeCA-1 Phase-3 trial of eryaspase in 2L PAC (Q4 2021)
- Potential eryaspase BLA filing for ALL (2H 2021)
- Initial data from the randomized Phase 2 TRYbeCA-2 trial of eryaspase in TNBC (Q4 2021)
- Determination of the maximum tolerated dose in rESPECT, Phase 1 IST in 1L PAC (2H 2021)

### **First Quarter 2021 Conference Call Details**

ERYTECH management will hold a conference call and webcast on **Wednesday, May 5, 2021 at 8:30am ET / 2:30 pm CET** on the business highlights and financial results for the quarter ended March 31, 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 call is accessible via the below teleconferencing numbers, followed by the Conference ID#: **3887923#**

USA/Canada: +1 (833) 818-6807

France: +33 1 70 80 71 53

International Dial-In Number: +1 (409) 350-3501

United-Kingdom: +44 2031070289

The webcast can be followed live online via the link: <https://edge.media-server.com/mmc/p/yuzu4z3u>

An archived replay of the call will be available for 7 days by dialing + 1 855 859 2056, Conference ID: 3887923#.

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 Second Quarter of 2021: September 20, 2021 (after U.S. market close), followed by a conference call & webcast on September 21, 2021 (2:30pm CET/8:30am ET)
- 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:**

- Jefferies 2021 Global Healthcare Conference, June 1-4, New-York (Virtual)
- JMP Securities Life Science Conference, June 16-17, New York (Virtual)
- European Midcap Event – June 24, Paris (Virtual)
- BTIG Biotechnology Conference – August 9-10, New York (Virtual)

### **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 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 for the treatment of triple-negative breast cancer. An investigator-sponsored Phase 2 trial (IST) in acute lymphoblastic leukemia was recently completed in the Nordic countries of Europe, and a Phase 1 IST in 1L advanced pancreatic cancer is ongoing. Eryaspase is not currently approved in any country.

Eryaspase received Fast Track designation from the U.S. Food and Drug Administration (FDA) for the treatment of advanced pancreatic cancer. 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.

*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: FRO011471135, 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)*

## CONTACTS

**ERYTECH**  
**Eric Soyer**  
CFO & COO

**LifeSci Advisors, LLC**  
**Corey Davis, Ph.D.**  
Investor relations

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

+33 4 78 74 44 38  
[investors@erytech.com](mailto:investors@erytech.com)

+1 (212) 915 - 2577  
[cdavis@lifesciadvisors.com](mailto:cdavis@lifesciadvisors.com)

+33 1 44 71 94 94  
[erytech@newcap.eu](mailto:erytech@newcap.eu)



European Rising Tech  
LABEL

### 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.