

# ERYTECH Provides Business Update and Reports Financial Results for the Third Quarter of 2020

Conference call and webcast on Friday, November 6 at 2:30 pm CET/8:30 am ET

- TRYbeCA-1 Phase 3 trial in second-line metastatic pancreatic cancer:
  - ✓ More than 95% of the approximately 500 patients enrolled
  - ✓ Number of events required for the interim superiority analysis has been reached
  - ✓ Interim superiority analysis expected to report in Q1 2021
- NOPHO-sponsored Phase 2 trial in acute lymphoblastic leukemia:
  - ✓ Patient enrollment completed: 55 patients enrolled
  - √ Topline final data selected for oral presentation at ASH in December 2020
- Appointment of Dr. Stewart Craig as Chief Technical Officer
- Cash and cash equivalents of €40.5 million (\$47.5 million) at the end of September 2020
- €10 million (\$11.7 million) in non-dilutive financing secured in the form of state-guaranteed loans

Lyon (France) and Cambridge, MA (U.S.), November 5, 2020 – 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 and financial update.

"The third quarter was marked by continued momentum and strong execution across our late-stage clinical programs despite the ongoing COVID-19 global pandemic," said Gil Beyen, CEO of ERYTECH Pharma. "TRYbeCA-1, our Phase 3 trial in 2L pancreatic cancer, has nearly completed enrollment and the NOPHO-sponsored Phase 2 trial in acute lymphoblastic leukemia (ALL) achieved full enrollment in August. As we look towards the balance of the year and into 2021, we are keenly focused on continued milestone execution in all of our clinical programs, but specifically the interim and final readouts in TRYbeCA-1 and the final data in the NOPHO Phase 2 clinical trial. If both are favorable, we would have the opportunity to prepare and submit applications for marketing approval in two indications of high unmet need. I am also pleased to report that we have secured financing alternatives despite the turbulent market conditions. Collectively, the recently secured state-guaranteed loan, the closing of a convertible debt financing, and the establishment of an ATM equity facility, give us the opportunity to extend our cash horizon until the end of next year."

### **Business Highlights**

■ TRYbeCA-1, the pivotal Phase 3 clinical trial evaluating ERYTECH's lead product candidate, eryaspase, in second-line metastatic pancreatic cancer, is nearing complete enrollment and the required number of events to trigger the interim superiority analysis has been reached. The Independent Data Monitoring Committee (IDMC) is expected to conduct the interim analysis in the first quarter of 2021. Since the interim analysis does not include a test for futility, there will be two possible outcomes: the trial will either (1) continue toward a final analysis, expected in the second half of 2021, or (2) conclude early for superiority if compelling improvement of overall survival is demonstrated. TRYbeCA-1 is being conducted in close to 90 clinical sites in the United States and 11 countries across Europe, and targets to enroll approximately 500 patients. 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 (OS). The trial is designed to identify an OS hazard ratio (HR) of 0.725 with close to 90% power.

- The Phase 2 clinical trial of eryaspase in acute lymphoblastic leukemia (ALL) patients who developed hypersensitivity to pegylated asparaginase, sponsored by the Nordic Organization of Pediatric Hematology and Oncology (NOPHO), completed enrollment in August 2020. Fifty-five patients have been enrolled at 22 clinical sites in the Nordic and Baltic countries of Europe. Preliminary findings of the trial suggest that eryaspase achieved the target level and duration of asparaginase activity in these patients. The addition of eryaspase to the combination chemotherapy was associated with an acceptable tolerability profile, enabling the majority of these patients to receive their fully intended courses of asparginase. Hypersensitivity to pegylated asparaginase represents an important unmet medical need, given the limited treatment choices for these patients. The abstract with interim data from the NOPHO trial has been selected for oral presentation at the ASH Annual Meeting in December 2020. Top-line final results will be presented at that occasion. ERYTECH plans to further discuss these data with the FDA to determine the potential next steps and to assess the path forward to potential approval for eryaspase in this indication.
- ERYTECH strengthened its leadership team with the appointment of Dr. Stewart Craig as its Chief Technical Officer (CTO) and member of the executive team. Dr. Craig brings 35+ years of experience in the development, manufacture, technical operations, quality systems and regulatory affairs for complex biologics and cell & gene therapies worldwide for companies such as Orchard Therapeutucs, Sangamo and Stem Cells Inc.

#### Financial Results for the first nine months of 2020

Key financial figures for the first nine months of 2020 compared with the same period of the previous year are summarized below:

In thousands of euros	3Q 2020 (9 months)	3Q 2019 (9 months)
Revenues	_	_
Other income	2,890	3,881
Total operating income	2,890	3,881
Research and development	(42,940)	(36,977)
General and administrative	(11,448)	(13,743)
Total operating expenses	(54,389)	(50,720)
Total operating loss	(51,499)	(46,839)
Financial income	573	3,975
Financial expenses	(2,625)	(392)
Financial income, net	(2,052)	3,582
Loss before tax	(53,551)	(43,257)
Income tax	(2)	1
Net loss	(53,553)	(43,256)

Net loss for the first nine months of 2020 was €53.6 million, up €10.3 million (+24%) year-over-year, with a €4.7 million increase (+10%) in operating loss and a €5.6 million decrease in financial income. The €4.7 million increase in operating loss was attributable to a €6.0 million increase in preclinical and clinical development expenses, mostly related to expenses for the Company's Phase 3 clinical trial in pancreatic cancer, a €2.3 million decrease in general and administrative expenses, which was related to the end of expenses related to the establishment of the manufacturing capacity, mostly incurred in 2019, and a €1.0 million decrease in income, of which €0.9 million consisted in the upfront payment from the June 2019 license agreement with SQZ Biotechnologies that did not recur in 2020.

- As of September 30, 2020, ERYTECH had cash and cash equivalents totaling €40.5 million (approximately \$47.5 million), compared with €73.2 million on December 31, 2019 and €45.4 million on June 30, 2020. The €32.7 million decrease in cash position during the first nine months of 2020, consisting of €14.6 million in the first quarter of 2020, €13.1 million in the second quarter and €4.9 million in the third quarter, was the result of a €32.3 million net cash utilization which was mostly comprised of a €38.2 million net cash utilization in operating activities, €1.4 million used for investing activities and €7.4 million generated in financing activities, while the depreciation at the end of the period of the U.S. dollar against the euro led to a €0.4 million negative currency exchange impact.
- Financing activities included the draw down of two tranches of €3 million each, in July and August 2020, under the convertible bond financing agreement with Alpha Blue Ocean, for net proceeds of €5.6 million. As of the date of this press release, all notes have been converted and have resulted in the issuance of 1,125,873 new shares, representing 5.90% of the Company's outstanding share capital to date.
- In September, ERYTECH announced the implementation of an at-the-market (ATM) equity financing program. A new shelf registration statement on Form F-3 was filed by the Company with the U.S. Securities and Exchange Commission (the "SEC") on September 21, 2020 to roll over the Company's previously filed shelf registration and to cover the ATM program and the registration statement was declared effective by the SEC on October 9, 2020. To date, the Company has not sold any securities pursuant to the ATM program.
- Earlier this week, ERYTECH announced that it had secured with Bpifrance and Société Générale a €10 million non-dilutive financing in the form of a state-guaranteed loan (PGE loan). Each of Bpifrance and Société Générale will provide ERYTECH with a loan in the amount of €5 million and the French government will guarantee 90% of the total amounts due under the loans. The loans will bear interest at a fixed rate of 1.75% and 0.25% per annum respectively, with an initial term of one year. At the end of this initial term, the Company, at its option, may defer repayment of the principal amount over a five-year period.
- The Company believes that the €10 million state-guaranteed loan, in combination with its current cash and cash equivalents, will extend its cash horizon into Q3 2021. When taking into account the potential proceeds under the convertible bonds financing and the ATM program, the horizon could be extended until the end of 2021.

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

- Topline final results of the Phase 2 investigator-sponsored NOPHO trial in acute lymphoblastic leukemia at ASH (Dec 2020)
- Interim (superiority) analysis in the TRYbeCA-1 Phase 3 clinical trial in 2L metastatic pancreatic cancer (Q1 2021)
- First patient enrolled in the Phase 1 investigator-sponsored trial in 1L metastatic pancreatic cancer (Q4 2020); interim updates and results expected in 2021
- Final results of TRYbeCA-1 trial (in case the IDMC recommends to continue the trial as planned at the interim superiority analysis) (Q4 2021)

## **Conference Call Details**

ERYTECH management will hold a conference call and webcast on **Friday November 6, 2020 at 02:30pm CEST / 08:30am ET** on the business and financial highlights for the quarter and nine months ended September 30, 2020. 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#: 2943988#

The webcast can be followed live online via the link: https://edge.media-server.com/mmc/p/cm8pkxrh

An archived replay of the call will be available for 7 days by dialing + 1 855 859 2056, Conference ID: 2943988#.

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 2020: March 8, 2021 (after U.S. market close), followed by a conference call & webcast on March 9, 2021 (2:30pm CET/8:30am ET)
- Business Update and Financial Highlights for the First Quarter of 2021: May 4, 2021 (after U.S. market close), followed by a conference call & webcast on May 5, 2021 (2:30pm CET/8:30am ET)
- 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 will Present at the Following Upcoming Investor Conferences:**

- Jefferies Healthcare Conference, November 17-19, 2020, London (virtual)
- LifeSci Advisors Corporate Access Event, January 6-13, 2021, San Francisco (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 cells' 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 first-line triple-negative breast cancer. An investigator-sponsored Phase 2 study in 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.

For more information, please visit <u>www.erytech.com</u>

## **Forward-looking information**

This press release contains forward-looking statements including but not limited to statements with respect to the clinical development plans of the Company's product candidates including the timing and progress of the interim superiority analysis, the impact of the COVID-19 pandemic on the Company's and the extension of the Company's anticipated cash runway to the end of 2021. 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, in the half-year report for the six-month period ended June 30, 2020 published on September 21, 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**

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