

# ERYTECH Provides Business Update and Reports Financial Results for the Full Year 2020

Conference call and webcast on Tuesday, March 9, 2021 at 8:30am EST/ 2:30pm CET

- Strong execution and achievement of key milestones in challenging year 2020
- Four clinical programs with lead product candidate eryaspase expected to report results and/or regulatory milestones in 2021. Two major catalysts:
  - TRYBeCA-1, Phase 3 in 2L pancreatic cancer, expected to report final results in Q4 2021
  - Update on potential path to BLA in hypersensitive ALL, expected in 1H 2021
- Cash and cash equivalents of €44.4 million (\$54.4 million) at the end of December 2020

**Cambridge, MA (U.S.) and Lyon (France), March 8, 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 fourth quarter and year ended December 31, 2020.

"2020 has been a year of strong execution and progress of our late-stage clinical programs despite the challenges caused by the ongoing COVID-19 global pandemic," said Gil Beyen, CEO of ERYTECH. "After more than three years of focused execution, we are looking forward to important catalysts in all four our clinical programs in 2021. Most important will be the results of our pivotal Phase 3 trial in second-line pancreatic cancer, expected in the fourth quarter of this year, as previously announced. The trial completed patient recruitment in December 2020, and is, with 512 patients enrolled, to our knowledge the largest ongoing clinical trial in this indication worldwide."

**Gil Beyen added**: "Pancreatic cancer is a devastating disease and remains a large unmet medical need. We are hopeful that eryaspase may provide survival benefit to these patients and look forward to reporting the results of the trial later this year. The positive results of the Phase 2 investigator-sponsored trial in acute lymphoblastic leukemia, reported at the end of last year, have the potential to be another important catalyst for the company, as we are evaluating whether this Phase 2 trial could potentially support an approval in this indication of high unmet medical need. Two other ongoing clinical trials, focused at further enlarging the scope of eryaspase, are expected to report results in 2021 as well. Our expertise in innovative red blood cell treatments as well as the excellence and dedication of our employees allow us to face the future with confidence."

## **Business Highlights**

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

TRYbeCA-1 is a randomized controlled Phase 3 trial, evaluating eryaspase in second-line advanced pancreatic cancer in close to 90 clinical sites in the United States and 11 countries 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).

- In April 2020, the U.S. Food and Drug Administration (FDA) granted eryaspase Fast Track Designation as a potential second-line treatment for patients with metastatic pancreatic cancer. Eryaspase also benefits from Orphan Drug status in pancreatic cancer, both in the United States and in Europe.
- Patient enrollment was completed in December 2020. A total of 512 patients were randomized in the trial, slightly 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). The IDMC recommended the trial to 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 is expected in the fourth quarter of 2021.

## Phase 2 trial in acute lymphoblastic leukemia, 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. Primary objectives of the trial were asparaginase enzyme activity and safety.

- Patient enrollment was completed in August 2020. A total of 55 patients participated in the trial.
- ✓ In December 2020, positive trial results were presented at the 2020 American Society of Hematology annual meeting. The primary endpoint was met and eryaspase demonstrated sustained asparaginase enzyme activity above the threshold of >100 U/L at trough levels, 14 days after first infusion in 54 of the 55 patients treated. Eryaspase was generally well tolerated when added to chemotherapy and almost all patients were able to receive the intended courses of asparaginase (median of 5 doses).

The Company is in dialogue with the FDA to evaluate the potential for approval based on these positive results and expects to provide an update in the first half of 2021. If the potential is confirmed, the Company expects to submit a Biologics License Application (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. Target enrollment is approximately 64 patients.

✓ The trial is enrolling patients in three European countries.

First results of the trial are expected in Q4 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.

- ✓ The trial was initiated in the fourth quarter of 2020 and started patient enrollment in January 2021.
- ✓ Two more patients were enrolled in February, completing the first treatment cohort.

Determination of the maximum tolerable dose is expected in the second half of 2021.

## • Leadership and governance

✓ In March 2020, ERYTECH strengthened the Board of Directors with the appointment of Dr Melanie Rolli, which was ratified at the General Meeting of Shareholders in June 2020. Dr. Rolli brings 17 years of experience in the global biopharmaceutical and biotechnology industry to the Board, of which 14 years at Novartis AG, where she held positions of increasing responsibilities across the Drug Development, Safety, and Medical Affairs functions both in Europe and the United States.

In October 2020, the Company reinforced 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 development, manufacturing, technical operations, quality systems and regulatory affairs for complex biologics and cell & gene therapies worldwide for companies such as Orchard Therapeutics, Sangamo and Stem Cells Inc.

#### **2020 Financial Results and Cash Guidance**

 Key financial figures for the full-year 2020 compared with the same period of the previous year are summarized below:

In thousands of euros	FY 2020	FY 2019
Revenues		—
Other income	3,718	5,283
Operating income	3,718	5,283
Research and development	(57,580)	(52,193)
General and administrative	(14,970)	(17,164)
Operating expenses	(72,550)	(69,357)
Operating loss	(68,832)	(64,074)
Financial income	889	2,947
Financial expenses	(5,354)	(1,533)
Financial income (loss)	(4,465)	1,414
Income tax	(3)	1
Net loss	(73,300)	(62,659)

- Net loss for the full year 2020 was €73.3 million, up €10.6 million (+17%) year-over-year, with a €4.8 million increase (+7%) in operating loss and a €5.9 million decrease in financial result. The €4.8 million increase in operating loss was attributable to the €5.4 million increase in preclinical and clinical development expenses, mostly related to expenses for the Company's Phase 3 clinical trial in pancreatic cancer, a €2.2 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 €1.6 million decrease in other income, of which €0.5 million were related to the decrease in R&D tax credits and €0.9 million consisted in the upfront payment from the June 2019 license agreement with SQZ Biotechnologies that did not recur in 2020. The €5.9 million negative dollar/euro foreign exchange impact, and a €1.0 million net expense due to the IFRS accounting of the convertible notes.
- As of December 31, 2020, ERYTECH had cash and cash equivalents totaling €44.4 million (approximately \$54.4 million), compared with €73.2 million on December 31, 2019 and €45.4 million on June 30, 2020. The €28.7 million decrease in cash position during the twelve months of 2020, consisting of net decreases 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, and a net cash position increase of €3.9 million in the fourth quarter, was the result of a 12-month 27.7 million net cash utilization, which was mostly comprised of a €51.7 million net cash utilization in operating activities, €1.5 million used for investing activities and €25.4 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 €1.0 million negative currency exchange impact.

- 2020 financing activities included the draw down of five tranches of €3.0 million each under the convertible notes (OCABSA) financing agreement signed with Alpha Blue Ocean in June 2020, for net proceeds of €14.2 million, a €10.0 million non-dilutive, state-guaranteed PGE loan granted by Bpifrance and Société Générale in November 2020, and €3.0 million loan milestone payments from Bpifrance on the preclinical R&D Tedac project.
- Since the beginning of 2021, ERYTECH has called a 6<sup>th</sup> OCABSA tranche for net proceeds of €2.9 million and has made a placement of 744,186 newly issued shares in the United States through its at-the-market (ATM) equity financing program for net proceeds of €6.4 million.
- As of the date of this press release, all notes of the first five OCABSA tranches have been converted and, together with the shares issued under the ATM program, have resulted in the issuance of 3,175,111 new shares, representing 16.4% of the Company's outstanding share capital to date.
- The Company believes that its current cash position can fund its planned operating expenses and current programs into the fourth quarter of 2021, and together with the remaining option of potential proceeds available under the convertible bonds financing agreement, into the first quarter of 2022.

## 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)
- Update on potential path forward for registration of eryaspase in ALL patients who developed hypersensititivities to pegylated asparaginase (1H 2021)
- Potential eryaspase BLA filing for ALL (2H 2021)
- First results from randomized Phase 2 TRYbeCA-2 trial of eryaspase in TNBC (Q4 2021)
- Determination of the maximum tolerated dose in rESPECT, Phase 1 1L PAC IST (2H 2021)

## FY 2020 Conference Call Details

ERYTECH management will hold a conference call and webcast on **Tuesday, March 9, 2021 at 8:30am ET / 2:30 pm CET** on the business highlights and financial results for the year ended December 31, 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#: 8861234#

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: <u>https://edge.media-server.com/mmc/p/tic4qkwg</u>

An archived replay of the call will be available for 7 days by dialing + 1855859 2056, Conference ID: 8861234#.

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 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 plans on attending the following upcoming investor conferences:**

- HC Wainwright Global Life Sciences Conference, March 9-10, virtual
- European SmallCap Event, April 14, virtual
- Kempen Healthcare & Life Sciences Conference, April 28, virtual
- Jefferies 2021 Global Healthcare Conference, June 1-3, New-York
- JMP Securities Life Science Conference, June 16-17, virtual
- European Midcap Event Spring, June 24, 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 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 in acute lymphoblastic leukemia recently reported positive results.

The U.S. Food and Drug Administration (FDA) and the European Medicines Agency granted eryaspase orphan drug status for the treatment of pancreatic cancer and ALL. Eryaspase received Fast Track designation from the FDA for the treatment of second-line pancreatic cancer.

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 <u>www.erytech.com</u>

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#### **Forward-looking information**

This press release contains forward-looking statements with respect to the clinical development plans of eryaspase, the potential indications for and benefits of eryaspase, the expected timing of the data readouts from the Company's ongoing clinical trials, the potential results of ongoing clinical trials, the potential effects of COVID-19 on the Company's trials and business strategy, the timing of future regulatory and development milestones for the Company's product candidates, including the Company's projected timelines for the submission of its first MAA and BLA for eryaspase, and expectations regarding financial position, including 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. All statements contained in this press release other than statements of historical facts are forward-looking statements, including, without limitation, statements regarding the ERYTECH's business strategy including its clinical development of eryaspase; the status of the TRYbeCA1 trial including the timeline for patient enrollment, expansion of trial into the United States and intended activities with respect to the interim analysis; the potential of ERYTECH's product pipeline; the timing of ERYTECH's preclinical studies and clinical trials and announcements of data from those studies and trials; ERYTECH's anticipated manufacturing capacity and ability to meet future demand and ERYTECH's anticipated cash runway and sufficiency of cash resources. 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 2018 Document de Référence filed with the AMF in March 2019 and in the Company's Annual Report on Form 20-F filed with the SEC on March 29, 2019 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.