



## ERYTECH Provides Business Update and Reports Financial Results for the Full Year 2019

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Conference call and webcast on Tuesday, March 17 at 1:30 pm CET/8:30 am ET

- **More than two-thirds of the expected number of patients have been enrolled in the TRYbeCA-1 Phase 3 clinical trial**
- **Cash position of €73.2 million (\$82.2 million) at the end of 2019**

LYON, France and CAMBRIDGE, Mass., March 16, 2020 (GLOBE NEWSWIRE) -- **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, 2019.

*"2019 has been a year of tremendous execution towards realizing our vision of helping cancer patients to live longer and better," said Gil Beyen, CEO of ERYTECH. "Not only did we fully operationalize a large Phase 3 trial of eryaspase in 11 European countries and the United States, we also launched a Phase 2 clinical trial of eryaspase in a new indication, triple-negative breast cancer, and supported two investigator-sponsored trials of eryaspase. We accomplished all of this while doubling our manufacturing capacity in France and building a new manufacturing facility in Princeton, New Jersey to meet ongoing and proposed European and U.S. clinical supply needs. After two years of building the foundation for these two clinical trials and the pursuit of our business strategy, we look forward to results coming from these trials throughout 2020 and 2021. For 2020, a significant milestone will be the interim superiority analysis in the TRYbeCA-1 Phase 3 trial. We also expect in 2020 to see data from the investigator-sponsored trial of eryaspase in acute lymphoblastic leukemia and potentially, initial results from the new investigator-sponsored trial of eryaspase in first-line pancreatic cancer. We are closely monitoring the potential impact of COVID-19 on the timing and conduct of our current and proposed clinical trials. We will remain attentive to any developments and take necessary steps to protect our patients and the integrity of the trials."*

### Business Highlights

- TRYbeCA-1, the pivotal Phase 3 clinical trial evaluating ERYTECH's lead product candidate, eryaspase, in second-line metastatic pancreatic cancer, is progressing on plan and is currently on track for complete enrollment in the third quarter of 2020, subject to any changes related to the uncertainty of the evolving COVID-19 situation. As of the end of February 2020, more than two-thirds of the approximately 500 patients to be enrolled in the trial have been randomized. As previously communicated, an interim superiority analysis, to be conducted by an independent data monitoring committee (IDMC), is planned for when two-thirds of the events have occurred. This is currently expected to take place in the third quarter of this year. Since the interim analysis will not include a test for futility, there will be two possible outcomes: (1) the trial will either continue toward a final analysis, expected in the first half of 2021, or (2) will be stopped for superiority if the primary endpoint is met by demonstrating a significant improvement in overall survival (OS). In the event the primary endpoint is met at the time of the interim analysis, ERYTECH would complete the full analysis of the trial results and proceed toward preparing both a Marketing Authorization Application (MAA) and a Biologics License Application (BLA) for eryaspase in Europe and the United States, respectively.
- In November 2019, the IDMC reviewed the safety data of the first 150 patients enrolled and treated in the TRYbeCA-1 trial. No safety issues were identified and the IDMC recommended to continue the trial as planned. The next IDMC safety review is planned to take place in the coming weeks.
- Also in November 2019, full results from the Phase 2b clinical trial evaluating eryaspase in 141 patients with second-line metastatic pancreatic cancer were published in the *European Journal of Cancer*. In this trial, eryaspase was added to gemcitabine or mFOLFOX chemotherapy and compared to the chemotherapy alone in a 2-to-1 randomization. Eryaspase in combination with chemotherapy significantly prolonged both overall survival (OS) and progression free survival (PFS) in the entire patient population, with a 40% reduction in the risk of death (OS HR, 0.60;  $P=0.008$ ), and a 44% reduction in risk of disease progression on average over time (PFS HR, 0.56;  $P=0.005$ ). No unexpected safety findings were reported and eryaspase did not add substantially to the toxicity of chemotherapy.
- A Phase 1 investigator-sponsored trial evaluating the safety of eryaspase in combination with FOLFIRINOX as a first-line treatment for metastatic pancreatic cancer, is being readied for launch. Georgetown Lombardi Comprehensive Cancer Center, the sponsor of the trial, has submitted an Investigational New Drug application (IND) to the U.S. Food and Drug Administration. Enrollment of the first patients in the trial is expected in the second half of 2020.
- TRYbeCA-2, the Company's randomized, open-label Phase 2 clinical trial in first-line triple-negative breast cancer (TNBC), started patient enrollment in June 2019. The trial is now enrolling patients in approximately 20 clinical sites in four countries in Europe (Spain, Belgium, Hungary and the United Kingdom). The TRYbeCA-2 trial is evaluating eryaspase in combination with gemcitabine and carboplatin chemotherapy, compared to chemotherapy alone. Target enrollment is approximately 64 patients and the primary endpoint is objective response rate. Results of the trial are expected in 2021.
- A Phase 2 investigator-sponsored trial sponsored by the Nordic Organization of Pediatric Hematology and Oncology (NOPHO), is approaching the enrollment target of 50 patients to be treated in the trial. The trial is evaluating the safety and efficacy of eryaspase in patients with acute lymphoblastic leukemia (ALL) who developed hypersensitivity to pegylated

asparaginase (Oncaspar) at 22 clinical sites throughout the Nordic and Baltic countries of Europe. The Company expects that an interim update on this trial will be available in the second quarter and final results by the end of this year.

- To ensure clinical supply for the Company's ongoing and planned clinical trials and potential future initial commercial demand, the Company has doubled the size of its manufacturing capacity in Lyon, France, and also has established a new 30,000 square feet GMP-compliant manufacturing facility in Princeton, New Jersey in 2019. Recently, ERYTECH also entered into a strategic partnership with the German Red Cross Blood Donor Service Baden-Württemberg-Hessen (GRCBDS) to complement its existing alliance with Établissement Français du Sang, the French blood bank (EFS) for the supply of donor red blood cells to manufacture its product candidates, including eryaspase, in Europe. In the United States, ERYTECH has established partnerships and supply agreements with the American Red Cross and the New York Blood Center.
- While the strategic focus of the Company has over the past several years shifted to prioritizing its late-stage clinical programs, ERYTECH continues to work at leveraging its ERYCAPS® platform towards extension of research into new indications and new product candidates, while also evaluating strategic partnership opportunities.
  - In April 2019, the Company presented an update on its preclinical results with erymethionase, methionine-gamma-lysase encapsulated in red blood cells, including its potential to be used in combination with checkpoint inhibitors and asparaginase. ERYTECH intends to continue the development of erymethionase as well as potential other therapeutic methionine-lowering strategies, the progress of which into the clinic will depend on the Company's financial resources and business strategy.
  - In June 2019, ERYTECH entered into an agreement with SQZ Biotechnologies, a cell therapy company developing novel treatments in multiple therapeutic areas, to advance novel red blood cell-based therapeutics for immune modulation. The strategic collaboration with SQZ Biotechnologies is in line with ERYTECH's strategy to leverage its red blood cell capabilities beyond its initial lead programs while increasing the Company's focus on advancing its late-stage product pipeline.
  - The prime focus of ERYTECH's research teams is currently on evaluating combinations of eryaspase with other treatment modalities, in view of potentially reinforcing the mode of action of the Company's lead product candidate and exploring other indications.
- Alexander Scheer, the Company's Chief Scientific Officer, has informed the Company of his resignation effective April 30, 2020 to pursue another opportunity. Dr. Scheer has been a member of the ERYTECH team since October 2016 and has been instrumental in advancing ERYTECH's preclinical programs and assisting ERYTECH into its transition into a late-stage clinical company. Dr. Scheer's team will continue to focus on executing its priority projects under the management of Françoise Horand, ERYTECH's Director of R&D Operations, who will be reporting on an interim basis to Gil Beyen, CEO. ERYTECH thanks Dr. Scheer for his contributions and wishes him all the best of success in his future endeavors.
- ERYTECH today announced the appointment of Melanie Rolli, M.D., to its Board of Directors effective March 13, 2020, and the intention to propose the ratification of her appointment at the next Company's General Meeting of Shareholders. Dr. Rolli currently serves as Chief Executive Officer of PIQUR Therapeutics AG, and 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. Dr. Rolli graduated from the University of Heidelberg with a doctorate in medicine and pharmacology.

## 2019 Financial Results

§ Key financial figures for the full-year 2019 compared with the same period of the previous year are summarized below:

<i>In thousands of euros</i>	<b>FY 2019</b>	<b>FY 2018</b>
Revenues	—	—
Other income	5,283	4,447
<b>Total operating income</b>	<b>5,283</b>	<b>4,447</b>
Research and development	(52,193)	(33,467)
General and administrative	(17,164)	(14,600)
<b>Total operating expenses</b>	<b>(69,357)</b>	<b>(48,067)</b>
<b>Total operating loss</b>	<b>(64,074)</b>	<b>(43,621)</b>
Financial income	2,947	5,427
Financial expenses	(1,533)	(29)
<b>Financial income (loss)</b>	<b>1,414</b>	<b>5,399</b>
<b>Loss before tax</b>	<b>(62,660)</b>	<b>(38,222)</b>
Income tax	1	(2)
<b>Net loss</b>	<b>(62,659)</b>	<b>(38,224)</b>

- Net loss for the full year 2019 was €62.7 million, up €24.4 million (+64%) year-over-year, with a €20.4 million increase (+47%) in operating loss and a €4.0 million decrease in financial income. The €20.4 million increase in operating loss was

attributable to the €18.7 million increase in preclinical and clinical development expenses, mostly related to expenses for the Company's Phase 3 clinical trial in pancreatic cancer, the €2.5 million increase in general and administrative expenses, of which €2.0 million was related to the expansion of the Company's manufacturing capacity in Lyon and the United States, and the €0.8 million increase in operating income, primarily consisting of the €0.9 million upfront payment from the Company's entry into a license agreement with SQZ Biotechnologies.

- As of December 31, 2019, ERYTECH had cash and cash equivalents totaling €73.2 million (approximately \$82.2 million), compared with €134.4 million on December 31, 2018 and €81.9 million at September 30, 2019. The €61.2 million decrease in cash position during the twelve months of 2019 was the result of a €63.1 million net cash utilization and was mostly comprised of a €43.3 million net cash utilization in operating activities, and €19.8 million used for investing activities, while the appreciation in the period of the U.S. dollar against the euro led to a €1.9 million favorable currency exchange impact. After a peak in capital expenditure disbursements in the first quarter of 2019 related to the expansion of the manufacturing facilities in Lyon and in the United States, cash utilization decreased during the remainder of the year. The Company believes that its cash position at the end of 2019 will be sufficient to fund operations into Q1 2021.

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

- Initiation of a Phase 1 investigator-sponsored trial in first-line metastatic pancreatic cancer (H1 2020)
- Interim results of a Phase 2 investigator-sponsored NOPHO trial in second-line acute lymphoblastic leukemia (Q2 2020)
- Interim (superiority) analysis in TRYbeCA-1, the Phase 3 clinical trial in second-line metastatic pancreatic cancer (Q3 2020)
- Final results of a Phase 2 investigator-sponsored NOPHO trial in second-line acute lymphoblastic leukemia (H2 2020)

#### **FY 2019 Conference Call Details**

ERYTECH management will hold a conference call and webcast on **Tuesday, March 17, 2020 at 01:30pm CET / 08:30am ET** on the business highlights and financial results for the year ended December 31, 2019. 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#: **1671839#**

**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/h2zjygca>

An archived replay of the call will be available for 7 days by dialing **+ 1 855 859 2056**, Conference ID: **1671839#**. 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**

- Business Update and Financial Highlights for the 1st Quarter of 2020: May 6, 2020 (after U.S. market close), followed by a conference call and webcast on May 7, 2020 (2:30pm CET/8:30am ET)
- Business Update and Financial Highlights for the 2nd Quarter of 2020: September 21, 2020 (after U.S. market close), followed by a conference call and webcast on September 22, 2020 (2:30pm CET/8:30am ET)
- Business Update and Financial Highlights for the 3rd Quarter of 2020: November 5, 2020 (after U.S. market close), followed by a conference call and webcast on November 6, 2020 (2:30pm CET/8:30am ET)

**ERYTECH plans on attending the following upcoming investor conferences** *(subject to potential modifications due to the evolving COVID-19 situation):*

- European SmallCap Event, April 14, Paris
- Kempen Healthcare & Life Sciences Conference, April 21-22, Amsterdam
- Jefferies 2020 Global Healthcare Conference, June 2-4, New-York
- JMP Life Science Conference, June 17-18, New-York
- Gilbert Dupont Annual Healthcare Conference, June 18, Paris
- France Biotech, Health Tech Investor Days, June 22-23, Paris
- European Midcap Event – Spring, June 23-24, Paris

#### **About TRYbeCA-1**

TRYbeCA-1 is a randomized, controlled Phase 3 clinical trial evaluating eryaspase in second-line metastatic pancreatic cancer. The trial is planned to enroll approximately 500 patients at approximately 100 clinical sites in Europe and the United States. 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. An interim superiority analysis will be conducted when approximately two-thirds of the events will have occurred.

**About ERYTECH and eryaspase:** [www.erytech.com](http://www.erytech.com)

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 first-line triple-negative breast cancer. An investigator-sponsored Phase 2 study in second-line 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.*

## 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 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.

## CONTACTS

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

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

**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  
[cdis@lif](mailto:cdis@lif)

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

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