



ERYTECH Provides Business Update and Reports Financial Results for Full Year 2018

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Conference call and webcast on Tuesday, March 12th at 1:30 pm CET/8:30 am EDT

- **TRYbeCA1, a pivotal Phase 3 trial for eryaspase in second line pancreatic cancer, now actively enrolling patients**
- **TRYbeCA2, a proof of concept Phase 2 trial in triple-negative breast cancer, open for patient enrolment**
- **Cash position of €134.4 million (\$153.9 million) at year-end**

LYON, France, March 11, 2019 (GLOBE NEWSWIRE) -- **ERYTECH Pharma**(Euronext: ERYP - Nasdaq: 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 year ended December 31, 2018.

"2018 was a year of execution for ERYTECH. We launched two important trials for our lead product eryaspase: TRYbeCA1, a pivotal Phase 3 trial in second-line metastatic pancreatic cancer, and TRYbeCA2, a Phase 2 trial in triple-negative breast cancer. Patient enrolment for TRYbeCA 1 is in line with our planning, and the first clinical sites are now open for patient enrolment for TRYbeCA 2," said Gil Beyen, CEO of ERYTECH. "In addition, we are finalizing the construction and validation of our new manufacturing site in Princeton and the expansion of our Lyon manufacturing facility. In 2019, we will continue to focus on execution of our clinical trials and we look forward to providing you with progress updates regarding these programs as well as data from our preclinical pipeline."

Full Year and Recent Business Highlights

- In 2018, following the positive Phase 2b results of its lead product candidate eryaspase in second-line metastatic pancreatic cancer, ERYTECH initiated TRYbeCA1, a pivotal Phase 3 trial, in this indication. In this trial, which is expected to enroll approximately 500 patients at more than 120 sites in Europe and the United States, ERYTECH is evaluating eryaspase in combination with standard chemotherapy (gemcitabine/nab-paclitaxel or an irinotecan-based regimen) compared to standard chemotherapy alone. The primary endpoint of the trial is overall survival. An interim efficacy analysis is foreseen when approximately two-thirds of events have occurred. The trial began in Europe, with the first patient enrolled in September 2018. TRYbeCA1 is now actively enrolling patients in several European countries. In view of opening the trial to patients in the United States, the company expects to submit an IND application to the US FDA in the coming weeks.
- In 2018, the Company also launched TRYbeCA2, a Phase 2 proof-of-concept trial for eryaspase in triple-negative breast cancer (TNBC). The TRYbeCA2 trial will evaluate eryaspase in combination with gemcitabine and carboplatin chemotherapy, compared to chemotherapy alone, in approximately 64 patients with previously untreated metastatic TNBC. The primary endpoint is objective response rate. First sites were initiated in December 2018, and the trial is now open for enrollment in Spain and France.
- In November 2018, ERYTECH hosted a Key Opinion Leader event with medical oncologists who discussed the pancreatic cancer and TNBC treatment landscapes and the continued medical need for additional therapies in these indications. The presenting oncologists confirmed the potential for therapies that target the altered metabolism of cancer cells as well as the high unmet medical need and the potential role of eryaspase in these two indications. They specifically highlighted the potential for a complementary approach to targeted therapies.
- The Company is establishing a GMP manufacturing facility for the US market in Princeton, New Jersey and is also expanding its European manufacturing capacity in Lyon, France. The two expansions are in the final stages of completion and validation activities are expected to be ready in the second quarter of 2019. ERYTECH believes that the expanded capacity will be sufficient to supply eryaspase for the planned Phase 3 and Phase 2 clinical trials, as well as for the anticipated initial commercial needs of eryaspase, if it is approved for marketing.
- ERYTECH is also advancing the preclinical programs to leverage its proprietary ERYCAPS encapsulation platform. The Company's lead preclinical program and next product candidate is erymethionase, methionine-gamma-lyase encapsulated in red blood cells. In 2018, the Company completed non-clinical studies, and activities in support of initiating a Phase 1 clinical trial of erymethionase in solid tumor indications are ongoing. The company expects to begin this Phase 1 trial in Europe in the first quarter of 2020.

Full Year 2018 Financial Results

Key financial figures for the full year of 2018 compared with the same period of the previous year are summarized below:

<i>In thousands of euros</i>	FY 2018	FY 2017
Revenues	—	—
Other income	4,447	3,364
Total operating income	4,447	3,364
Research and development	(33,467)) (25,463
General and administrative	(14,600)) (8,791
Total operating expenses	(48,067)) (34,254
Total operating loss	(43,621)) (30,889
Financial income	5,427	539
Financial expenses	(29)) (3,183
Financial income (loss)	5,399	(2,644
Loss before tax	(38,222)) (33,533
Income tax	(2)) 3
Net loss	(38,224)) (33,530

Net loss for the full year 2018 was €38.2 million, compared to €33.5 million in 2017. The €4.7 million increase was primarily attributable to the increase in clinical development expenses, mostly related to the initiation of the company's Phase 3 clinical trial in pancreatic cancer, the Phase 2 clinical trial in TNBC, pre-clinical studies of erymethionase, and the strengthening of the company's infrastructure in Europe and in the United States. The €13.8 million increase in operating expenses was partially offset by the €1.1 million increase in operating income and the €8.0 million positive variation in financial income.

- R&D expenses increased by €8.0 million. The increase was mostly attributable to a €4.5 million acceleration in clinical and regulatory expenses due to the initiation of the additional clinical trials, as well as a €3.5 million increase in preclinical R&D expenses, mostly focused on the development of erymethionase and the eryaspase product platform.
- G&A expenses increased by €5.8 million, primarily due to the company's expanded operations in the United States, as well as increased costs associated with being a public company in the United States. ERYTECH is listed on Nasdaq since November 2017.
- Operating income increased by €1.1 million, primarily the result of an increase in research tax credits.
- The €5.4 million financial income in 2018 was comprised of a €4.0 million currency exchange variation on the company's cash position denominated in U.S. dollars and consolidated in euros, and €1.4 million of interest income.

As of December 31, 2018, ERYTECH had cash and cash equivalents totaling €134.4 million (approximately \$153.9 million), compared with €185.5 million on December 31, 2017. The €51.1 million decrease in cash position year-over-year was the result of a €55.1 million net cash utilization, comprised of a €39.3 million net cash utilization in operating activities, €15.0 million in capital expenditures and €0.8 million in loan reimbursement, offset by the €4.0 million favorable currency exchange impact on the company's cash position denominated in U.S. dollars. The company expects a further increase in cash utilization for the year 2019, with the peak of the clinical development activities linked to its TRYbeCA-1 and TRYbeCA-2 clinical studies, and the completion of its manufacturing capacity expansions in Europe and in the United States. The Company confirms that it estimates its current cash runway to last until the end of 2020.

Key News Flow and Milestones Expected over Next 12 Months

- First patient enrolled in TRYbeCA-2, Phase 2 proof-of-concept clinical trial in TNBC
- Start of GMP production at Princeton facility and Lyon extension
- Start of US patient enrolment in TRYbeCA 1, Phase 3 trial in second-line pancreatic cancer
- Initiation of Phase 1 clinical trial with erymethionase

Full Year Results 2018 Conference Call Details

ERYTECH management will hold a conference call and webcast on **Tuesday, March 12th, 2019 at 01:30pm CET / 08:30am EDT** on business highlights and full year 2018 financials. Gil Beyen, Chairman and 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#: **3291426#**:

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

France: +33 1 76 74 89 88

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/m6/p/bdbuhozf>

An archived replay of the call will be available for 7 days by dialing + 1 855 859 2056, Conference ID: **3291426#**.

An archive of the webcast will be available on ERYTECH's website, under the "Investors" section at investors.erytech.com

2019 Financial Calendar:

- General Assembly Meeting of Shareholders: Friday, June 21, 2019 at 9:30am CET in Paris
- Quarterly financial updates:
 - Business Update and Financial Highlights for the 1st quarter of 2019: May 6, 2019 (after U.S. market close), followed by a conference call and webcast on May 7, 2019 (2:30pm CET/8:30am ET)
 - Business Update and Financial Highlights for the 2nd quarter and first-half of 2019: September 17, 2019 (after U.S. market close), followed by a conference call and webcast on September 18, 2019 (2:30pm CET/8:30am ET)
 - Business Update and Financial Highlights for the 3rd quarter of 2019: November 7, 2019 (after U.S. market close), followed by a conference call and webcast on November 8, 2019 (2:30pm CET/8:30am ET)

ERYTECH will Present at the Following Upcoming Investor Conferences:

- Cowen Annual Health Care Conference, March 11-13, Boston
- Market Solutions Forum, April 5, Paris
- Kempen Healthcare & Life Sciences Conference, April 16-17, Amsterdam
- European Smallcap Event, April 17, Paris
- Gilbert Dupont Annual Healthcare Conference, May 23, Paris
- Jefferies 2019 Global Healthcare Conference, June 4-7, New-York
- European Midcap Event – Spring, June 18-19, Paris
- France Biotech, Health Tech Investor Day, June 25, Paris

About ERYTECH: 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 triple-negative breast cancer. ERYTECH is also developing erymethionase, which consists of methionine-gamma-lyase encapsulated in red blood cells to target methionine-dependent cancers.

ERYTECH produces product candidates at its GMP-approved manufacturing site in Lyon, France, and at the American Red Cross in Philadelphia, USA. A large-scale GMP manufacturing facility is under construction in 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.

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Forward-looking information

This press release contains forward-looking statements, forecasts and estimates with respect to the clinical results from and the development plans of eryaspase, business and regulatory strategy, expansion of manufacturing capacity and anticipated future performance of ERYTECH and of the market in which it operates. 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 potential of ERYTECH's product pipeline, its clinical development of eryaspase, and the timing of ERYTECH's preclinical studies and clinical trials and announcements of data from those studies and trials. 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 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 2017 Document de Référence filed with the AMF in April 2018 and in the Company's Annual Report on Form 20-F filed with the SEC on April 24, 2018 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.



Source: Erytech Pharma S.A.