

ERYTECH Provides Business Update and Reports Financial Results for the Third Quarter of 2019

Nov 07, 2019 | Press Releases

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

- **TRYbeCA1, Phase 3 trial of eryaspase in second line pancreatic cancer:**
 - positive safety review by independent data monitoring committee
 - opened for patient enrollment in the United States
 - first U.S. clinical sites activated
- **Princeton manufacturing facility ready for production of clinical batches**
- **Cash position of €81.9 million (\$89.2 million) at the end of September**

LYON, France and CAMBRIDGE, Mass., Nov. 07, 2019 (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 quarter ended September 30, 2019.

"Our lead program, TRYbeCA1, the Phase 3 trial in pancreatic cancer, is progressing on plan and recently reached two important milestones," said Gil Beyen, CEO of ERYTECH. "A planned safety review by an independent data monitoring committee of the first 150 patients in the study revealed no safety concerns, and the study was opened for patient enrollment in the United States. Our new production facility in Princeton is ready to produce the batches for the U.S. patients in the trial."

Recent Business Highlights

- Patient enrollment is on track in TRYbeCA1, the pivotal Phase 3 trial evaluating ERYTECH's lead product candidate eryaspase in second-line metastatic pancreatic cancer. Clinical trial authorizations have been obtained in all twelve participating countries, eleven countries in Europe plus the United States, and the trial is actively enrolling patients in close to 50 clinical sites in Europe.
- TRYbeCA1 was opened for patient enrollment in the United States last week, and the first of a total of approximately 30 planned U.S. sites were activated.
- The newly established U.S. manufacturing facility in Princeton, N.J. is ready to produce clinical batches, and will supply eryaspase for the U.S. patients in the TRYbeCA1 trial.
- Separately, also last week, the independent data monitoring committee (IDMC) reviewed the safety data of the first 150 patients enrolled and treated in the TRYbeCA1 trials. No safety issues were identified and the IDMC recommended to continue the trial as planned.

Q3 2019 Financial Results

- Key financial figures for the first nine months of 2019 compared with the same period of the previous year are summarized below:

<i>In thousands of euros</i>	Q3 2019 ytd (9 months)	Q3 2018 ytd (9 months)
Revenues	—	—
Other income	3,881	2,666
Total operating income	3,881	2,666
Research and development	(36,977)	(25,726)
General and administrative	(13,743)	(10,566)
Total operating expenses	(50,720)	(36,292)
Total operating loss	(46,839)	(33,627)
Financial income	3,975	3,994
Financial expenses	(392)	(15)
Financial income (loss)	3,582	3,979
Loss before tax	(43,257)	(29,648)
Income tax	1	(1)
Net loss	(43,256)	(29,649)

- Net loss for the first nine months of 2019 was €43.3 million, up €13.6 million (+46%) as compared to the same period in

2018, with a €13.2 million increase (+39%) in operating loss and a €0.4 million decrease in financial income. The €13.2 million increase in operating loss was attributable to the €11.3 million increase in preclinical and clinical development expenses, mostly related to expenses incurred related to the Company's Phase 3 clinical trial in pancreatic cancer, the €3.2 million increase in G&A expenses, of which €1.9 million related to the launch readiness of the Company's additional manufacturing capacity, and the €1.2 million increase in operating income, of which €0.9 million upfront payment from the license agreement with SQZ Biotechnologies.

- As of September 30, 2019, ERYTECH had cash and cash equivalents totaling €81.9 million (approximately \$89.2 million), compared with €134.4 million on December 31, 2018 and €94.5 million at the end of June 2019. The €52.4 million decrease in cash position in the first nine months of 2019 was the result of a €55.6 million net cash utilization, comprised of a €36.7 million net cash utilization in operating activities, €19.3 million used for investing activities and €0.4 million of cash generation in financing activities, while the appreciation in the period of the U.S. dollar against the euro led to a €3.2 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 Princeton, cash utilization has slowed in the second and third quarter. The Company's cash position at the end of September remains in line with the earlier guidance of sufficient cash resources to fund operations until the end of 2020.

Key News Flow and Milestones Expected Over the Next 12 Months

- First U.S. patients randomized in TRYbeCA1, the Phase 3 clinical trial in second-line metastatic pancreatic cancer (Q4 2019)
- Initiation of investigator sponsored Phase 1 trial in first-line metastatic pancreatic cancer (H1 2020)
- Interim results of investigator sponsored Phase 2 trial in second-line acute lymphoblastic leukemia (H1 2020)
- Interim (superiority) analysis in TRYbeCA1 (Q3 2020)

Q3 2019 Conference Call Details

ERYTECH management will hold a conference call and webcast on **Friday, November 8th, 2019 at 02:30pm CET / 08:30am ET** on the business highlights and financial results for the third quarter of 2019. Gil Beyen, CEO, Eric Soyer, CFO/COO, and Iman El-Hariy, 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#: **7394954#**

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/irt7vk6s>

An archived replay of the call will be available for 7 days by dialing + 1 855 859 2056, Conference ID: **7394954#**.

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

Financial Calendar

- Next quarterly financial updates:
 - Business Update and Financial Highlights for the 4th Quarter and Full Year of 2019: March 16, 2020 (after U.S. market close), followed by a conference call and webcast on March 17, 2020 (2:30pm CET/8:30am ET)
 - 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 will Present at the Following Upcoming Investor Conferences:

- Jefferies Healthcare Conference, November 20-21, London
- Salon Actionaria, November 22, Paris
- ODDO Investor Conference, January 9, Lyon
- LifeSci Advisors Corporate Access Event, January 13-14, San Francisco

About TRYbeCA1

TRYbeCA1 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 TRYbeCA1 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

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 recently opened 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.

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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 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 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.

PDF available at: <http://ml.globenewswire.com/Resource/Download/44e02960-2638-4f9f-813c-01a066e728d0>



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