



ERYTECH Reports First Half of 2018 Financial Results and Provides Business Update

Sep 10, 2018 | Press Releases

Conference call and webcast scheduled for Tuesday, September 11th
at 2:30 pm CET/8:30 am EDT

- **Strategic shift to development of eryaspase for solid tumors confirmed**
- **Phase 3 trial for eryaspase in second line pancreatic cancer initiated and open for patient enrollment**
- **Phase 2 trial in triple-negative breast cancer on track for start of patient enrollment in Q4**
- **Cash position of €165 million (\$193 million) as of June 30, 2018**

LYON , France and CAMBRIDGE, Mass., Sept. 10, 2018 (GLOBE NEWSWIRE) -- **ERYTECH Pharma (Euronext: ERYP - Nasdaq: ERYP), a clinical-stage biopharmaceutical company developing innovative therapies by encapsulating drug substances inside red blood cells, today provided a business update and reported its financial results for the quarter ended June 30, 2018.**

"In the first half of 2018, we completed our strategic transition towards solid tumor indications of high unmet medical need," said Gil Beyen, Chief Executive Officer at ERYTECH. "Specifically, we are excited that our pivotal Phase 3 trial with eryaspase in second line pancreatic cancer is open for enrollment. In addition, we are launching a Phase 2 trial in a first line triple-negative breast cancer, our second solid tumor indication and patient enrollment is expected to begin in the fourth quarter of this year. With both trials on track, we are expanding our teams and manufacturing capacity in Europe and the United States to support the anticipated clinical demand for product supply. Simultaneously, we are advancing our preclinical programs."

Business Highlights

- Following the positive Phase 2b results with its lead product candidate eryaspase in second line metastatic pancreatic cancer and feedback from the U.S. Food and Drug Administration (FDA) and the Commission for Human Medicinal Products (CHMP) of the European Medicines Agency (EMA), ERYTECH has initiated activities on a pivotal Phase 3 trial in the same indication during the first half of this year. The study, named TRYbeCA1, is on track for first patient enrollment before the end of the third quarter. Clinical trial authorizations and ethical committee approvals have been received in different European countries and the first clinical sites have been opened. Start of patient enrolment in the United States is expected early next year. The TRYbeCA1 trial is evaluating eryaspase in combination with standard chemotherapy (gemcitabine/paclitaxel or irinotecan-based regimen) compared to standard chemotherapy alone in approximately 500 patients at 120-130 sites within the United States and Europe. The primary endpoint is overall survival (OS). An interim analysis is foreseen when approximately two-thirds of events have occurred.
- In February, the Company selected triple-negative breast cancer (TNBC) as the next solid tumor indication for the development of eryaspase. A Phase 2 proof-of-concept clinical trial, TRYbeCA2, has been designed. The TRYbeCA2 trial will evaluate eryaspase in combination with gemcitabine and carboplatin, compared to chemotherapy alone, in approximately 65 previously untreated patients with metastatic TNBC in Europe and the United States. The primary endpoint will be objective response rate. Set up activities are ongoing and start of patient enrollment is expected around year end.
- In order to ensure adequate supply of eryaspase for its planned clinical trials, as well as the anticipated initial commercial needs of eryaspase, if approved in these larger indications, the Company is establishing a manufacturing facility in the United States (Princeton, New Jersey) and is also expanding its manufacturing capacity in Lyon, France.
- In May, the Company announced the expansion of its executive management team with the addition of Alex Dusek as VP of Commercial Strategy to lay the groundwork for planned commercial launch and ensure commercial product preparedness, primarily in the United States. He brings over 25 years of experience including commercial strategic roles at Argos Therapeutics, Bayer and United Therapeutics.
- In June, the Company announced that it would cease the development of eryaspase in acute lymphoblastic leukemia (ALL) and confirmed its strategic shift to solid tumors. The resources that become available as a result of this decision will be utilized to broaden the development in selected solid tumors where metabolic pathways are activated, including in other settings in pancreatic cancer. ERYTECH believes that the solid tumor indications being pursued represent a significantly larger market opportunity than ALL.
- Several preclinical programs, all leveraging the Company's proprietary ERYCAPS encapsulation platform, are ongoing. The Company's next product candidate, erymethionase, methionine-gamma-lyase encapsulated in red blood cells, is also

targeting solid tumor indications. Erymethionase recently completed non-clinical development and activities in support of initiating a Phase 1 clinical trial are ongoing. ERYMMUNE, the Company's immuno-oncology program, and ERYZYME, the encapsulation of enzymes used in therapies to treat metabolic diseases, are also progressing.

Financial Highlights

- ERYTECH's key financial figures for the first six months of 2018, compared with the same period of the previous year are summarized below:

Key figures (in thousands of euros):

| | 1H (6 months) 2018 | 1H (6 months) 2017 | Variation |
|---------------------------------|-----------------------|-----------------------|----------------|
| Revenues | 0 | 0 | 0 |
| Other income | 2,265 | 1,788 | (477) |
| Total operating income | 2,265 | 1,788 | (477) |
| Operating expenses: | | | |
| Research & development | (16,752) | (12,082) | (4,669) |
| General & administrative | (7,393) | (3,895) | (3,499) |
| Total operating expenses | (24,145) | (15,977) | (8,168) |
| Operating loss | (21,880) | (14,189) | (7,691) |
| Financial income | 2,924 | 114 | 2,810 |
| Income tax | (14) | (5) | (9) |
| Net Loss | (18,970) | (14,081) | (4,890) |

- Net loss for the six-month period ended June 30, 2018 was €19.0 million, compared to €14.1 million in the same period of 2017. The €4.9 million increase was primarily attributable to:
 - An increase in R&D expenses by €4.7 million, mostly related to the Company's intensified clinical and regulatory activities (€2.9 million), as well as the continued increase (€1.7 million) in preclinical research activities.
 - An increase in G&A expenses by €3.5 million, reflecting the continued structuring of the company (€2.5 million) and the increased costs associated with becoming a public company in the U.S. (€1.0 million).
 - The accounting of a €2.9 million financial income, as the Company's cash position denominated in euros was impacted by the positive currency exchange variation in the period of the U.S. dollar against the euro in the overall period.
- As of June 30, 2018, ERYTECH had cash and cash equivalents totaling €165.4 million, compared with €185.5 million as of December 31, 2017. The €20.1 million decrease in total cash and cash equivalents in the six-month period comprised a total net cash utilization of €22.5 million for operating, investing and financing activities, and a €2.4 million favorable foreign exchange impact on the Company's cash position denominated in U.S. dollars, related to the appreciation of the U.S. dollar against the Euro in the first half of 2018. The company expects an increase in cash utilization in the second half of 2018, associated with the execution of the clinical plan and the related manufacturing capacity investments.

Key Upcoming Milestones

- First patient in the pivotal Phase 3 clinical trial in second-line pancreatic cancer in Europe and the United States
- First patient in the Phase 2 proof-of-concept clinical trial in TNBC
- Completion of CMC activities with erymethionase in preparation of the start of a Phase 1 clinical trial

Second Quarter Results 2018 Conference Call Details

As a reminder, ERYTECH management will hold a conference call and webcast on **Tuesday, September 11, 2018 at 02:30pm CET / 08:30am EDT** to discuss business highlights and financial results for the second quarter of 2018. Gil Beyen, Chairman and CEO, Eric Soyer, CFO and COO and Iman El-Hariry, CMO will host a brief presentation, followed by a Q&A session.

The call is accessible via the below teleconferencing numbers, followed by the Conference ID#: **4983808#**

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

France: +33 176748988

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/z452iwaf>

An archived replay of the call will be available for 7 days by dialing + 1 800 585 8367, Conference ID: **4983808#**.

2018 Financial Calendar:

- Business Update and Financial Highlights for the third quarter of 2018: November 12, 2018 (after U.S. market close), followed by a conference call and webcast on November 13, 2018 (2:30pm CET/8:30am ET)

Upcoming Investor Conferences:

- Morgan Stanley Healthcare Conference, September 13, New York
- BoursoCap, September 18, Paris
- Midcap Event Paris, October 9, Paris
- Jefferies Healthcare Conference, November 14-15, London
- Actionaria, November 22-23, Paris

About ERYTECH: www.erytech.com

Founded in Lyon, France in 2004, ERYTECH is a clinical-stage biopharmaceutical company developing innovative therapies for rare forms of cancer and orphan diseases. Leveraging its proprietary ERYCAPS platform, which uses a novel technology to encapsulate therapeutic drug substances inside red blood cells, ERYTECH has developed a pipeline of product candidates targeting markets with high unmet medical needs. ERYTECH's initial focus is on the development of products that target the altered amino acid metabolism of cancer cells, depriving them of nutrients necessary for their survival.

The Company's lead product, eryaspase, also known under the trade name GRASPA®, consists of an enzyme, L-asparaginase, encapsulated inside donor-derived red blood cells. L-asparaginase depletes asparagine, a naturally occurring amino acid essential for the survival and proliferation of cancer cells. L-asparaginase has been a standard component of multi-agent chemotherapy for the treatment of pediatric acute lymphoblastic leukemia (ALL), but side effects limit treatment compliance, especially in adults and patients with weak performance status.

Eryaspase demonstrated promising efficacy and safety results in various clinical trials in ALL, as well as in a Phase 2 trial in second-line pancreatic cancer. ERYTECH is preparing for the launch of a pivotal Phase 3 clinical trial in second line pancreatic cancer and Phase 2 trials in first line pancreatic cancer and triple-negative breast cancer.

ERYTECH produces eryaspase at its own GMP-approved and operational manufacturing site in Lyon (France), and at a site for clinical production in Philadelphia (USA). A large-scale manufacturing facility is under construction in New Jersey (USA).

In addition to eryaspase, ERYTECH is developing erymethionase, methionine-γ-lyase encapsulated in red blood cells, to target cancer cells' amino acid metabolism and induce tumor cell starvation. ERYTECH is also exploring the use of its ERYCAPS platform for developing cancer immunotherapies (ERYMMUNE) and enzyme replacement therapies (ERYZYME).

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 and regulatory plans for eryaspase, the timing of ERYTECH's clinical studies and trials and announcements of data from those studies and trials, and the contents and timing of decisions by the FDA and EMA regarding ERYTECH's product candidates. 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.



Erytech Pharma S.A.