

ERYTECH Reports Third Quarter 2017 Financial Results and Provides Business Update

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- Presented full results of Phase 2b trial of eryaspase for the treatment of second-line metastatic pancreatic cancer at ESMO 2017 Congress and met with the U.S. Food & Drug Administration (FDA) to discuss plans for a proposed pivotal Phase 3 trial
- Resubmitted Marketing Authorization Application (MAA) to the European Medicines Agency (EMA) for eryaspase (GRASPA®) for the treatment of patients with relapsed or refractory (R/R) acute lymphoblastic leukemia (ALL) in October 2017
- Completed dosing of three treatment cohorts in U.S. Phase 1 dose-escalation trial of eryaspase in first-line adult ALL patients and determined the recommended dose for further development in this indication
- Cash position of €80.3 million as of September 30, 2017

LYON, France--(BUSINESS WIRE)--Nov. 6, 2017-- Regulatory News:

ERYTECH Pharma (Paris:ERYP) (ADR:EYRY) (Euronext Paris: ERYP) (ADR: EYRY), a clinical-stage biopharmaceutical company developing innovative therapies by encapsulating therapeutic drug substances inside red blood cells ("ERYTECH" or the "Company"), today provided a business update and reported its financial results for the quarter ended September 30, 2017.

Business Highlights

- In September 2017, ERYTECH presented full results from its open-label, multi-center, randomized Phase 2b trial of eryaspase in combination with chemotherapy for the treatment of second-line metastatic pancreatic cancer at the European Society for Medical Oncology (ESMO) 2017 Congress in Madrid. In October 2017, the Company met with the FDA to discuss further development of eryaspase for the pancreatic cancer indication and intends to meet with the EMA to also discuss the design of a Phase 3 clinical trial that the Company hopes to initiate during the third quarter of 2018. The Company expects that the Phase 3 clinical trial will be designed to study the safety and efficacy of eryaspase combined with chemotherapy in patients with second-line metastatic pancreatic cancer. The trial is expected to enroll approximately 400 to 600 patients across clinical sites in the United States and Europe. The Company expects the primary endpoint of the trial to measure overall survival, and the main secondary endpoints will include progression-free survival, objective response rate, disease control rate, quality of life and safety. ERYTECH is also considering proof-of-concept studies in first-line pancreatic cancer and other settings and has initiated further preclinical work to assess the combinability of eryaspase with other compounds used in the treatment of first-line pancreatic cancer patients.
- In October 2017, the Company resubmitted its MAA for eryaspase (GRASPA®) for the treatment of patients with R/R ALL to the EMA. The validation of the MAA by the EMA is ongoing, after which the EMA will begin its formal assessment.
- In September 2017, the Company announced the determination of the recommended Phase 2 dose in its U.S. Phase 1 dose escalation trial of eryaspase (GRASPA®) as a first-line treatment of adult ALL patients at the level of 100 U/kg. This dose had been previously recommended following ERYTECH's Phase 2 trial in elderly ALL patients. It is also the dose level used in the Company's Phase 2b trial in second-line, metastatic pancreatic cancer and in its ongoing Phase 2b trial in AML, from which top-line results are expected by the end of 2017.
- Preclinical development activities of other product candidates are progressing:
 - In September, ERYTECH presented preclinical data on its eryminase and erymethionase programs at the 13th International Congress of Inborn Errors of Metabolism (ICIM). Both programs underscore ERYTECH's opportunities with companies active in the field of metabolic diseases and enzyme replacement therapies. Further proof of concept data are expected during the course of 2018.
 - ERYTECH continues to explore the use of its proprietary ERYCAPS platform to encapsulate tumor antigens within red blood cells as an innovative approach to cancer immunotherapy. The Company expects to complete preclinical proof-of-concept studies of ERYMMUNE during the course of 2018.

Financial Highlights

- Net loss for the nine-month period ended September 30, 2017 was €20.8 million, compared to €16.1 million for the same period in the prior year. The €4.7 million increase reflected increased activity to advance the Company's ongoing preclinical and clinical development programs and was primarily related to the clinical and regulatory progress of product development projects, and higher personnel costs incurred due to the previously announced staffing of key positions in the Company's preclinical, clinical and pharmaceutical operations, to address the Company's activity expansion and prepare the Company for the next stages of its development strategy.
- As of September 30, 2017, ERYTECH had cash and cash equivalents totaling €80.3 million, compared with €88.6 million

as of June 30, 2017 and €37.6 million as of December 31, 2016. Total net cash utilization was €8.3 million in the third quarter of 2017 and €22.8 million for the nine-month period ended September 30, 2017, excluding the €65.2 million net proceeds from the Company's April 2017 capital raise.

- The financial results for the three and nine months ended September 30, 2017 were in line with ERYTECH's established strategy for 2017 and reflected the strengthening of the Company's operations, which focuses on preparing the Company for its next stage of development, including its expected launch in 2018 of a Phase 3 clinical trial in second line metastatic pancreatic cancer in Europe and the United States. Management believes that its cash and cash equivalents available at September 30, 2017 are sufficient to fund our clinical trials that have already commenced, on the basis of its current cost structure and its ongoing programs, to ensure its viable going concern through the 2020 horizon.

Key newsflow and milestones expected over the next 12 months

- Expect to report results from EU Phase 2b AML study in Europe
- Meeting with CHMP on PDAC development plan
- Meeting with FDA on ALL development plan
- Potential initiation of Phase 3 trial in second-line PDAC in Europe and the U.S.
- Potential initiation of clinical studies in first-line PDAC and other solid tumors
- Potential launch of Phase 3 trial in first-line adult ALL
- Potential launch of Phase 3 trial in AML
- Expected initiation of erymethionase Phase 1 study

Next financial updates:

- Financial highlights for the 4th quarter and full-year 2017: March 12, 2018 (after market close), followed by a conference call and webcast on March 13, 2018 (1:30pm CET/8:30am EDT)

Upcoming participations at investor conferences:

- Jefferies Global Healthcare Conference, November 15-16, 2017, London
- Actionaria, November 23-24, 2017, Paris
- Geneva European Midcap Event, November 28-29, Geneva
- Biomed Invest Securities, December 19, Paris
- Investor access event at the J.P. Morgan Healthcare Conference, January 8-11, 2018, San Francisco
- ODDO BHF Forum, January 11-12, 2018, Lyon

About ERYTECH and eryaspase (GRASPA®): 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 amino acid metabolism of cancer, 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 acute lymphoblastic leukemia (ALL), but side effects limit treatment compliance, especially in adults and patients with weak performance status. With its improved safety profile, eryaspase aims to provide L-asparaginase to patients who cannot tolerate current non-encapsulated asparaginases.

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). ERYTECH has entered into licensing and distribution partnership agreements for eryaspase for ALL and AML in Europe with Orphan Europe (Recordati Group), and for ALL in Israel with TEVA, which will market the product under the GRASPA® brand name. The European Medicines Agency (EMA) and the U.S. Food and Drug Administration (FDA) have granted orphan drug designations for eryaspase for the treatment of ALL, AML and pancreatic cancer.

In addition to eryaspase, ERYTECH is developing two other product candidates, erymethionase and eryminase, that focus on using encapsulated enzymes to target cancer metabolism and induce tumor 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 Euronext regulated market in Paris (ISIN code: FR0011471135, ticker: ERYP) and is part of the CAC Healthcare, CAC Pharma & Bio, CAC Mid & Small, CAC All Tradable, EnterNext PEA-PME 150 and Next Biotech indexes.

Financial Information

This press release contains financial information relating to results for the three and nine months ended September 30, 2017. These amounts are unaudited, are subject to completion of financial closing procedures that could result in changes to the amounts, and do not present all information necessary for an understanding of our financial condition as of September 30, 2017. Our independent registered public accounting firm has not audited, reviewed or performed any procedures with respect to this financial data and accordingly does not express an opinion or any other form of assurance with respect thereto. These results are not necessarily indicative of any future period.

Forward-looking information

This press release contains forward-looking statements, forecasts and estimates with respect to the clinical development plans, business and regulatory strategy, 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. They include all matters that are not historical facts. 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. Documents filed by ERYTECH with the French Autorité des Marchés Financiers, and U.S. Securities and Exchange Commission, also available on ERYTECH's website (www.erytech.com) describe such risks and uncertainties. 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.

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