

ERYTECH Provides Business Update and Reports Financial Results for Full Year 2017

Mar 12, 2018 | Press Releases

Conference call and webcast on Tuesday, March 13th at 1:30 pm CET/8:30 am EDT

- **Reported positive data from Phase 2b clinical trial of eryaspase in second-line metastatic pancreatic cancer**
- **Resubmitted the European Marketing Authorization Application (MAA) for eryaspase (GRASPA®) in relapsed and refractory acute lymphoblastic leukemia (ALL)**
- **Raised approximately €194 million (\$226 million) in capital through a private placement in April 2017 and a global public offering in connection with Nasdaq listing in November 2017**
- **Cash position of €185.5 million (\$223 million) at year-end**

LYON, France--(BUSINESS WIRE)--Mar. 12, 2018-- Regulatory News:

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, 2017.

"2017 was a transformative year for ERYTECH with the achievement of a number of important clinical, regulatory and financial objectives," said Gil Beyen, Chairman and CEO of ERYTECH. "We are extremely pleased with the positive outcome of our Phase 2b trial of eryaspase in second-line metastatic pancreatic cancer and the success of our two financing operations, which generated gross proceeds of approximately \$226 million, and our resulting dual listing on Nasdaq and Euronext Paris. With the proceeds of these transactions, we believe we are well capitalized to advance our pipeline programs, most notably the pivotal Phase 3 clinical trial of eryaspase for the treatment of second-line metastatic pancreatic cancer. We met with the FDA to discuss the proposed design of this trial and also obtained similar feedback from the CHMP. We are also exploring the launch of proof of concept studies in first-line pancreatic cancer, and other solid tumor indications, beginning with triple negative breast cancer. Lastly, we resubmitted our MAA for potential approval of eryaspase (GRASPA®) for the treatment of relapsed and refractory ALL in Europe. We expect our momentum to continue as we progress towards potential approval in ALL, and anticipate significant advances from other clinical and preclinical research programs in our pipeline."

Full Year and Recent Business Highlights

- In September 2017, ERYTECH reported the full data set from its open-label, multi-center, randomized Phase 2b trial evaluating eryaspase in combination with chemotherapy for the treatment of second-line metastatic pancreatic cancer. In the trial, patients treated with eryaspase achieved significant improvement in both overall survival (OS) and progression-free survival (PFS).
- The company is now preparing for the launch of a pivotal Phase 3 clinical trial in this same indication in the United States and Europe. Feedback on the design of the trial was obtained from the U.S. Food and Drug Administration (FDA) and the Commission for Human Medicinal Products (CHMP) of the European Medicines Agency (EMA). The proposed Phase 3 trial will evaluate eryaspase in combination with standard chemotherapy, compared to standard chemotherapy alone, in approximately 500 patients in the United States and Europe. The primary endpoint will be overall survival (OS). Enrollment of the first patient in this trial is expected in the third quarter of 2018.
- ERYTECH is also broadening the scope of eryaspase to first-line pancreatic cancer, as well as to other solid tumor indications. Recently, the company announced the selection of triple negative breast cancer (TNBC) as the next target indication for expanding the potential treatment scope of eryaspase. ERYTECH is preparing a Phase 2 proof-of-concept clinical trial for this indication and expects to enroll the first patient in this trial in the third quarter of 2018.
- In October 2017, ERYTECH resubmitted its MAA for eryaspase (GRASPA) for the treatment of relapsed and refractory (R/R) ALL. The MAA resubmission includes the Phase 2/3 clinical trial data from children and adults with R/R ALL as well as additional data to address the outstanding questions of the CHMP. CHMP feedback is expected by the end of 2018.
- In October 2017, the company also identified the recommended dosing from its open-label, dose escalation Phase 1 clinical trial evaluating the safety of eryaspase in combination with chemotherapy for first-line treatment of adult ALL patients, conducted at five clinical sites across the United States. The steering committee reviewed the safety data of the three treatment cohorts and approved further development at a dose level of 100 U/kg. Based on these data and the clinical results obtained in Europe, the company is preparing to discuss next steps for its development in ALL with the FDA in the second quarter of this year.
- In December 2017, the company announced topline results from the Phase 2b clinical trial evaluating eryaspase for the treatment of AML. The open-label, randomized, multi-center clinical trial enrolled a total of 123 patients at 30 European sites. The trial did not meet its primary endpoint of OS. Patient selection is likely the most important factor: the median age of patients in the trial was 78 years, and the median duration of treatment was 5-6 weeks in both treatment arms.
- Throughout 2017, the company also advanced its preclinical pipeline programs:
 - In spring 2017, the company presented preclinical data on its erymethionase product candidate at the 2017

American Association for Cancer Research (AACR) Annual Meeting. Based on these preclinical studies, the company believes that erymethionase represents a promising new treatment approach against a broad range of cancers that rely on methionine metabolism.

- o In September 2017, ERYTECH presented early preclinical data on its eryminase and erymethionase programs at the 13th International Congress of Inborn Errors of Metabolism (ICIEM). The findings from the research on eryminase, consisting of arginine deiminase encapsulated in red blood cells, showed a decrease in arginine levels in a disease model of arginase-1 deficiency, supporting a potential treatment approach for hyperargininemia. This study was conducted in collaboration with Queen's University in Canada. The company's preclinical data involving erymethionase, which is methionine- γ-lyase encapsulated in red blood cells, showed lower homocysteine levels, supporting a potential treatment approach for homocystinuria. This study was conducted through a research collaboration with the Fox Chase Cancer Center (FCCC).
- o ERYTECH also continues to explore its ERYMMUNE program, in which it intends to use its proprietary ERYCAPS platform to encapsulate tumor antigens within red blood cells as a potentially innovative approach to cancer immunotherapy. Preclinical proof-of-concept studies of ERYMMUNE are ongoing.

Full Year 2017 Financial Results

- ERYTECH's key financial figures for the full year of 2017 compared with the same period of the previous year are summarized below:

<i>In thousands of euros</i>	FY 2017	FY 2016
Revenues	—	—
Other income	3,364	4,138
Total operating income	3,364	4,138
Research and development	(25,463)	(19,720)
General and administrative	(8,791)	(6,808)
Total operating expenses	(34,254)	(26,528)
Total operating loss	(30,889)	(22,390)
Financial income	539	558
Financial expenses	(3,183)	(70)
Financial income (loss)	(2,644)	488
Loss before tax	(33,533)	(21,902)
Income tax	3	(10)
Net loss	(33,530)	(21,913)

Net loss for the full year 2017 was €33.5 million, compared to €21.9 million in 2016. The €11.6 million increase was primarily attributable to the increase in clinical and regulatory development expenses, related to the company's ongoing clinical programs in ALL, AML and pancreatic cancer, the continuation of its regulatory initiatives in Europe and preparatory work related to additional clinical programs. R&D expenses also comprise pre-clinical developments on additional product candidates and the broadening of the ERYCAPS platform to include the potential development of immune therapies and enzyme-related therapies.

- R&D expenses increased by €5.7 million. The increase included additional expenses in external provider services in relation with the company's intensified clinical and regulatory activities, as well as the additional staffing for preclinical research and clinical development.
- G&A expenses increased by €2.0 million, as a result of infrastructure developments to sustain the company's growth.
- Operating income decreased by €0.8 million, reflecting primarily a decrease in research tax credits.
- The €2.6 million financial loss in 2017 was impacted by a €3.0 million currency exchange variation on the company's cash position denominated in U.S. dollars and consolidated in euros.
- In April 2017, ERYTECH completed a €70.5 million (\$82 million) private placement in which it issued 3,000,000 new ordinary shares.
- In November 2017, ERYTECH completed a global offering of its ordinary shares (including in the form of American Depositary Shares or ADSs) in the United States and Europe, with gross proceeds of approximately €124 million (\$144 million). The offering resulted in the issuance of a total of 5,374,033 new ordinary shares, comprising 4,686,106 ADSs, at an offering price of \$23.26 per ADS in the United States and 687,927 ordinary shares through a concurrent private placement in Europe and other countries outside of the United States and Canada at a price of €20.00 per ordinary share. Each ADS represents the right to receive one ordinary share. The underwriters exercised their overallotment option in full to purchase 702,915 additional ADSs and 103,189 additional ordinary shares in the global offering. Upon the consummation of the global offering, ERYTECH's ADSs began trading on the Nasdaq Global Select Market on November 10, 2017.
- As of December 31, 2017, ERYTECH had cash and cash equivalents totaling €185.5 million (approximately \$223 million), compared with €37.6 million on December 31, 2016. The net cash increase of €147.9 million was primarily the result of

€177.4 million in net proceeds from the company's financing activities in April and November 2017. Excluding the financing rounds, total cash utilization in 2017 was €26.4 million, comprised of a €24.7 million net cash utilization in operating activities and €1.7 million in capital expenditures.

Key News Flow and Milestones Expected over Next 12 Months

- Meeting with the FDA to discuss next steps in ALL
- Initiation of a pivotal Phase 3 clinical trial in second-line pancreatic cancer in Europe and the United States
- Initiation of a Phase 2 proof-of-concept clinical trial in first-line pancreatic cancer
- Initiation of a Phase 2 proof-of-concept clinical trial in TNBC
- Advance U.S. registration-directed activities for ALL
- CHMP feedback on MAA resubmission for GRASPA in R/R ALL
- Initiation of Phase 1 clinical trial with erymethionase
- Updates on preclinical pipeline programs

Full Year Results 2017 Conference Call Details

As a reminder, ERYTECH management will hold a conference call and webcast on **Tuesday, March 13th, 2018 at 01:30pm CET / 08:30am EDT** to business highlights and full year 2017 financials. Gil Beyen, Chairman and CEO, Eric Soyer, CFO and 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#: **7997444#**:

USA: +1 8338186807	United-Kingdom: +44 02031070289
Switzerland: +080 0836508	Germany: +49 06922224728
France: +33 0176748988	Belgium: +32 024003547
Sweden: +46 0856619361	Finland: +358 0972519310
Netherlands: +31 0207075547	Spain: +34 914142503

The webcast can be followed live online via the link: <https://edge.media-server.com/m6/p/qa7wj9by>

An archived replay of the call will be available for 7 days by dialing (US & Canada): +1 833 818 6807, (UK): +44(0) 203 107 0289, (France): +33(0)1 726 74 89 88, (Spain): +34 91412503, Conference ID # 7997444#

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

2018 Financial Calendar:

- General Assembly Meeting of Shareholders: Friday, June 22, 2018 at 10:00am CET in Paris
- Quarterly financial updates:
 - Business Update and Financial Highlights for the 1st quarter of 2018: May 14, 2018 (after U.S. market close), followed by a conference call and webcast on May 15, 2018 (2:30pm CET/8:30am ET)
 - Business Update and Financial Highlights for the 2nd quarter and first-half of 2018: September 17, 2018 (after U.S. market close), followed by a conference call and webcast on September 18, 2018 (2:30pm CET/8:30am ET)
 - Business Update and Financial Highlights for the 3rd 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:

- Cowen Annual Health Conference, March 12-14, Boston
- H.C. Wainwright Global Life Sciences Conference, April 8-10, Monaco
- European Smallcap Event, April 16-17, Paris
- Kempen Healthcare & Life Sciences Conference, April 18-19, Amsterdam
- BioEquity Europe 2018, May 14-16, Ghent
- Gilbert Dupont Annual Healthcare Conference, May 29, Paris
- Jefferies 2018 Global Healthcare Conference, June 5-8, New-York
- Journée Valeurs Moyennes SFAF, June 12, Paris
- European Midcap Event – Spring, June 27-28, 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 positive efficacy and safety results in various clinical trials in ALL, including in a Phase 2 study in patients over 55 years of age and in a Phase 2/3 trial in relapsed or refractory ALL patients, as well as in pancreatic cancer, where it achieved positive results in a Phase 2b trial of second-line treatment of patients with metastatic 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). 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 erymethionase, methionine-γ-lyase encapsulated in red blood cells, to target cancer cells' amino acid 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 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, forecasts and estimates with respect to the clinical results from and the development plans of eryaspase, 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. 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, the Company's Securities and Exchange Commission filings and reports, including in the Company's prospectus filed pursuant to Rule 424(b)(4) under the Securities Act of 1933, as amended, on November 13, 2017 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.

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