ERYTECH Provides Business Update and Reports Financial Results for Full Year 2016

Mar 02, 2017 | Press Releases

Conference call and webcast on Friday, March 3rd at 15:00 pm CET/09:00 am EST

- **Activities for resubmission of European Marketing Authorization Application (MAA) for eryaspase (GRASPA) in relapsed and refractory acute lymphoblastic leukemia (ALL)ongoing after withdrawal in November 2016; resubmission targeted in Q3 2017**
- **Patient enrollment completed in Phase 2 study of eryaspase in pancreatic cancer; top-line results expected end Q1 2017**
- **Patient enrollment completed in Phase 2b study of eryaspase in acute myeloid leukemia (AML); results expected in Q4 2017**
- **Promising new data with erymethionase (ERY-MET) presented at ASCO GI in January 2017**
- **Board and executive management strengthened**
- **€10 million raised through a private placement in December 2016**
- **Cash position of €37.7 million at year-end**

LYON, France--(BUSINESS WIRE)--Mar. 2, 2017-- Regulatory News:

ERYTECH Pharma (Paris:ERYP) (ADR:EYRYY) (Euronext Paris: ERYP), the clinical-stage biopharmaceutical company developing innovative therapies for rare forms of cancer and orphan diseases based on its proprietary ERYCAPS platform, encapsulating therapeutic drug substances inside red blood cells, today provided a business update and reported its financial results for the year ended December 31, 2016.

"In 2016, we made important progress moving our pipeline forward despite our decision to withdraw and resubmit our European Marketing Authorization Application for GRASPA. We are committed to bringing GRASPA to the market and continue to make significant strides in pursuing its first regulatory approval," said Gil Beyen, Chairman and CEO of ERYTECH. *"Our team is working diligently to provide the requested additional data to the CHMP and we plan to resubmit our MAA this summer. In addition, we presented important new findings related to the mechanism of action of GRASPA, as well as new preclinical data further supporting the anti-tumor activity of our new product candidate erymethionase (ERY-MET) in preclinical models. Looking ahead to 2017 we expect to reach several important milestones, most notably the results of our Phase 2 studies in pancreatic cancer and AML, the resubmission of the MAA for ALL, and the initiation of new trials. We strengthened our balance sheet with a successful private placement in the fourth quarter of 2016 and have the capacity to execute on our key strategic objectives for 2017. We strongly believe 2017 will be another transformative year in support of our mission of advancing novel anti-cancer therapies using our ERYCAPS technology for the benefit of patients in need."*

Full Year and Recent Business Highlights

- In November 2016, ERYTECH withdrew its Marketing Authorization Application (MAA) for eryaspase (GRASPA) for the treatment of relapsed and refractory ALL. The Company recognized that the time allowed in the CHMP procedure was not adequate to provide the additional data needed to answer the remaining questions in the CHMP's Day 180 List of Outstanding Issues (LOI). The company is working toward collecting the data regarding comparability between the old and new forms of asparaginase encapsulated in GRASPA and the development of a new immunogenicity assay, as well as the pharmacodynamics effects of eryaspase. ERYTECH expects to resubmit the MAA this summer. The re-submission process has been initiated and interactions with the EMA and CHMP are being organized.
- The US Phase 1 dose-escalating study of eryaspase in first line adult ALL is progressing and is now expected to reach its recommended Phase 2 dose in mid-2017, after which the company intends to discuss further development plans with the FDA.
- The company is continuing to provide access to eryaspase under its expanded access program (EAP) in France, treating patients who cannot tolerate any of the available asparaginase products. Some patients have also been treated on a compassionate use basis, both in Europe and the US. The Company is also discussing with several investigators the potential for conducting investigator-initiated studies as a means to provide eryaspase to patients suffering from ALL.
- During the third quarter of 2016, complete enrollment was reached in the Phase 2b study with eryaspase in first line AML patients and in the Phase 2 study of eryaspase in second line metastatic pancreatic cancer. Respectively 123 and 141 patients have been treated. Reporting of the primary results of the pancreatic cancer study is expected by the end of Q1 2017. Results of the AML study are expected by the end of the year.
- In January 2017, ERYTECH presented findings from preclinical studies demonstrating strong tumor inhibiting activity of its new product candidate erymethionase (or ERY-MET) in a murine model of human gastric adenocarcinoma. Previous studies had also demonstrated erymethionase as a tumor starvation agent in glioblastoma mouse models.
- Preclinical development programs leveraging the use of the ERYCAPS encapsulation technology in immuno-oncology (ERYMMUNE) and enzyme therapies for certain metabolic diseases (ERYZYME) are progressing. Further proof of concept data is expected in the second half of this year.

- During 2016, the Company strengthened its board of directors and its executive management through the appointments of Allene Diaz as an independent board member, Alexander Scheer as Chief Scientific Officer (CSO) and Jean-Sébastien Cleiftie as Chief Business Officer (CBO). All three bring tremendous experience in the biopharmaceuticals field. Allene Diaz currently serves as Senior Vice President, Global Commercial Development at TESARO Inc. after having served for more than 20 years in senior executive functions at Merck Serono, EMD Serono, Amylin Pharmaceuticals, Cancervax Corporation, Biogen Idec, Pfizer and Parke-Davis Pharmaceuticals. Alexander was the Head of Research at Pierre Fabre, and Jean-Sébastien Cleiftie was Associate Vice-President, Global Business Development & Licensing at Sanofi before joining ERYTECH.

Full Year 2016 Financial Results

- ERYTECH's key financial figures for the full year of 2016 compared with the same period of the previous year are summarized below:

In thousands of euro	**FY 2016**	**FY 2015**
Revenues	0	0
Other income	4,138	2,929
Total operating income	**4,138**	**2,929**
Operating expenses:		
Research & development	(19,813)	(10,776)
General & administrative	(6,861)	(7,736)
Total operating expenses	**(26,674)**	**(18,512)**
Operating loss	**(22,537)**	**(15,583)**
Financial income	482	567
Income tax	42	3
Net Loss	**(22,012)**	**(15,013)**

Net loss for the full year 2016 was €22.0 million, compared to €15.0 million in 2015. The €7.0 million increase was primarily due to the €8.2 million increase in operating expenses, primarily due to the increase in clinical and regulatory development expenses, related to ongoing clinical programs in ALL, AML and Pancreatic cancer, the continuation of regulatory developments in Europe and the preparation of further clinical programs. R&D expenses also include pre-clinical developments on additional product candidates and the expansion of the ERYCAPS platform to other modes of action for immune therapies and enzyme-related therapies. The increase in operating expenses was partially offset by an increase in operating income.

- R&D expenses increased by €9.0 million. The increase was primarily the result of a €8.0 million increase in consumables and third-party services related to pre-clinical programs and clinical trials conducted in 2016 and a €1.4 million increase in personnel expenses due to increasing headcount, including staffing of the company's new U.S. office in Boston.
- G&A expenses decreased by €0.9 million. The decrease was mainly related to a €1.6 million decrease in share-based payments, while personnel expenses increased by €1.1 million and travel-related expenses increased by €0.4 million, a reflection of the broader international base of the company's operations.
- The increase in expenses was partially offset by the €1.2 million increase in operating income, related to higher French research tax credits of €1.1 million, which reflected the increased effort in R&D activities, as well as a €0.1 million increase in non-refundable grants from Bpifrance for the TEDAC program.
- Financial income decreased by €0.1 million, mostly as a result of lower average interest rates on interest-bearing investments.
- In December 2016, ERYTECH completed a €10.0 million private placement with a group of qualified investors in the Unites States and Europe. 793,877 ordinary shares were issued in the private placement. The proceeds from the private placement will enable ERYTECH to further advance several key strategic initiatives related to the development of its lead product candidate, eryaspase (GRASPA®), as well as for working capital and general corporate purposes.
- As of December 31, 2016, ERYTECH had cash and cash equivalents totaling €37.7 million, compared with €45.6 million on December 31, 2015. Net cash utilization for the 12-month period ended December 31, 2016 was €8.0 million and included the €9.2 million net proceeds from the Company's December 2016 private placement of ordinary shares. Excluding the December 2016 capital raise, total cash utilization in 2016 was €17.2 million, comprised of a €19.3 million net cash utilization in operating activities and capital expenditures, as a result of ERYTECH's continued efforts to advance its research and development programs, as well as increased general and administrative expenses, and a €2.1 million increase in borrowings, including a €1.5 million bank loan to support the design of the next generation ERYCAPS platform and a €0.6 million net increase in conditional advances from Bpifrance.
- As of December 31, 2016, ERYTECH's cash position of €37.7 million represented approximately a two-year cash runway with the current company's structure and ongoing studies.

The consolidated financial accounts for the full year 2016, approved by the board of directors on March 1st, 2017, are available on ERYTECH's website (www.erytech.com).

Key newsflow and milestones expected over next 12 months

- Results from Phase 2 pancreatic cancer study
- MTD defined in US Phase 1 adult ALL study
- Meeting with FDA on further ALL development plan
- Resubmission of EU marketing authorization application for GRASPA in R/R ALL
- Launch of erymethionase Phase 1 study
- Preclinical proof of concept data with ERYMMUNE and ERYZYME programs
- Results from EU Phase 2b AML study

Full Year results 2016 Conference Call Details

As a reminder, ERYTECH management will hold a conference call and webcast on Friday, March 03, 2017 at 15:00 CET / 9:00am EST to review the Q4 2016 operational highlights. 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.

Investors and analysts wishing to participate can access the call via the following teleconferencing numbers:

USA: +1 6467224907	**United-Kingdom:** +44 2030432440
Switzerland: +41 225809022	**Germany:** +49 69222229031
France: +33 172001510	**Belgium:** +32 24029640
Sweden: +46 850334664	**Finland :** +358 942599700
Netherlands: +31 107138194	

Confirmation Code: **35823698#**

The webcast can be followed live online via the link:
http://www.anywhereconference.com?UserAudioMode=DATA&Name=&Conference=135307282&PIN=35823698

Following the live call, a replay will be available for 90 days. To listen to the replay, please dial:

USA: +1 877 64 230 18
United-Kingdom: +44(0) 2033679460
France: +33(0)1 72 00 15 00

Confirmation Code: **307282#**

Additionally, an archive of the webcast will be available on the “Webcast” section of the Company’s investor relations site at www.erytech.com

Next financial updates:

Business Update and Financial Highlights for the 1st quarter of 2017: May 18, 2017 (after market close), followed by a conference call and webcast on May 19, 2017 (3:00pm CET/9:00am ET).

Upcoming participations at investor conferences:

- Cowen Annual Healthcare Conference, March 6-8, Boston
- European SmallCap Event, April 18, Paris
- Kempen Healthcare & Life Sciences Conference, April 19, Amsterdam
- Euronext and Oddo Tech40 Investor Forum, April 27, Frankfurt
- BioEquity Europe 2017, May 22-23, Paris
- Gilbert Dupont Annual Healthcare Conference, May 30, Paris
- Jefferies 2017 Global Healthcare Conference, June 6-9, New-York
- European MidCap Spring Event, June 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 treatment of blood cancers, including acute lymphoblastic leukemia (ALL) and acute myeloid leukemia (AML), by depriving tumors of nutrients necessary for their survival. ERYTECH plans to pursue regulatory approvals for its lead product candidate, eryaspase, also known under the trade name GRASPA®, having achieved positive efficacy and safety results from its completed Phase 2/3 pivotal clinical trial in Europe in children and adults with relapsed or refractory ALL. ERYTECH also has an ongoing Phase 1 clinical trial of eryaspase in the United States in adults with newly diagnosed ALL, and a Phase 2b clinical trial in Europe in elderly patients with newly diagnosed AML, each in combination with chemotherapy. ERYTECH believes that eryaspase also has the potential as a treatment approach in solid tumors and is conducting a Phase 2 clinical trial in Europe in patients with metastatic pancreatic cancer.

Eryaspase 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, from circulating blood plasma. 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 that focus on using encapsulated enzymes to induce tumor starvation. The company is also exploring the use of its ERYCAPS platform for developing cancer immunotherapies and enzyme replacement therapies.

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. ERYTECH is also listed in the U.S. under an ADR level 1 program (OTC, ticker EYRYY).

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 Pharma with the French Autorité des Marchés Financiers (www.amf-france.org), 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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