

ERYTECH Provides Business Update and Reports Financial Results for Full Year 2015

Conference call and webcast on Wednesday, February 24th
at 15:00 pm CET/09:00 am EST

- GRASPA entered European MAA registration phase for treatment of patients with acute lymphoblastic leukemia (ALL)
- Further EU and US clinical development plans in ALL established
- Clinical programs in acute myeloid leukemia (AML) and pancreatic cancer on track
- €25.4 million raised in December 2015 private placement
- Solid cash position of €45.6 million at year-end

Lyon (France), February 23, 2016 – ERYTECH Pharma (Euronext Paris: ERYP), the French biopharmaceutical company developing ‘tumor starvation’ treatments for acute leukemia and other oncology indications with unmet medical needs, today provided a business update and reported its financial results for the year ended December 31, 2015.

Business Highlights

- Centralized Marketing Authorization Application (MAA) for GRASPA submitted to the European Medicines Agency (EMA) for the treatment of patients with acute lymphoblastic leukemia (ALL)
- Further development plans of ERY-ASP (GRASPA) for treatment of ALL finalized
- Third safety review completed in Phase 2b acute myeloid leukemia (AML) study
- Original recruitment objective reached in Phase 2 pancreatic cancer study; enrollment continues to further increase statistical power of study
- Preclinical development of new product candidates progressing and IP portfolio strengthened

Financial Highlights

- €25.4 million raised in successful private placement in December 2015 with prominent institutional investors in the United States and Europe
- Net loss of €15.0 million reflecting increased activity level in advancing clinical trials
- Entered 2016 with solid cash position of €45.6 million
- Level 1 ADR program in the U.S. initiated; intention to conduct registered IPO in the U.S. announced

Anticipated Key 2016 Milestones

- EU marketing authorization of GRASPA for ALL
- Completion of U.S. Phase 1 ALL study
- Results of Phase 2 study for treatment of pancreatic cancer
- Initiation of new clinical studies

“2015 was a transformational year for ERYTECH as we executed on a variety of key strategic, clinical and operational initiatives. In the third quarter, we submitted our EMA Marketing Authorization Application for GRASPA for the treatment of ALL,” said Gil Beyen, Chairman and CEO of ERYTECH. “In addition, we have made substantive progress in the clinical development of GRASPA in other indications including AML and pancreatic cancer, and advanced our preclinical product pipeline. Looking ahead to the next twelve months, we have a number of anticipated catalysts including continued progress in our ongoing studies, the initiation of new trials, the results of our Phase 2 study of GRASPA in pancreatic cancer, and our potential first product approval in Europe. We believe that our novel ERYCAPS platform technology has significant potential in transforming the treatment of rare cancers and orphan diseases. Our December 2015 private placement strengthened our balance sheet and has positioned ERYTECH for further advancing key development projects.”

Business Update

Centralized Marketing Authorization Application (MAA) for GRASPA submitted to the European Medicines Agency (EMA) for treatment of patients with acute lymphoblastic leukemia (ALL)

In September 2015, ERYTECH submitted its MAA for GRASPA to the EMA for the treatment of ALL. The MAA for GRASPA, ERYTECH’s lead product candidate, consisting of asparaginase encapsulated in red blood cells, is based on the positive findings of the GRASPALL 2009-06 study, a pivotal Phase 2/3 clinical trial comparing GRASPA to native L-asparaginase in children and adults suffering from relapsed or refractory ALL. The Company is in the process of addressing the EMA’s Committee on Human Medicinal Products (CHMP) questions, and plans to complete its responses as expeditiously as possible to target a potential approval of GRASPA by the end of the year.

In June 2015, ERYTECH reported complete results of its GRASPALL 2009-06 study in a plenary session at the 51st Annual Meeting of the American Society of Clinical Oncology (ASCO). Additional two-year follow-up data were presented in December at the 2015 American Society of Hematology (ASH) Annual Meeting.

Further development plans of ERY-ASP (GRASPA) for treatment of ALL finalized

ERYTECH currently has two other clinical studies of ERY-ASP (GRASPA) in ALL ongoing: a dose-escalating Phase 1 study in adults newly diagnosed with ALL in the US and an Expanded Access Program (EAP) in France in ALL patients that cannot be treated with other forms of asparaginase due to the risk of developing allergic reactions or other adverse events.

Leveraging the data generated in the previous clinical studies of ERY-ASP and building on its two ongoing studies, ERYTECH is preparing two global pivotal studies in ALL patients aiming at product approval in the United States and label extension in Europe. Upon completion of the U.S. Phase 1 study, ERYTECH also intends to continue with a pivotal study in adults with newly diagnosed ALL in the U.S.

Third safety review completed in Phase 2b acute myeloid leukemia (AML) study

The ENFORCE 1 study is a multinational, randomized, controlled Phase 2b clinical trial evaluating the efficacy and tolerability of GRASPA in the treatment of newly diagnosed AML patients over 65 years of age and unfit for intensive chemotherapy. At the end of 2015, an independent Data Safety Monitoring Board (DSMB) completed its third safety assessment of data from 105 patients enrolled in the trial, based on the positive review, ERYTECH continued enrollment in the trial. Earlier safety reviews took place when 30 and 60 patients had been treated in the study. The Company is on-track to complete enrollment in 2016, with primary results expected in 2017.

Original recruitment objective reached in Phase 2 pancreatic cancer study; enrollment continues to further increase statistical power of study

The ERY-ASP pancreatic cancer Phase 2 study is a multicenter, randomized trial in second-line treatment of patients with metastatic pancreatic cancer. In this study, conducted in France, ERY-ASP in addition to the standard of care (gemcitabine or FOLFOX regimen) is being compared to the standard of care alone in a 2-to-1 randomization. The primary endpoint is progression-free survival (PFS) at 4 months. A pre-planned safety analysis of the first 24 patients treated was performed by an independent DSMB. The DSMB raised no safety concerns, and recommended the continuation of enrollment in the study. The original target enrollment of approximately 90 patients was recently reached. ERYTECH has elected to continue enrollment with a goal of increasing the statistical power of the study and better evaluating the treatment in subgroups. Primary results of the study are expected in Q4 2016.

Preclinical development of new product candidates progressing and IP portfolio strengthened

Progress has been made in the following preclinical development programs:

- The work accomplished in the government co-funded TEDAC program to broaden the use of ERYTECH's encapsulation technology to other enzymes has led to the identification of two promising new 'tumor starvation' drug candidates, ERY-MET and ERY-ADI. ERY-MET consists of methionine-γ-lyase (MGL) encapsulated inside red blood cells. ERY-ADI is arginine-deiminase (ADI) encapsulated in red blood cells. Based on these promising preclinical results, the Company intends to continue the development of these candidates with the goal of initiating clinical trials.
- In addition to the use of the ERYCAPS platform to encapsulate enzymes to increase their circulating activity and reduce their toxicity, the Company is expanding the use of its ERYCAPS technology to the field of immunotherapy. By loading red blood cells with specific antigens and subsequently modifying the cells' membranes to make them target specific antigen-presenting cells in the liver or spleen, ERYTECH has observed promising proof-of-concept data in three different tumor models. It plans to continue developing this platform in order to confirm preclinical data and to determine its development strategy.

During 2015, certain of ERYTECH's patents were granted and a patent application was filed. ERYTECH currently holds 13 patent families encompassing 136 granted patents and 90 patent applications. These patents cover the technology platform and applications thereof in and outside oncology. In addition, the Company holds an exclusive license from the National Institutes of Health (USA), covering a diagnostic method to predict the efficacy of L-asparaginase.

Financial Update

€25.4 million raised in private placement supported by prominent U.S. and European institutional investors

In December 2015, ERYTECH completed a €25.4 million private placement with a group of qualified investors in the United States and Europe. 940,000 ordinary shares were issued in the private placement. The proceeds from the private placement will enable ERYTECH to further expand key clinical programs, including the development of ERY-ASP/GRASPA for the treatment of ALL as a first line therapy in the United States and Europe and for the treatment of non-Hodgkin lymphoma, as well as a Phase 1 clinical trial of ERY-MET. Additionally, the funds will be used to advance certain preclinical programs, such as ERYTECH's immunotherapy program, support the further development of its ERYCAPS technology platform and help prepare the company for future expansion.

Net loss of €15.0 million reflecting increased activity level in advancing clinical programs

ERYTECH's key financial figures for the full year of 2015 compared with the same period of the previous year are summarized below:

Key figures (in thousands of euros):

	FY 2015	FY 2014
Revenues	0	0
Other income	2,929	2,026
Total operating income	2,929	2,026
Operating expenses:		
Research & development	(10,776)	(6,613)
General & administrative	(7,736)	(4,361)
Total operating expenses	(18,512)	(10,974)
Operating loss	(15,583)	(8,948)
Financial income	567	68
Income tax	3	20
Net Loss	(15,013)	(8,860)

Net loss for 2015 was €15.0 million, compared to €8.9 million in 2014. The €6.2 million increase was primarily due to the €7.5 million increase in operating expenses, both for R&D and G&A activities. The increase included €1.4 million related to the preparation for a potential registered public offering in the United States and a €1.5 million non-cash expense related to the issuance of share-based warrants. The increase in operating expenses was partially offset by a €0.9 million increase in operating income and a €0.5 million increase in financial income.

- R&D expenses increased by €4.2 million. The increase was primarily the result of a €1.5 million increase in consumables and third-party services related to clinical trials conducted in 2015; a €1.5 million increase in personnel expenses due to increasing headcount and share-based compensation issued to R&D personnel; and a €1.2 million increase in direct research and development expenses, mostly related to the TEDAC program.
- G&A expenses increased by €3.4 million. The increase was primarily due to a €1.9 million increase in services, subcontracting and fees, including €1.4 million related to the preparation of a potential registered public offering in the United States, and a €2.0 million increase in other expenses, including a €1.6 million expense related to share-based warrants issued to board members.
- The increase in expenses was partially offset by the €0.9 million increase in operating income, related to higher research tax credits (CIR) of €0.7 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 and a €0.1 million increase in other income related to the re-invoicing to ERYTECH's partner Orphan Europe of AML study expenses.
- Financial income increased €0.5 million with the full-year impact of interest-bearing investments related to ERYTECH's October 2014 follow-on offering on Euronext Paris.

Entered 2016 with solid cash position of €45.6 million

As of December 31, 2015, ERYTECH had cash and cash equivalents totaling €45.6 million, compared with €37.0 million on December 31, 2014. Net cash generation for the 12-month period ended December 31, 2015 was €8.6 million. The cash generation in 2015 was mainly the result of the €22.7 million net proceeds from the Company's December 2015 private placement of ordinary shares. Total cash utilization in 2015, excluding the December 2015 capital raise, was €14.1 million, mainly related to operating activities, as a result of ERYTECH's continued efforts to advance its research and development programs, as well as increased general and administrative expenses. Total cash utilization in 2015 included a €1.4 million expense for the preparation of a potential registered public offering in the United States, as well as a €2.3 million increase in receivables related to delays in the receipt of 2014 research tax credits and other tax credits.

Level 1 ADR program in the U.S. initiated; intention to conduct registered initial public offering in the U.S. announced

In January 2015, ERYTECH initiated an American Depositary Receipt (ADR) Level 1 program in the United States as part of its strategy to increase visibility with investors in the United States. ERYTECH's ADRs are traded in the U.S. on the over-the-counter (OTC) market under the ticker symbol "EYRY." Each ERYTECH ADR represents one ERYTECH ordinary share as traded on Euronext Paris. The Bank of New York Mellon acts as the depository for the Level 1 ADR program.

ERYTECH continues to assess its financing options depending on market conditions, including, as previously announced, a registered initial public offering in the United States whose timing and terms have not yet been determined.

The financial report for the full year 2015, approved by the board of directors on February 19, 2016, is available on ERYTECH's website.

ERYTECH is also pleased to announce the launch of its newly redesigned website and corporate logo as part of its new branding strategy. Visitors are encouraged to visit www.erytech.com.

Next financial updates:

Financial highlights for the 1st quarter of 2016: May 10, 2016 (after market close), followed by a conference call and webcast on May 11, 2016 (3:00pm CET/9:00am ET)

Upcoming participations at investor conferences:

- BioCapital Europe, March 9, Amsterdam
- ODDO Biotech/Medtech Forum, March 31, Paris
- Kempen Life Sciences Conference, April 7, Amsterdam
- Gilbert Dupont Healthcare Meeting, May 10, Paris
- SFAF Bio Day, May 17, Paris
- Jefferies Healthcare Conference, June 7-10, New-York
- France Biotech Life Sciences Day, June 9, San Francisco

About ERYTECH and ERY-ASP (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 treatment of blood cancers, including acute lymphoblastic leukemia (ALL) and acute myeloid leukemia (AML), by depriving tumors of nutrients necessary for their survival. ERYTECH has recently filed for European Marketing Authorization for its lead product candidate, ERY-ASP, also known under the trade name GRASPA®, following 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 ERY-ASP 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.

ERY-ASP 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. Every year over 50,000 patients in Europe and the United States are diagnosed with ALL or AML. For about 80% of these patients, mainly adults and relapsing patients, current forms of L-asparaginase cannot be used due to their toxicity or as a result of allergic reactions. ERYTECH believes that the safety and efficacy profile of ERY-ASP/GRASPA®, as observed in its Phase 2/3 pivotal clinical trial, offers an attractive alternative option for the treatment of leukemia patients.

ERYTECH believes that ERY-ASP 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. In addition to its current product candidates that focus on using encapsulated enzymes to induce tumor starvation, ERYTECH is exploring the use of its platform for developing cancer vaccines and enzyme replacement therapies.

The EMA and the U.S. Food and Drug Administration (FDA) have granted orphan drug designations for ERY-ASP/GRASPA for the treatment of ALL, AML and pancreatic cancer. ERYTECH produces ERY-ASP 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 ERY-ASP 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.

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 EYRY).

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Forward-looking information

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