



# **PRESS RELEASE**

# **ERYTECH provides business update and financial results for the first half of 2015**

Conference call and webcast (in English) on Tuesday, September 29<sup>th</sup> at 14:30 pm CET/08:30 am EST

- ERY-ASP (GRASPA) enters European registration phase in acute lymphoblastic leukemia (ALL)
- Further EU and U.S. clinical development plans in ALL established
- Ongoing clinical and preclinical development programs on target
- Cash balance of €31.0 million

Lyon (France), September 28<sup>th</sup>, 2015 – ERYTECH Pharma (Euronext Paris: ERYP), the French biopharmaceutical company developing 'tumor starvation' treatments for acute leukemia and other oncology indications with unmet medical needs, provides a business update and reports its financial results for the six-month period ending June 30, 2015.

#### **Business Highlights**

- Centralized Marketing Authorization Application (MAA) for GRASPA submitted to the European Medicines Agency (EMA) for the treatment of patients with ALL
- U.S. Phase 1 study with ERY-ASP in adult ALL escalated to next dose and protocol amended for faster enrollment
- Thirteen 'double allergic' patients treated in Expanded Access Program (EAP) in France
- Further development plans of ERY-ASP/GRASPA in ALL finalized with input of key opinion leaders
- Patient enrollment in the European Phase 2b study in acute myeloid leukemia (AML) on target
- No safety concerns identified in DSMB<sup>1</sup> safety reviews of Phase 2 pancreatic cancer study
- Preparing launch of clinical studies in non-Hodgkin lymphoma (NHL)
- Preclinical development programs progressing
- IP portfolio reinforced
- Executive management team strengthened
- New independent board member added

# **Financial Highlights**

- Net loss of €6.5 million, reflecting increased activity level
- Net cash utilization of €5.9 million, in line with operating plan
- Cash position of €31.0 million on June 30, 2015
- Received EnterNext Tech 40 label
- Initiated Level 1 ADR program in U.S. and announced plans to conduct registered initial public offering in U.S.

<sup>&</sup>lt;sup>1</sup> A DSMB (data safety monitoring board) is an independent external committee of clinical research experts who review data in ongoing clinical trials with particular attention to safety.

# **Upcoming Milestones**

- Third DSMB review in Phase 2b AML study
- Launch of global pivotal Phase 2 study for the treatment of 'double allergic' ALL patients
- Further update on U.S. Phase 1 ALL study and U.S. development plan
- Launch clinical studies in NHL
- Launch pivotal Phase 3 study in first line ALL
- Launch Phase 1 study with new product candidate ERY-MET
- Results of U.S. Phase 1 study
- Primary results of Phase 2 pancreatic cancer study

"With our lead product candidate filed for marketing authorization in its first target indication in Europe, with our development strategy to extend GRASPA's proposed label and bring the product to the United states, and with the solid progress of our clinical and preclinical pipeline and platform technologies, ERYTECH is gearing up for its next phase of growth. With these key components of our strategy in place, our goal is to become the leading biopharmaceutical company focused on developing, manufacturing and commercializing innovative therapies based on our ERYCAPS platform to treat rare forms of cancer and other orphan diseases" comments Gil Beyen, Chairman and CEO of ERYTECH.

# **Business Update**

# Centralized Marketing Authorization Application (MAA) for GRASPA submitted to the EMA for the treatment of patients with ALL

On September 11, 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. If approved, we believe that GRASPA can become the asparaginase of choice for the treatment of pediatric and adult ALL patients that have either relapsed or failed first line treatment or who have an allergic reaction to free-form L-asparaginase.

# U.S. Phase 1 study in adult ALL escalated to next dose and protocol amended for faster enrollment

The Phase 1 study with ERY-ASP is a dose escalation study evaluating the safety of ERY-ASP in adults with newly diagnosed ALL. Three centers are currently open for patient recruitment (The University of Chicago, Duke University Medical Center and Ohio State University). Professor Larson, Director of the Hematological Malignancies Clinical Research Program at the University of Chicago, is the principal investigator of the study. The study includes a safety review after each cohort of patients treated and requires FDA approval for moving to the next dose. In June of this year, the study steering committee reviewed the safety data of the first cohort of patients (at dose level of 50 IU/kg). There were no safety concerns and the steering committee recommended escalating ERY-ASP dose to the next dose level of 100 IU/kg. Further, the study has been amended to lower the age for patient inclusion from 40 to 18, and removing waiting time between each patient. The protocol amendment has been submitted to the respective Institutional Review Boards (IRB). ERYTECH expects the study to be completed in 2016.

# Thirteen 'double allergic' patients treated in Expanded Access Program (EAP) with GRASPA in France

In 2014, ERYTECH launched an open label Expanded Access Program (EAP) in France to provide access to GRASPA to first line and relapsed ALL patients up to 55 years of age who could not be treated with available forms of asparaginase due to their risk of developing allergic reactions or other adverse events. To date, 13 patients have been treated in this EAP with multiple doses of GRASPA and ERYTECH has received a favorable DSMB safety review of the first seven patients treated. All of the patients treated, a mix of children and adults in first line and relapse, were 'double allergic', i.e. they had developed allergies to both the *E. coliderived* and the *Erwinia*-derived asparaginase products in their prior treatments. Enrollment will continue in the EAP until ERYTECH starts a global pivotal clinical study in these double allergic patients.

# Further development plan for ERYASP/GRASPA in ALL finalized with input from key opinion leaders

Building on the data generated in the clinical studies with ERY-ASP to date and the ongoing studies in double allergic patients in the United States, ERYTECH intends to commence two global pivotal studies in ALL patients aimed at label extension to first line treatment in Europe and at product approval in the United States, first in double allergic patients, later in first line treatment. The first of these global studies ERYTECH intends to start is a pivotal single arm Phase 2 study in double allergic patients. The next will be a pivotal Phase 3 study in first line pediatric ALL patients, also in Europe and the United States. Once the U.S. Phase 1 study is completed, ERYTECH intends to continue with a pivotal Phase 2 study in the United States in adults newly diagnosed with ALL. These development plans have been discussed with clinicians at different clinical advisory board meetings and will be the subject of further discussion with the regulatory authorities, EMA and FDA in the coming months.

# Patient enrollment in the European Phase 2b study in acute myeloid leukemia (AML) on target

In 2013, ERYTECH initiated a multicenter, open, randomized, controlled Phase 2b 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. Today, more than 80% out of a total of 123 patients to be treated have been enrolled in the study in over 20 active centers in France, Spain, Finland, Germany and Italy. Two safety assessments were performed by an external DSMB when 30 patients and 60 patients had been treated in the study. No safety concerns were identified. A third DSMB safety review is scheduled for the fourth quarter of 2015. Primary results of the study at one year follow-up are expected in 2017.

# Positive DSMB safety reviews in Phase 2 pancreatic cancer 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 of approximately 90 patients, 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 at 4 months. A pre-planned DSMB safety analysis of the first 24 patients treated was performed in July. The DSMB raised no safety concerns, and recommended the continuation of enrollment in the study. Two earlier DSMB reviews recommended proceeding with the combination of ERY-ASP with Gemcitabine and FOLFOX after safety evaluation of the first three patients in each treatment regimen. Primary results are expected in 2016.

# Preparing launch of clinical studies in non-Hodgkin lymphomas

Based on ERYTECH's preclinical studies and available data on the use of asparaginases in non-Hodgkin lymphomas (NHL), ERYTECH believes that ERY-ASP could also be an effective agent against certain forms of NHL. Based on feedback from key opinion leaders, ERYTECH is in the process of preparing clinical trials in diffuse large B-cell lymphoma and Natural Killer T-Cell lymphoma.

### Preclinical development programs progressing

Progress has been made in the preclinical development in the field of oncology

- The work done 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 promising preclinical results, ERYTECH intends to continue the development of ERY-MET and ERY-ADI, including initiating clinical trials. The industrial scale-up of the manufacturing is being initiated to enable a Phase 1 study with ERY-MET in 2016, with a Phase 1 study with ERY-ADI expected to follow about one year later.
- In addition to the use of ERYTECH's ERYCAPS platform to encapsulate enzymes to increase their circulating activity and reduce their toxicity, ERYTECH has explored the use of ERYTECH's ERYCAPS technology to develop cancer vaccines. By loading red blood cells with specific antigens and modifying the membrane of the cells subsequently to make them target specific antigen-presenting cells in the liver or the spleen, ERYTECH believes that ERYTECH has promising preclinical research in cancer vaccination applications. In preclinical studies with three different antigens loaded in red blood cells, ERYTECH has observed promising proof-of-concept data in three different tumor models. In these studies, ERYTECH

observed significantly increased antigen-specific T-cell responses and delays in tumor growth when the encapsulated antigens, modified to target the liver or spleen, were injected in mice with tumors, as compared to the injection of the unloaded antigens alone. ERYTECH plans to continue incubating this platform in order to confirm ERYTECH's earlier preclinical data and to determine ERYTECH's development strategy for these earlier-stage programs.

ERYTECH's ERYCAPS platform also offers attractive development opportunities for enzyme replacement therapies, or ERT, outside of the oncology field. Over the past years, ERYTECH has performed preclinical research with enzymes like phenylalanine hydroxylase in phenylketonuria in collaboration with Genzyme, and ERYTECH is investigating other potential ERT applications as collaboration opportunities.

# IP portfolio reinforced

During the first half of 2015, the patent entitled "Medicament for the Treatment of Cancer of the Pancreas" has been issued by the U.S. Patent and Trademark Office (USPTO) as U.S. Patent No. 8,974,802. It covers the use of ERY-ASP, ERYTECH's lead product candidate, for the treatment of pancreatic cancer. In accordance with the USPTO's mechanism of patent term adjustment (PTA), the USPTO has added almost a year of additional protection, extending the patent term to October 2029. The patent was filed in 2007 and its counterparts have since been granted in Europe, Australia, Israel and Singapore.

Separately, the USPTO has granted an additional one and a half year of patent term adjustment to ERYTECH's core process patent "Lysis/Resealing Process for Preparing Erythrocytes" (U.S. Patent No. 8,617,840), bringing the validity of the patent through at least 2030. In total, ERYTECH has been able to obtain five years of patent term adjustment for this core patent that covers the heart of its encapsulation technology and product candidates like GRASPA/ERY-ASP. The counterparts of this patent were already granted in Europe, Japan, China, Hong-Kong, Australia, India and South Korea.

Earlier this month, the patent entitled "Erythrocytes Containing Arginine Deiminase" was issued by the USPTO under U.S. Patent No. 9,125,876. This patent covers the use of ERY-ADI, a tumor starvation product candidate arising from ERYTECH's encapsulation platform. In accordance with the USPTO's mechanism of PTA, this patent received almost a year of additional protection, extending the patent term to April 2027. This patent has already been granted in Europe, China, Japan, Canada, Korea and Australia.

The term of these patents may also be eligible for limited patent term extension in the United States under the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the Hatch-Waxman Amendments.

ERYTECH's patent portfolio today consists of 12 patent families, covering the technology platform and applications in and outside oncology, and an exclusive license from the U.S. National Institutes of Health covering a diagnostic method to predict the efficacy of L-asparaginase.

#### **Executive management team reinforced**

In June, ERYTECH announced the appointment of Iman El-Hariry, M.D., Ph.D., as Chief Medical Officer. Dr. El-Hariry is a clinical oncologist with more than 15 years of global product development experience in the global biopharmaceutical industry, including as VP of Clinical Research with Synta Pharmaceuticals (Boston), Global Head of Oncology at Astellas Pharma, Inc. (Chicago) and Director of Clinical Development at GSK (London). She has successfully led the development and regulatory approvals of different products both in Europe and in the United States. Dr. El-Hariry holds an M.D. from Alexandria Medical School (Alexandria, Egypt) and a Ph.D. from the Imperial College of Science and Medicine (London). As Chief Medical Officer at ERYTECH Inc., based in Boston, Dr. El-Hariry is responsible for global clinical development, medical and regulatory affairs. She had already been advising ERYTECH on a consulting basis since the end of last year.

Earlier this month, ERYTECH also announced the appointment of Eric Soyer as Chief Financial and Chief Operating Officer (CFO/COO). Mr. Soyer brings more than 20 years of experience in executive leadership positions with responsibility for financial and operational functions with established and emerging public and private companies. Over the past eight years, Mr. Soyer served as the CFO of the Lyon based, NASDAQ listed therapeutic ultrasound company EDAP TMS, where he was responsible for finance, administration, investor relations, legal affairs, and human resources. During the past three years at EDAP TMS, Mr. Soyer was also Managing Director of the French affiliate of the group with responsibility for R&D and manufacturing operations and distribution for France, South America and EMEA. Previously, he was the CFO

and Chief Information Officer for Medica, a French leader in nursing homes and post-acute care clinics, and CFO and Legal Director for April Group, a leading French insurance company. He started his career as International Financial Controller at the Michelin Group. Mr. Soyer received his Executive M.B.A. from the HEC Paris School of Management (France), his M.B.A. from the University of Kansas (U.S.) and graduated from ESC Clermont School of Management (France).

# New independent board member added

At the general shareholders' meeting in June 2015, Luc Dochez was appointed as an independent member of the Board of Directors of ERYTECH. Mr. Dochez has been the Chief Business Officer and Senior Vice President of Business Development of Dutch-based Prosensa Holding N.V. (NASDAQ: RNA) until its acquisition by Biomarin. In this role, he was the architect of a €500M+ licensing deal with GSK, was heavily involved in Prosensa's IPO on NASDAQ, and led the sale of the company to Biomarin for \$860M. Before Prosensa, Mr. Dochez was VP of Business Development at TiGenix (Euronext: TIG), Director Business Development at Methexis Genomics and a consultant at Arthur D. Little. Mr. Dochez is currently CEO of Tusk Therapeutics, a private immune-therapy company.

Pierre-Olivier Goineau resigned from the Board in January 2015. The Board now consists of two executive member and five independent members.

# **Financial Update**

# Net loss of €6.5 million reflecting increased activity level

The financial report for the six months ending June 30, 2015, approved by the board of directors on August 24, 2015, is available on ERYTECH's website (<a href="www.erytech.com">www.erytech.com</a>). The report has been subject to a limited review procedure by ERYTECH's statutory auditors.

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

Key figures (in thousands of euros):

	H1 2015	H1 2014
Revenues	0	0
Other income	1,474	722
Total operating income	1,474	722
Operating expenses:		
Research & development	(5,231)	(1,914)
General & administrative	(3,107)	(1,991)
Total operating expenses	(8,338)	(3,905)
Operating loss	(6,863)	(3,183)
Financial income	325	4
Income tax	5	(4)
Net result	(6,533)	(3,184)

Net loss for the first half of 2015 was €6.5 million, compared to €3.2 million for the first half of 2014. The €3.3 million increase was mostly due to the €4.4 million increase in operating expenses, both for R&D and G&A activities. The increase in operating expenses was partly compensated by the €0.8 million increase in operating income and the €0.3 million increase in financial income.

• R&D expenses increased by €3.3 million. The increase was primarily the result of a €0.6 million increase in third-party services, subcontracting and consulting fees paid to CROs and other service providers for ERYTECH's manufacturing and clinical trials conducted in the first half of 2015 and a €1.3 million increase in personnel expenses due to increasing headcount and share-based compensation issued to R&D personnel. ERYTECH also experienced a €0.2 million increase in consumables, which primarily related to purchases of clinical products such as enzyme and blood samples. Finally, ERYTECH also experienced a €1.1 million increase in direct research and development expenses related to ERY-ASP as a result of clinical trials performed in relation to pancreatic cancer and TEDAC, which is expected to continue in future periods given ERYTECH's intention to commence a Phase 1 clinical trial of ERY-MET in 2016.

- G&A expenses increased by €1.1 million. The increase was primarily due to a €0.6 million increase in services, subcontracting and fees associated with the development of ERYTECH's regulatory and commercialization strategy in the United States, as well as consulting fees and third-party fees in connection with the recruiting of ERYTECH's Chief Medical Officer and Chief Financial and Chief Operating Officer. ERYTECH also experienced an increase of €0.5 million in other expenses, primarily as a result of share-based warrants issued to board members.
- These increased expenses were mitigated by the €0.8 million increase in operating income, related to higher research tax credits (CIR) for €0.5 million, which reflected the increased effort in R&D activities, as well as a €0.2 million increase in non-refundable grants from BPI France 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 €0.3 million as a result of interest-bearing investments following ERYTECH's October 2014 follow-on offering on Euronext Paris.

# Net cash utilization of €5.9 million in line with operating plan

Net cash utilization for the six-month period ended June 30, 2015 was €5.9 million, mainly due to negative cash flows from operating activities, as a result of ERYTECH's continued efforts in advancing ERYTECH's research and development programs as well as increased general and administrative expenses.

# Cash position of €31.0 million on June 30, 2015

ERYTECH had a balance sheet with cash and cash equivalents of €31.0 million at end of June 2015, compared with €37.0 million on December 31, 2014.

#### **EnterNext Tech 40 Label received**

In an effort to highlight Euronext-listed technology companies, every year EnterNext grants its Tech 40 label to 40 out of over 320 small and midcap technology companies listed on the various Euronext markets. In April 2015, an independent group of European experts selected ERYTECH among the first forty grantees on the basis of its business, financial and stock market performance.

# Level 1 ADR program in U.S. initiated and plans to conduct registered initial public offering in U.S. announced

Following the initial public offering of its ordinary shares on Euronext Paris in 2013 and an additional offering of ordinary shares in 2014, in January 2015, ERYTECH announced the launch of an American Depositary Receipt (ADR) Level 1 listing 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 "EYRYY." 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.

In July 2015, ERYTECH announced its plans to conduct a registered initial public offering in the United States. The timing and terms of this initial public offering have not yet been determined.

# **Next financial updates:**

Financial highlights for the 3<sup>rd</sup> quarter of 2015: November 3, 2015 (after market close)

# **Upcoming participations at investor conferences:**

- BioEurope, November 2-4 in Munich
- BryanGarnier Healthcare Conference, November 12-13 in Paris
- Jefferies Global Healthcare Conference, November 18-19 in London
- Actionaria, November 20-21 in Paris
- German Equity Forum, November 24-25 in Frankfurt
- ODDO Midcap event, January 7-8 in Lyon
- LifeSci Capital Investor access meeting at JPM, January 11-14 in San Francisco

# About ERYTECH and ERY-ASP (GRASPA®): www.erytech.com

Created 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 announced positive efficacy and safety results from its completed Phase 2/3 pivotal clinical trial in Europe with its lead product candidate, ERY-ASP, also known under the trade name GRASPA®, 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 2 clinical trial in Europe evaluating GRASPA as a first-line therapy for the treatment of elderly patients with 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, who 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 EYRYY).

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# Forward-looking information

This document may contain forward-looking statements and estimates with respect to the financial position, results of operations, business strategy, plans, objectives 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 the 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.amffrance.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,

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