

# ERYTECH Reports Third Quarter 2018 Financial Results and Provides Business Update

Conference call and webcast scheduled for Tuesday, November 13 at 14:30 CET/8:30 am EST

- Phase 3 trial for eryaspase in second line pancreatic cancer enrolling patients
- Phase 2 trial in triple-negative breast cancer to enroll patients by year end
- Cash position of €146.9 million (\$170 million) as of September 30, 2018

Lyon (France), Cambridge (MA), November 12, 2018 – ERYTECH Pharma (Euronext: ERYP - Nasdaq: ERYP), a clinical-stage biopharmaceutical company developing innovative therapies by encapsulating drug substances inside red blood cells, today provided a business update and reported its financial results for the quarter ended September 30, 2018.

"ERYTECH has launched its pivotal Phase 3 TRYbeCA1 trial for eryaspase in second line metastatic pancreatic cancer, as projected," said Gil Beyen, Chief Executive Officer at ERYTECH. "We are on track with our clinical site activations and enrollment projections and look to continue our momentum with the TRYbeCA1 trial into 2019. In addition, our Phase 2 trial for eryaspase in triple-negative breast cancer, which we refer to as the TRYbeCA2 trial, has received its first clinical trial authorizations, and we expect patient enrollment to commence by the end of the year. To ensure adequate clinical supply of eryaspase for these planned trials, we are continuing our efforts to expand our facility in Lyon and establish a U.S. manufacturing facility."

# **Business Highlights**

- Following the positive Phase 2b results of its lead product candidate eryaspase in second line metastatic pancreatic cancer and feedback from the U.S. Food and Drug Administration (FDA) and the Commission for Human Medicinal Products (CHMP) of the European Medicines Agency (EMA), ERYTECH has initiated the TRYbeCA1 trial. TRYbeCA1 is a pivotal Phase 3 trial in second line metastatic pancreatic cancer. The trial started enrolling patients in September 2018 and is evaluating eryaspase in combination with standard chemotherapy (gemcitabine/nab-paclitaxel or irinotecan-based regimen) compared to standard chemotherapy alone in approximately 500 patients at approximately 130 sites within the United States and Europe. The primary endpoint is overall survival (OS). An interim analysis is foreseen when approximately two-thirds of events have occurred.
- In view of exploring the potential use of eryaspase in other solid tumor indications, the Company is preparing the launch of a Phase 2 proof-of-concept trial for eryaspase in triple-negative breast cancer (TNBC). The TRYbeCA2 trial will evaluate eryaspase in combination with gemcitabine and carboplatin chemotherapy, compared to chemotherapy alone, in approximately 64 patients with previously untreated metastatic TNBC in Europe and the United States. The primary endpoint is objective response rate. The trial is expected to start enrollment by the end of this year.
- Last week, on November 7, ERYTECH hosted a Key Opinion Leader (KOL) event with medical oncologists who discussed the pancreatic cancer and triple-negative breast cancer treatment landscapes and the continued medical need for additional therapies in these indications. They highlighted the potential for targeting cancer cells' altered amino acid metabolism and the potential role of eryaspase.

- In order to ensure adequate supply of eryaspase for its planned Phase 3 and Phase 2 clinical trials, as well as the anticipated initial commercial needs of eryaspase if approved in these large indications, the Company is establishing a manufacturing facility in the United States (Princeton, New Jersey). ERYTECH is also expanding the manufacturing capacity in Lyon, France.
- Several preclinical programs, all leveraging the Company's proprietary ERYCAPS encapsulation platform, are ongoing. The Company's next product candidate, erymethionase, methionine-gamma-lyase encapsulated in red blood cells, is also targeting solid tumor indications. Erymethionase recently completed the non-clinical development and activities in support of initiating a Phase 1 clinical trial are ongoing. ERYMMUNE, the Company's immuno-oncology program, and ERYZYME, the encapsulation of enzymes used in therapies to treat metabolic diseases, are also progressing. An update on the results of these preclinical programs is planned for the first quarter of next year.

# **Financial Highlights**

 ERYTECH's key financial figures for the first nine months of 2018, compared with the same period of the previous year are summarized below:

	Q3 year-to-date (9 months) 2018	Q3 year-to-date (9 months) 2017	Variation
Revenues	0	0	0
Other income	2,629	2,864	(235)
Total operating income	2,629	2,864	(235)
Operating expenses:			
Research & development	(25,881)	(17,841)	(8,040)
General & administrative	(10,883)	(6,102)	(4,781)
Total operating expenses	(36,764)	(23,943)	(12,821)
Operating loss	(34,135)	(21,079)	(13,056)
Financial income	3,982	243	3,739
Income tax	(14)	19	(33)
Net loss	(30,167)	(20,818)	(9,350)

#### Key figures (in thousands of euros):

- Net loss for the nine-month period ended September 30, 2018 was €30.2 million, compared to €20.8 million in the same period of 2017. The €9.4 million increase was primarily attributable to:
  - An increase in R&D expenses by €8.0 million, mostly related to the Company's increased clinical and regulatory activities (€5.6 million), as well as the continued increase (€2.4 million) in preclinical research activities.
  - An increase in G&A expenses by €4.8 million, reflecting the continued structuring of the company (€3.7 million) and the increased costs associated with becoming a public company in the U.S. (€2.1 million).
  - A €3.7 million increase in financial income, including the accounting of a €3.1 million currency translation impact, as the Company's consolidated cash position denominated in euros was positively impacted by the translation in euros of the portion of the Company's cash position held in U.S. dollars.
- As of September 30, 2018, ERYTECH had cash and cash equivalents totaling €146.9 (\$170) million, compared with €185.5 (\$215) million as of December 31, 2017. The €38.6 million decrease in total cash and cash equivalents in the nine-month period comprised a total net cash utilization of €41.7 million for operating, investing and financing activities, and a €3.1 million favorable foreign exchange impact on the Company's cash position denominated in U.S. dollars. The acceleration in cash utilization in the third quarter 2018 was in line with the Company's expectations and was associated with the execution of the clinical plan and investments in the expansion of the Company's manufacturing capacity. The Company expects a further increase in cash utilization in the remainder of 2018, associated with the execution of the clinical plan and the related manufacturing capacity investments.

### **Key Upcoming Milestones**

- First patient to be dosed in the Phase 2 proof-of-concept clinical trial in TNBC
- First U.S. patient to be dosed in the pivotal Phase 3 trial with eryaspase in second line pancreatic cancer
- Completion of CMC activities with erymethionase in preparation of the start of a Phase 1 clinical trial

### Third Quarter Results 2018 Conference Call Details

As a reminder, ERYTECH management will hold a conference call and webcast on **Tuesday, November 13, 2018 at 14:30 CET / 08:30am EST** to discuss business highlights and financial results for the third quarter of 2018. Gil Beyen, Chairman and CEO, Eric Soyer, CFO and COO and Iman El-Hariry, CMO will host a brief presentation, followed by a Q&A session.

The call is accessible via the below teleconferencing numbers, followed by the Conference ID#: 9487808#:

 USA/Canada: +1 (833) 818-6807
 Fr

 International Dial-In Number: +1 (409) 350-3501
 Ui

France: +33 176748988 United-Kingdom: +44 2031070289

The webcast can be followed live online via the link: <u>https://edge.media-server.com/m6/p/kx3a3zti</u> An archived replay of the call will be available for 7 days by dialing **+ 1 800 585 8367**, Conference ID: **9487808#**:

#### 2018 Financial Calendar:

Business Update and Financial Highlights for the fourth quarter and full-year 2018: March 11, 2019 (after U.S. market close), followed by a conference call and webcast on March 12, 2019 (14:30 CET/8:30am ET)

#### **Upcoming Investor Conferences:**

- Jefferies Healthcare Conference, November 14-15, London
- Actionaria, November 22-23, Paris
- Piper Jaffray Annual Healthcare Conference, November 27-29, New York
- Investor access event at the J.P. Morgan Healthcare Conference, January 7-10, 2019, San Francisco
- ODDO BHF Forum, January 11-12, 2019, Lyon

#### About ERYTECH: www.erytech.com

ERYTECH is a clinical-stage biopharmaceutical company developing innovative red blood cell-based therapeutics for cancer and orphan diseases. Leveraging its proprietary ERYCAPS platform, a novel technology to encapsulate drug substances inside red blood cells, ERYTECH is developing a pipeline of product candidates to address markets with high unmet medical needs.

ERYTECH's primary focus is on the development of product candidates that target the altered metabolism of cancer cells by depriving them of amino acids necessary for their growth and survival. The Company's lead product candidate, eryaspase, which consists of L-asparaginase encapsulated inside donor-derived red blood cells, targets the cancer cell's altered asparagine and glutamine metabolism. Eryaspase is in Phase 3 clinical development for the treatment of second-line pancreatic cancer and in preparations to enter Phase 2 clinical development for the treatment of triple-negative breast cancer. ERYTECH's next product candidate erymethionase, which consists of methionine-gamma-lyase encapsulated in red blood cells to target methionine-dependent cancers, has demonstrated promising preclinical results and is in preparations to enter Phase 1 clinical development.

ERYTECH is also exploring the use of its ERYCAPS platform for developing cancer immunotherapies (ERYMMUNE) and enzyme therapies (ERYZYME).

ERYTECH produces product candidates at its GMP-approved and operational manufacturing site in Lyon, France, and the American Red Cross in Philadelphia, USA. A large-scale GMP manufacturing facility is under construction in New Jersey, USA.

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.

#### **CONTACTS**

ERYTECH	NewCap	
Eric Soyer	Mathilde Bohin	Nordor
CFO & COO	Investor relations	Nasdaq
	Nicolas Merigeau	
	Media relations	ERYP
+33 4 78 74 44 38	+33 1 44 71 98 52	LISTED
investors@ervtech.com	ERYTECH@newcap.eu	EURONEAT

#### **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, expansion of manufacturing capacity, status of preclinical programs 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. All statements contained in this press release other than statements of historical facts are forward-looking statements, including, without limitation, statements regarding the potential of ERYTECH's product pipeline, its clinical development and regulatory plans for eryaspase, the timing of ERYTECH's clinical studies and trials and announcements of data from those studies and trials, and the contents and timing of decisions by the FDA and EMA regarding ERYTECH's product candidates. 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 (AMF), the Company's Securities and Exchange Commission (SEC) filings and reports, including in the Company's 2017 Document de Référence filed with the AMF in April 2018 and in the Company's Annual Report on Form 20-F filed with the SEC on April 24, 2018 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.