

# **ERYTECH Provides Business Update and Reports Financial Results for First Quarter 2019**

Conference call and webcast on Tuesday, May 7 at 2:30 pm CET/8:30 am EDT

- TRYbeCA1, pivotal Phase 3 trial for eryaspase in second line pancreatic cancer, actively enrolling patients
- Construction of new manufacturing site in Princeton and extension of Lyon facility completed
- Cash position of €110.5 million (\$124 million) at the end of March Cash utilization guidance confirmed

Lyon (France), May 6, 2019 – ERYTECH Pharma (Euronext: ERYP - Nasdaq: ERYP), a clinical-stage biopharmaceutical company developing innovative therapies by encapsulating therapeutic drug substances inside red blood cells, today provides a business update and reports its financial results for the quarter ended March 31, 2019.

"The first quarter of 2019 has been particularly intense in terms of execution of our late stage clinical trials and the extension of our manufacturing capacity, all while making progress on our earlier stage programs. Patient enrollment for TRYbeCA 1, our pivotal Phase 3 trial in second-line metastatic pancreatic cancer, continues ahead of plan in Europe, and we recently filed an IND in the United States in order to begin enrollment there," said Gil Beyen, CEO of ERYTECH. "Construction of the new manufacturing site in Princeton and the expansion of our Lyon manufacturing facility have been completed and validation is now ongoing."

### **Recent Business Highlights**

- TRYbeCA1, the pivotal Phase 3 trial evaluating ERYTECH's lead product candidate eryaspase in second-line metastatic pancreatic cancer, is actively enrolling patients in several European countries. In view of opening the trial to patients in the United States, the company recently submitted an IND application to the US FDA. In this trial, ERYTECH is evaluating eryaspase in combination with standard chemotherapy (gemcitabine/nab-paclitaxel or an irinotecan-based regimen) compared to standard chemotherapy alone. The primary endpoint of the trial is overall survival. An interim efficacy analysis is planned when approximately two-thirds of events have occurred. The trial is expected to enroll approximately 500 patients at more than 120 sites in Europe and the United States.
- TRYbeCA2, a Phase 2 proof-of-concept trial in patients with previously untreated metastatic triple-negative breast cancer (TNBC), is evaluating eryaspase in combination with gemcitabine and carboplatin chemotherapy, compared to chemotherapy alone in approximately 64 patients. The primary endpoint is objective response rate. First sites were initiated in December 2018, and the trial is now open for enrollment in Spain and France.
- To ensure supply of the product for the clinical trials and potential initial commercial needs, the Company is establishing a GMP manufacturing facility in Princeton, New Jersey. It is also expanding its European manufacturing capacity in Lyon, France. Construction has now been completed at both sites and validation activities are ongoing, as planned.

- ERYTECH is also advancing the preclinical programs to leverage its proprietary ERYCAPS encapsulation platform. The Company's lead preclinical program and next product candidate is erymethionase, methionine-gamma-lyase encapsulated in red blood cells. Activities in support of initiating a Phase 1 clinical trial of erymethionase in solid tumor indications are ongoing. The company expects to begin this Phase 1 trial in Europe in the first quarter of 2020.
- In preparation for the next stage of the company's development, ERYTECH recently announced that its Board of Directors will propose the appointment of Jean-Paul Kress as a Director at the Annual General Meeting on June 21, 2019, with a view to appointing him as Chairman of the Board of Directors. Dr. Kress has over 25 years' experience as a senior executive in international biotech and pharma groups. He was President and Chief Executive Officer of Syntimmune (Cambridge, MA, US) until the end of 2018, when the company was acquired by Alexion Pharmaceuticals.

#### Q1 2019 Financial Results

Key financial figures for the first quarter of 2019 compared with the same period of the previous year are summarized below:

In thousands of euros	Q1 2019	Q1 2018
Revenues	_	_
Other income	757	1,204
Total operating income	757	1,204
Research and development	(9,173)	(7,729)
General and administrative	(4,847)	(2,735)
Total operating expenses	(14,020)	(10,463)
Total operating loss	(13,263)	(9,259)
Financial income	1,663	79
Financial expenses	(64)	(2,592)
Financial income (loss)	1,599	(2,513)
Loss before tax	(11,664)	(11,772)
Income tax	0	27
Net loss	(11,664)	(11,745)

- Net loss for the first quarter of 2019 was €11.7 million, stable from the same period in 2018. The €4.0 million increase in operating loss was offset in the period by the €4.1 million improvement in financial Income. The €4.0 million increase in operating loss was attributable to the €1.5 million increase in preclinical and clinical development expenses, mostly related to the Phase 3 clinical trial in pancreatic cancer, the €2.1 million increase in G&A expenses, primarily driven by professional fees in relation to the launch readiness of the Company's additional production capacity, and the €0.4 million decrease in research tax-credit income. The €4.1 million improvement in financial Income was mainly related to the translation into Euro of the portion of the Company's cash position denominated in U.S. Dollar, which had a positive foreign exchange impact and explained most of the €1.6 million financial Income in the first quarter of 2019, compared to a negative foreign exchange impact and a €2.5 million financial expense in the first quarter of 2018.
- As of March 31, 2019, ERYTECH had cash and cash equivalents totaling €110.5 million (approximately \$124 million), compared with €134.4 million on December 31, 2018. The €23.9 million decrease in cash position in the first quarter of 2019 was the result of a €25.2 million net cash utilization, comprised of a €15.9 million net cash utilization in operating activities, €8.9 million in capital expenditures and €0.4 million in loan and lease reimbursement, while the appreciation in the period of the U.S. Dollar against the Euro lead to a €1.3 million favorable currency exchange impact. Cash utilization in the first quarter of 2019 was, as anticipated, relatively high due to the non-recurring capital expenditure disbursements

for the production facility expansions in Lyon and in Princeton. As both projects are now close to completion, cash utilization is expected to be lower again in the coming quarters and the Company continues to expect its cash resources to be sufficient to fund operations until the end of 2020.

## **Key News Flow and Milestones Expected over Next 12 Months**

- First patient enrolled in TRYbeCA-2, Phase 2 proof-of-concept clinical trial in TNBC
- Start of GMP production at Princeton facility and Lyon extension
- Start of US patient enrollment in TRYbeCA 1, Phase 3 trial in second-line pancreatic cancer
- Initiation of Phase 1 clinical trial with erymethionase

### Q1 2019 Conference Call Details

ERYTECH management will hold a conference call and webcast on **Tuesday, May 7<sup>th</sup>, 2019 at 02:30pm CEST** / **08:30am EDT** on business highlights and financial results for the first quarter of 2019. Gil Beyen, CEO, Eric Soyer, CFO/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#: 2199912#:

The webcast can be followed live online via the link: <a href="https://edge.media-server.com/m6/p/t9xnoz52">https://edge.media-server.com/m6/p/t9xnoz52</a>

An archived replay of the call will be available for 7 days by dialing **+ 1 855 859 2056**, Conference ID: **2199912**#

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

#### 2019 Financial Calendar:

- General Assembly Meeting of Shareholders: Friday, June 21, 2019 at 9:30am CET in Paris
- Quarterly financial updates:
  - Business Update and Financial Highlights for the 2nd quarter and first-half of 2019: September 17, 2019 (after U.S. market close), followed by a conference call and webcast on September 18, 2019 (2:30pm CET/8:30am ET)
  - Business Update and Financial Highlights for the 3rd quarter of 2019: November 7, 2019 (after U.S. market close), followed by a conference call and webcast on November 8, 2019 (2:30pm CET/8:30am ET)

## **ERYTECH will Present at the Following Upcoming Investor Conferences:**

- Gilbert Dupont Annual Healthcare Conference, May 23, Paris
- Jefferies 2019 Global Healthcare Conference, June 4-7, New-York
- European Midcap Event Spring, June 18-19, Paris
- JMP Securities Life Sciences Conference, June 19, New York
- France Biotech, Health Tech Investor Day, June 25, Paris

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

ERYTECH is a clinical-stage biopharmaceutical company developing innovative red blood cell-based therapeutics for severe forms of cancer and orphan diseases. Leveraging its proprietary ERYCAPS platform, which uses a novel technology to encapsulate drug substances inside red blood cells, ERYTECH is developing a pipeline of product candidates for patients 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 Phase 2 for the treatment of triple-negative breast cancer. ERYTECH is also developing erymethionase, which consists of methionine-gamma-lyase encapsulated in red blood cells to target methionine-dependent cancers.

ERYTECH produces product candidates at its GMP-approved manufacturing site in Lyon, France, and at the American Red Cross in Philadelphia, USA. A large-scale GMP manufacturing facility has recently completed construction in Princeton, 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 / Louis-Victor Delouvrier
CFO & COO Investor relations

Nicolas Merigeau Media relations

+33 4 78 74 44 38 +33 1 44 71 98 52 <u>investors@erytech.com</u> <u>erytech@newcap.eu</u>





#### **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 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 of eryaspase, and the timing of ERYTECH's preclinical studies and clinical trials and announcements of data from those studies and trials. 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 2018 Document de Référence filed with the AMF on March 29, 2019 and in the Company's Annual Report on Form 20-F filed with the SEC on March 29, 2019 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.