



## ERYTECH Provides Business Update and Reports Financial Results for the First Half of 2019

Sep 17, 2019 | Press Releases

Conference call and webcast on Wednesday, September 18  
at 2:30 pm CET/8:30 am EDT

- **TRYbeCA1, Phase 3 trial for eryaspase in second line pancreatic cancer, progressing on plan**
- **Immune modulation collaboration entered into with SQZ Biotechnologies**
- **Board strengthened with appointment of Dr. Jean Paul Kress as Chairman**
- **Cash position of €94.5 million (\$107.5 million) at the end of June**

LYON, France, Sept. 17, 2019 (GLOBE NEWSWIRE) -- **ERYTECH Pharma**(Euronext: ERYP - Nasdaq: ERYP), a clinical-stage biopharmaceutical company developing innovative therapies by encapsulating therapeutic drug substances inside red blood cells, today provided a business update and reported its financial results for the quarter ended June 30, 2019.

*"The second quarter of 2019 remained focused on the execution of our late stage clinical trials of eryaspase and the extension of our manufacturing capacity. Patient enrollment in TRYbeCA 1, our pivotal Phase 3 trial in second-line metastatic pancreatic cancer, continues at a strong pace in Europe, and we expect enrollment in the United States to begin shortly," said Gil Beyen, CEO of ERYTECH. "Our new manufacturing site in Princeton and our expanded Lyon facility are on track to support our increasing clinical trial demand."*

### Recent Business Highlights

- Patient enrollment in TRYbeCA1, the pivotal Phase 3 trial evaluating ERYTECH's lead product candidate eryaspase in second-line metastatic pancreatic cancer, is on track. The trial began enrolling patients in Spain in September 2018 and is now actively enrolling patients in several European countries. In May of this year, the U.S. Food and Drug Administration (FDA) accepted ERYTECH's Investigational New Drug (IND) application for the trial. Patient enrollment in the United States is expected to start in Q4 of this year. The trial is plans to enroll approximately 500 patients at more than 120 clinical sites in Europe and the United States. Eligible patients are randomized 1-to-1 to receive eryaspase in combination with standard chemotherapy (gemcitabine/nab-paclitaxel or an irinotecan-based regimen) or chemotherapy alone. The primary endpoint of TRYbeCA1 is overall survival. An interim superiority analysis, planned for when approximately two-thirds of events have occurred, is anticipated to be conducted within the next twelve months.
- TRYbeCA2, a randomized Phase 2 trial in patients with previously untreated metastatic triple-negative breast cancer (TNBC), started patient enrollement in June. The trial is evaluating eryaspase in combination with gemcitabine and carboplatin chemotherapy, compared to chemotherapy alone.
- To ensure supply of the product for the clinical trials and potential future initial commercial demand, the Company has extended its manufacturing capacity in Lyon, France, and established a new GMP manufacturing facility in Princeton, New Jersey. The Lyon facility began producing clinical batches for the TRYbeCA1 trial in July, and the recently inaugurated Princeton site is expected to do so as well in the fourth quarter of this year.
- In June, ERYTECH entered into a strategic collaboration with SQZ Biotechnologies (SQZ), a cell therapy company developing novel treatments in multiple therapeutic areas, granting SQZ an exclusive worldwide license to develop antigen-specific immune modulating therapies employing red blood cell-based technology. ERYTECH is eligible to receive up to \$57 million in combined upfront and potential development, regulatory and commercial milestone payments for the first product successfully developed by SQZ under this agreement. ERYTECH will also be eligible to receive sales royalties, and up to a total of \$50 million in commercial milestone payments related to each additional approved product or approved indication. The strategic collaboration with SQZ is aligned with ERYTECH's strategy to leverage its unique red blood cell capabilities beyond its initial lead programs while increasing the Company's focus on advancing its late-stage product pipeline.
- In preparation for the next stage of the company's development, Jean-Paul Kress was appointed as a director at the Company's Annual General Meeting of Shareholders held on June 21, 2019. He was subsequently elected as Chairman by the Company's Board of Directors. Dr. Kress has over 25 years' experience as a senior executive in international biotech and pharma groups in Europe and the United States. He was recently appointed Chief Executive Officer of Morphosys AG.
- Allene Diaz has notified ERYTECH of her intention to resign from the Company's Board of Directors, effective September 30, 2019. Ms. Diaz's resignation was not caused by any disagreement with the Company on any matter relating to the Company's operations, policies or practices. The Company thanks Allene for her years of service on the board.

## 1H 2019 Financial Results

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

| <i>In thousands of euros</i>    | <b>1H 2019</b>  | <b>1H 2018</b>  |   |
|---------------------------------|-----------------|-----------------|---|
| Revenues                        | —               | —               |   |
| Other income                    | 2,965           | 2,265           |   |
| <b>Total operating income</b>   | <b>2,965</b>    | <b>2,265</b>    |   |
| Research and development        | (22,718)        | (16,752)        | ) |
| General and administrative      | (10,493)        | (7,393)         | ) |
| <b>Total operating expenses</b> | <b>(33,210)</b> | <b>(24,145)</b> | ) |
| <b>Total operating loss</b>     | <b>(30,245)</b> | <b>(21,880)</b> | ) |
| Financial income                | 1,265           | 2,966           |   |
| Financial expenses              | (305)           | (42)            | ) |
| <b>Financial income (loss)</b>  | <b>960</b>      | <b>2,924</b>    |   |
| <b>Loss before tax</b>          | <b>(29,285)</b> | <b>(18,956)</b> | ) |
| Income tax                      | (1)             | (14)            | ) |
| <b>Net loss</b>                 | <b>(29,286)</b> | <b>(18,970)</b> | ) |

- Net loss for the second quarter of 2019 was €29.3 million, up €10.3 million (+54%) as compared to the same period in 2018, with a €8.4 million increase (+38%) in operating loss and a €1.9 million decrease in financial income. The €8.4 million increase in operating loss was attributable to the €6.0 million increase in preclinical and clinical development expenses, mostly related to expenses incurred related to the Company's Phase 3 clinical trial in pancreatic cancer, the €3.1 million increase in G&A expenses, of which €1.8 million related to the launch readiness of the Company's additional manufacturing capacity, and the €0.7 million increase in operating income, of which €0.9 million of milestone payment upon the signature of the license agreement with SQZ Biotechnologies, while research tax-credit income decreased €0.2 million. The €1.9 million decrease in financial income was mainly related to the translation into euro of the portion of the Company's cash position denominated in U.S. dollars.
- As of June 30, 2019, ERYTECH had cash and cash equivalents totaling €94.5 million (approximately \$107.5 million), compared with €134.4 million on December 31, 2018. The €39.9 million decrease in cash position in the first half of 2019 was the result of a €40.5 million net cash utilization, comprised of a €23.8 million net cash utilization in operating activities, €17.6 million in investing activities and €0.8 million in financing activities, while the appreciation in the period of the U.S. dollar against the euro lead to a €0.6 million favorable currency exchange impact. After a peak in capital expenditure disbursements in the first quarter of 2019 related to the expansion of manufacturing facilities in Lyon and in Princeton, cash utilization has lowered in the second quarter as expected, and the Company's cash position at the end of June is in line with the earlier guidance of sufficient cash resources to fund operations until the end of 2020.

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

- Start of U.S. patient enrollment in TRYbeCA 1, Phase 3 clinical trial in second-line pancreatic cancer
- Start of GMP production at Princeton facility
- Initiation of investigator sponsored Phase 1 trial with eryaspase in first-line pancreatic cancer
- Results of Phase 2 IST in second-line acute lymphoblastic leukemia (ALL)
- Anticipated interim (superiority) analysis in TRYbeCA1

### Q2 2019 Conference Call Details

ERYTECH management will hold a conference call and webcast on **Wednesday, September 18<sup>th</sup>, 2019 at 02:30pm CEST / 08:30am EDT** on business highlights and financial results for the second 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#: **1396310#**

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

**France:** +33 1 70 80 71 53

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

**United-Kingdom:** +44 2031070289

The webcast can be followed live online via the link: <https://edge.media-server.com/mmc/p/fjhy9qqr>

An archived replay of the call will be available for 7 days by dialing + 1 855 859 2056, Conference ID: **1396310#**.

An archive of the webcast will be available on ERYTECH's website, under the "Investors" section at [investors.erytech.com](https://investors.erytech.com)

## 2019 Financial Calendar

- Next quarterly financial update:
  - 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:

- Investir Day, October 3<sup>rd</sup>, Paris
- Jefferies Healthcare Conference, November 20-21, London
- Salon Actionaria, November 22, Paris

### About ERYTECH: [www.erytech.com](http://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 opened for operations in Princeton, New Jersey, USA and will begin manufacturing later this year.

*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.*

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### 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 ERYTECH's business strategy including its clinical development of eryaspase; the status of the TRYbeCA 1 trial including the timeline for patient enrollment, expansion of trial into the United States and intended activities with respect to the interim analysis; the potential of ERYTECH's product pipeline; the timing of ERYTECH's preclinical studies and clinical trials and announcements of data from those studies and trials; ERYTECH's anticipated manufacturing capacity and ability to meet future demand and ERYTECH's anticipated cash runway and sufficiency of cash resources. 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 in March 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.



