ERYTECH Announces Presentation of Results of Expanded Access Program in ALL at 2021 ASH Annual Meeting and Acceptance of Two Abstracts at ASCO GI

Dec 13, 2021 | Press Releases

ERYTECH Announces Presentation of Results of Expanded Access Program in ALL at 2021 ASH Annual Meeting and Acceptance of Two Abstracts at ASCO GI

- **Full results of the Expanded Access Program in 'Double Allergic' acute lymphoblastic leukemia (ALL) patients were presented this weekend at ASH 2021, highlighting the feasibility of eryaspase (GRASPA®) to continue the intended course of treatment of ALL patients who developed hypersensitivities to other asparaginases**
- **Full results from Phase 3 TRYbeCA-1 study of eryaspase in second-line metastatic pancreatic cancer accepted for oral presentation on January 21st at ASCO GI as a late-breaking abstract**
- **Interim data from the Phase 1 rESPECT trial of eryaspase plus mFOLFIRINOX in first-line pancreatic cancer patients will be provided in a poster session at ASCO GI on January 21st**

Cambridge, MA (U.S.) and Lyon (France), December 13, 2021 – ERYTECH Pharma (Nasdaq & Euronext: ERYP), a clinical-stage biopharmaceutical company developing innovative therapies by encapsulating therapeutic drug substances inside red blood cells, today announced a summary of its poster presentation at the 2021 ASH Annual Meeting evaluating GRASPA® (eryaspase) in acute lymphoblastic leukemia (ALL) as well as the acceptance of two abstracts evaluating eryaspase in advanced pancreatic cancer at the American Society of Clinical Oncology Gastrointestinal Cancers Symposium (ASCO GI), which will be held January 20-22, 2022, both in San Francisco, CA and virtually.

Poster presentation at ASH 2021

On Saturday, December 11, 2021, Prof Dr. Yves Bertrand, Oncologist at the Institute of Pediatric Hematology and Oncology, Civil Hospital of Lyon, France, presented the results of the Expanded Access Program (EAP) with GRASPA® (eryaspase) in ALL patients who had developed treatment limiting hypersensitivities to both *E. coli*- and *Erwinia*-derived asparaginase therapies.

Abstract # 1214 Direct Hyperlink
Expanded Access Program: Evaluating Safety of Erythrocytes Encapsulating L-Asparaginase in Combination with Polychemotherapy in Patients Under 55 Years Old with Acute Lymphoblastic Leukemia (ALL) at Risk to Receive Other Formulations of Asparaginase

The eryaspase EAP was conducted at ten clinical sites in France and enrolled 18 patients. The EAP evaluated tolerability and pharmacological profile in patients under 55 years of age with ALL and unable or at risk to receive any other available asparaginase formulation.

The highlights of the presentation by Prof Bertrand were:

- This study is the first study to demonstrate activity of an asparaginase (ASNase) therapy in a double (and even triple) allergic patient population who received prior *E. coli*- and *Erwinia*-derived asparaginase
- The ASNase concentration exceeded the therapeutic target level of 100 U/L for all patients
- ASNase activity was associated with complete asparagine (ASN) reduction (<0.1 µM/L) in 39% of patients, and with at least 50% ASN reduction relative to baseline in an additional 39% of patients
- All except one of the 18 patients in the study achieved complete remission and 14 (77.8%) were still alive at the end of the study
- Eryaspase was well-tolerated when combined with chemotherapy for treatment of patients with ALL
- Eryaspase provides an additional option for patients for whom further ASNase treatment is contraindicated due to toxicity

Hypersensitivity is the most common cause of truncated asparaginase therapy which has been associated with decreased event free survival. The EAP results provide additional support for the feasibility of eryaspase (GRASPA®) to continue the intended course of treatment of ALL patients who developed hypersensitivities to other asparaginases.

In the EAP and consistently across eryaspase ALL studies, eryaspase provides a sustained asparaginase enzyme activity level with few hypersensitivity reactions and is generally well tolerated in combination with chemotherapy. The company is currently preparing a BLA to seek approval for ALL patients who developed hypersensitivity to *E. coli*-derived asparaginase, based on the results of a Phase 2 clinical trial sponsored by the NOPHO group[1]. The Company intends to submit the BLA in the first quarter of 2022, subject to completion of remaining data requested by the FDA.

Oral presentations at ASCO GI 2022

Two abstracts have been accepted for presentation at the ASCO GI annual conference in January 2022. The full results from the TRYbeCA-1 Phase 3 trial of eryaspase in second-line metastatic pancreatic cancer have been accepted for oral presentation on January 21st at ASCO GI as a late-breaking abstract (abstract #518), and an update on the ongoing Phase 1 investigator sponsored trial in first-line advanced pancreatic cancer (abstract #581)

has been accepted for a poster presentation.

Abstract # 518 - ***TRYbeCA-1****: A randomized, phase 3 study of eryaspase in combination with chemotherapy versus chemotherapy alone as second-line treatment in patients with advanced pancreatic adenocarcinoma (NCT03665441).*

The study findings will be featured as an oral presentation at ASCO GI by Prof. Pascal Hammel, MD, PhD, on Friday January 21st 2022 at 4:35pm EST / 22:35 CET.

Abstract # 581 - ***rESPECT****: A phase I dose-escalation study of eryaspase in combination with modified FOLFIRINOX in locally advanced and metastatic pancreatic ductal adenocarcinoma: Interim update (NCT04292743).*

An interim analysis will be presented as a poster by Dr Marcus Noel, on Friday January 21st 2022 at 3:05pm EST / 21:05 CET.

The full abstracts will be made available online via https://meetinglibrary.asco.org at 5:00pm EST on January 18th 2022.

As reported in late October, the Phase 3 TRYbeCA-1 trial did not meet the primary efficacy endpoint of overall survival (OS), but the prespecified subgroup of patients treated with eryaspase and FOLFIRI, a fluoropyrimidine- and irinotecan-based chemotherapy, demonstrated a nominal increase in median OS of 2.3 months, from 5.7 to 8 months (HR = 0.77; per protocol population), which the Company believes merits further investigation. The rESPECT, Phase 1 IST in first-line pancreatic cancer is evaluating eryaspase in combination with mFOLFIRINOX, also a fluoropyrimidine and irinotecan-based chemotherapy. Based on the full results of TRYbeCA-1 and the available results of the rESPECT trial, the Company will evaluate a potential path forward for eryaspase in pancreatic cancer.

About ERYTECH and eryaspase (GRASPA®)

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 (GRASPA®), which consists of L-asparaginase encapsulated inside donor-derived red blood cells, targets the cancer cells' altered asparagine and glutamine metabolism. The proof of concept of eryaspase as a cancer metabolism agent was established in different trials in acute lymphoblastic leukemia (ALL) and pancreatic cancer. An investigator sponsored Phase 2 trial (IST) evaluating the use of GRASPA® in ALL patients who developed hypersensitivity reactions to pegylated asparaginase recently reported positive results, based on which the Company intends to request approval in the United States and potentially other territories. The Company is also pursuing a Phase 1 investigator-sponsored clinical trial in first-line pancreatic cancer.

Eryaspase received Fast Track designation from the U.S. Food and Drug Administration (FDA) for the treatment of advanced pancreatic cancer and treatment of acute lymphoblastic leukemia (ALL) patients who have developed hypersensitivity reactions to E. coli-derived pegylated asparaginase. The FDA and the European Medicines Agency have granted eryaspase orphan drug status for the treatment of pancreatic cancer and ALL.

ERYTECH produces its product candidates for treatment of patients in Europe at its GMP-approved manufacturing site in Lyon, France, and for patients in the United States at its GMP manufacturing site in Princeton, New Jersey, USA. Eryaspase is not an approved medicine.

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.

For more information, please visit www.erytech.com

CONTACTS

ERYTECH
Eric Soyer
CFO & COO

+33 4 78 74 44 38
investors@erytech.com

LifeSci Advisors, LLC
Corey Davis, Ph.D.
Investor relations

+1 (212) 915 - 2577
cdavis@lifesciadvisors.com

NewCap
Mathilde Bohin / Louis-Victor Delouvrier
Investor relations
Nicolas Merigeau
Media relations

+33 1 44 71 94 94
erytech@newcap.eu

Forward-looking Information

This press release contains forward-looking statements including, but not limited to, statements with respect to the clinical development and regulatory plans of eryaspase including the timing of a potential BLA submission to the FDA for the treatment of acute lymphoblastic leukemia, the Company's ability to obtain regulatory approval for the treatment of patients with acute lymphoblastic leukemia who developed hypersensitivity reactions to *E. coli*-derived asparaginase, the Company's ability to extend the indication scope of eryaspase, the Company's ability for additional funding under the OCABSA financing agreement or other financing attempts, and the Company's anticipated cash runway. 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. 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 and timeline 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 2020 Document d'Enregistrement Universel filed with the AMF on March 8, 2021 and in the Company's Annual Report on Form 20-F filed with the SEC on March 8, 2021 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. In addition, the COVID-19 pandemic and the associated containment efforts have had a serious adverse impact on the economy, the severity and duration of which are uncertain. Government stabilization efforts will only partially mitigate the consequences. The extent and duration of the impact on the Company's business and operations is highly uncertain, and that impact includes effects on its clinical trial operations and supply chain. Factors that will influence the impact on the Company's business and operations include the duration and extent of the pandemic, the extent of imposed or recommended containment and mitigation measures, and the general economic consequences of the pandemic. The pandemic could have a material adverse impact on the Company's business, operations and financial results for an extended period of time.

---

1 DOI: https://doi.org/10.1182/blood-2020-139373

Attachment

- 211213 ERYTECH_PR_ASCO-GI and ASH_EN_vf