

PHARMAESSENTIA TO PRESENT LONG-TERM DATA ON ROPEGINTERFERON ALFA-2B IN POLYCYTHEMIA VERA AT VIRTUAL ASH ANNUAL MEETING

Results from five-year PROUD-PV/CONTINUATION-PV studies in rare blood cancer featured as oral presentation

November 4, 2020, Burlington, MA – [PharmaEssentia Corporation](#) (TPEX: 6446), a global biopharmaceutical innovator leveraging deep expertise and proven scientific principles to deliver new biologics in hematology and oncology, today announced that data reflecting five years of experience with ropeginterferon alfa-2b in polycythemia vera (PV) will be presented during the virtual 62nd American Society of Hematology (ASH) Annual Meeting and Exposition.

Findings from “*Long-Term Use of Ropoginterferon Alpha-2b in Polycythemia Vera: 5-Year Results from a Randomized Controlled Study and Its Extension*” ([Presentation 481 in Session 634](#)) will be featured as an oral presentation on Sunday, December 6th at 2:30 PM PT.

“We look forward to contributing to the scientific dialogue around opportunities to improve care in the area of myeloproliferative neoplasms, and specifically in PV, during the virtual ASH meeting,” said Meredith Manning, U.S. General Manager for PharmaEssentia. “Our robust research offers a new, innovative perspective in this category and illustrates our goal to reset expectations and improve patient outcomes.”

PharmaEssentia has focused its efforts on therapeutic innovation in the category of myeloproliferative neoplasms (MPNs), which are caused by specific genetic mutations that lead to overproduction of blood components including white or red blood cells, or platelets. In PV, the vast majority of which is caused by a JAK2 V617F mutation, the bone marrow produces excessive red blood cells, causing the blood to be thicker than normal and potentially leading to a range of complications.^{1,2} PV is estimated to affect more than 160,000 people in the U.S. alone,¹ who have progressively burdensome symptoms. Without proper management, the disease can progress into myelofibrosis and malignancies including acute myeloid leukemia.³

Follow PharmaEssentia on [LinkedIn](#) to get news and updates on our activity at the virtual ASH Annual Meeting.

About Ropoginterferon alfa-2b

Ropoginterferon alfa-2b is a novel, long-acting, mono-pegylated proline interferon that has been engineered with an optimized profile to support improved pharmacokinetic properties, tolerability and convenience. It is designed for administration once every two weeks, or once every four weeks during long-term maintenance. Ropoginterferon alfa-2b has Orphan Drug designation for treatment of polycythemia vera (PV) in the United States. Marketed as Besremi® in Europe, the product was approved by the European Medicines Agency (EMA) in 2019. Ropoginterferon alfa-2b was discovered and is manufactured by PharmaEssentia in its Taichung plant, which was cGMP certified by TFDA in 2017 and by EMA in January 2018.

About Polycythemia Vera

Polycythemia Vera (PV) is a cancer originating from a disease-initiating stem cell in the bone marrow resulting in a chronic increase of red blood cells, white blood cells, and platelets. This condition may result in cardiovascular complications such as thrombosis and embolism, as well as transformation to secondary myelofibrosis or leukemia. While the molecular mechanism underlying PV is still subject of intense research, current results point to a set of acquired mutations, the most important being a mutant form of JAK2.³

About PharmaEssentia

PharmaEssentia Corporation (TPEX: 6446) is a rapidly growing biopharmaceutical innovator. Leveraging deep expertise and proven scientific principles, the company aims to deliver effective new biologics for challenging diseases in the areas of hematology and oncology, with one product already approved in Europe and a diversifying pipeline. Founded in 2003 by a team of Taiwanese-American executives and renowned scientists from U.S. biotechnology and pharmaceutical companies, today the company is expanding its global presence with operations in the U.S., Japan, China, and Korea, along with a world-class biologics production facility in Taichung.

Forward Looking Statement

Some of the statements included in this press release, particularly those relating to the results of clinical trials, the clinical benefits to be derived from ropeginterferon alfa-2b, regulatory submissions and the timing of any such review, approvals, the commercial opportunity and competitive positioning, and any business prospects for ropeginterferon alfa-2b, may be forward-looking statements that involve a number of risks and uncertainties. For those statements, we claim the protection of the safe harbor for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995 and similar legislation and regulations under Taiwanese law. Among the factors that could cause our actual results to differ materially are the following: acceptance of the BLA filing does not represent final evaluation of the adequacy of the data submitted in the BLA; whether the FDA will complete its review of the BLA on a timely basis; the risk that the FDA ultimately denies approval of the BLA; whether the FDA concurs with our interpretation of our Phase 3 study results, supportive data, or the conduct of the studies; whether, ropeginterferon alfa-2b, if approved, will be successfully launched and marketed; and other risk factors identified from time to time in our reports filed with any global securities regulator or agency. Any forward-looking statements set forth in this press release speak only as of the date of this press release. We do not undertake to update any of these forward-looking statements to reflect events or circumstances that occur after the date hereof. The information found on our website, and the FDA website, is not incorporated by reference into this press release and is included for reference purposes only.

Media Contact:

Kellie Hotz, kellie_hotz@pharmaessentia.com

###

¹ Mehta J, Wang H, Iqbal SU, Mesa R. Epidemiology of myeloproliferative neoplasms in the United States. *Leuk Lymphoma*. 2014 Mar;55(3):595-600.

² Mesa R et al. Patient-Reported Outcomes Data From REVEAL at the Time of Enrollment (Baseline): A Prospective Observational Study of Patients With Polycythemia Vera in the United States. *Clin Lymphoma Myeloma Leuk*. 2018 Sep;18(9):590-596. doi: 10.1016/j.clml.2018.05.020.

³ Cerquozzi S, Tefferi A. Blast transformation and fibrotic progression in polycythemia vera and essential thrombocythemia: a literature review of incidence and risk factors. *Blood Cancer Journal* (2015) 5, e366; doi:10.1038/bcj.2015.95.