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REVIEW OF SURPASS-ET TRIAL EVALUATING ROPEGINTERFERON ALFA-2B-NJFT FOR ESSENTIAL THROMBOCYTHEMIA (ET) PUBLISHED IN *FUTURE ONCOLOGY*

Pivotal study will offer insights on the effectiveness of a unique monopegylated interferon as an alternative to currently available options for people with ET

Program intended to support expanded use for ropeginterferon alfa-2b-njft following approved indication for polycythemia vera (PV)

August 8, 2022, Burlington, MA – PharmaEssentia USA Corporation, a subsidiary of PharmaEssentia Corporation (TPEx:6446), a global biopharmaceutical innovator based in Taiwan leveraging deep expertise and proven scientific principles to deliver new biologics in hematology and oncology, today announced that the clinical rationale and protocol for the SURPASS-ET trial evaluating ropeginterferon alfa-2b-njft as a second-line treatment option for adults with high-risk essential thrombocythemia (ET) has been published in the journal, *Future Oncology*.

ET is a myeloproliferative neoplasm (MPNs), a group of rare blood cancers caused by genetic mutations that trigger the overproduction of blood cells; ET is characterized by the overproduction of platelets. Without proper treatment, these disorders carry a higher risk of thrombosis or other cardiovascular complications, or may progress toward myelofibrosis or secondary acute myeloid leukemia (sAML). Yet many patients who receive conventional approved treatments for ET experience resistance or intolerance, or the efficacy wanes over time, so new therapeutic options are needed to help address these limitations and improve treatment outcomes.

Ropeginterferon alfa-2b-njft is a unique monopegylated, long-acting interferon that was recently approved to treat adults with polycythemia vera (PV), another type of MPN. Given the well-established safety and efficacy profile demonstrated in prior studies, the treatment may represent a useful alternative to approved options for ET.

“Physicians treating people with MPNs have lacked effective, durable therapeutics that are designed specifically for these cancers. To help improve the long-term outlook for these patients, we need to focus not only on normalizing symptoms and improving quality of life, but also targeting driver mutations to more completely control the disease,” said Srdan Verstovsek, M.D., Ph.D., Director of the Hanns A. Pielenz Clinical Research Center for Myeloproliferative Neoplasms, Department of Leukemia at the University of Texas MD Anderson Cancer Center. “This trial will provide critical data on how use of a monopegylated interferon for the first time in this disease state could reduce the risk of progression for these patients over time.”

The global phase 3, randomized, open-label, multicenter SURPASS-ET (NCT04285086) trial is evaluating the safety, efficacy, tolerability, and pharmacokinetics of ropeginterferon alfa-2b-njft compared to anagrelide as second-line therapy in high-risk ET. Approximately 160 patients are being enrolled from 61 study sites across the United States, Canada and multiple regions across Asia, and will be randomized to receive treatment with ropeginterferon alfa-2b-njft (via subcutaneous injection every two weeks starting at 250 mcg, with a target optimal dose of 500 mcg by week four and onwards) or a daily anagrelide capsule (0.5 mg).

The primary efficacy endpoint is durable patient response, as defined by modified ELN response criteria (peripheral blood count remission; improvement or non-progression in disease-related signs; improvement or non-progression based on the MPN-SAF TSS; absence of hemorrhagic or thrombotic events; and durability at months 9 and 12). Other endpoints being evaluated include quality of life and change in allelic burden (the proportion of mutated cells in the blood). Data from the trial are expected by 2024.

“With nearly a decade of ongoing research with interferons in MPNs, we have strong evidence supporting the use of ropeginterferon alfa-2b-njft to treat individuals with ET,” said Raymond Urbanski, M.D., Ph.D., U.S. Head of Clinical Development and Medical Affairs, PharmaEssentia. “The series of clinical trials currently underway are providing an increasingly clear picture of the profile of this treatment to potentially improve care standards and patient outcomes across the MPN category.”

About Ropeginterferon alfa-2b

Ropeginteferon alfa-2b-njft is an innovative monopegylated, long-acting interferon. With its unique pegylation technology, the product has a long duration of activity in the body.

Ropeginteferon alfa-2b-njft (marketed as BESREMi®) has orphan drug designation for treatment of polycythemia vera (PV) in adults in the United States. The product was approved by the European Medicines Agency (EMA) in 2019, in the United States in 2021, and has recently received approval in Taiwan and South Korea. The product was invented by PharmaEssentia and is manufactured in the company’s Taichung plant, which was cGMP certified by TFDA in 2017 and by EMA in January 2018. PharmaEssentia retains full global intellectual property rights for the product in all indications.

BESREMi was approved with a boxed warning for risk of serious disorders including aggravation of neuropsychiatric, autoimmune, ischemic and infectious disorders.

About Essential Thrombocythemia

Essential thrombocythemia (ET) is a myeloproliferative neoplasm (MPN) characterized by an overproduction of platelets in the blood that results from a genetic mutation; data indicates a JAK2 gene mutation is present in approximately half of diagnosed patients. ET is estimated to affect up to 57 per 100,000 people in the U.S. The disease is most commonly diagnosed through routine blood work, and is most common in people over the age of 50, with women 1.5 more times more likely to be diagnosed than men. As a chronic, progressive disease, ET requires regular monitoring and appropriate treatment. Over time, the disease may progress into more deadly conditions such as myelofibrosis or acute leukemia.[1,2]

About PharmaEssentia

PharmaEssentia Corporation (TPEx: 6446), based in Taipei, Taiwan, 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 approved product 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. For more information, visit our website or find us on LinkedIn and Twitter.

Forward Looking Statement

This press release may contain forward-looking statements, including statements regarding the commercialization plans and expectations for commercializing BESREMi in the United States, and the potential benefits or competitive position of BESREMi. 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. These forward-looking statements are based on management expectations and assumptions as of the date of this press release, and actual results may differ materially from those in these forward-looking statements as a result of various factors. These factors include PharmaEssentia's ability to launch BESREMi in the United States, whether BESREMi is successfully commercialized and adopted by physicians and patients, the extent to which reimbursement is available for BESREMi, and the ability to receive FDA and other regulatory approvals for additional indications for BESREMi. 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.

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[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] "What is Essential Thrombocythemia?" MPN Research Foundation. 2020. Available at: http://www.mpnresearchfoundation.org/Essential-Thrombocythemia