PharmaEssentia to Present Phase 3 SURPASS-ET Data in Oral Session at 2025 ASCO Annual Meeting

Presentation to include positive clinical results from the Phase 3 SURPASS-ET clinical trial of ropeginterferon alfa-2b-njft for the treatment of essential thrombocythemia (ET)

BURLINGTON, Mass, May. 20, 2025 -- PharmaEssentia USA Corporation, a subsidiary of PharmaEssentia Corporation (TWSE: 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 it will present results from the Phase 3 SURPASS-ET clinical trial in an oral session at the 2025 American Society of Clinical Oncology (ASCO) Annual Meeting, taking place May 30-June 3 in Chicago.

SURPASS-ET (NCT04285086) is evaluating ropeginterferon alfa-2b-njft as a second-line treatment for patients with essential thrombocythemia (ET). Earlier this year, PharmaEssentia announced positive topline Phase 3 results, with ropeginterferon alfa-2b-njft demonstrating a significantly higher durable clinical response rate compared to anagrelide (42.9% vs. 6.0%; p=0.0001), along with a favorable safety profile and a greater reduction in JAK2 V617F allelic burden over 12 months.

Ropeginterferon alfa-2b-njft is currently FDA-approved and marketed as BESREMi® for the treatment of adults with polycythemia vera (PV). BESREMi® has been recognized by the National Comprehensive Cancer Network® (NCCN®) as a preferred first-line cytoreductive therapy for adults with symptomatic, low-risk PV and the only preferred therapeutic option for both high-risk and low-risk (symptomatic) patients, regardless of treatment history.

“Current options for patients with ET are limited. Standard therapies like hydroxyurea have notable drawbacks and do not target the underlying biology of the disease, while anagrelide has been associated with toxicity concerns and limited efficacy,” said Ruben Mesa, M.D., co-principal investigator, presenting author, and President of Atrium Health Levine Cancer Institute, the largest cancer program in the Carolinas which includes the Comprehensive Cancer Center at Wake Forest Baptist. “This marks the first registrational Phase 3 trial of a long-acting interferon in ET, demonstrating not only well-tolerated blood count control but also a measurable reduction in JAK2 mutation allele burden. These findings support further investigation of ropeginterferon as a second-line option for patients with ET who are seeking additional treatment approaches.”

“The ASCO meeting is an important opportunity to share detailed findings of our positive data from the SURPASS-ET study with the medical community,” said Albert Qin, M.D., Ph.D., Chief Medical Officer of PharmaEssentia USA. “These data highlight a significant advance in the treatment of essential thrombocythemia and reinforce our commitment to delivering innovative, non-chemotherapy options for patients living with myeloproliferative neoplasms.“

Presentation Details

Title: Ropeginterferon alfa-2b versus anagrelide for the treatment of essential thrombocythemia: Topline results of the phase 3 SURPASS-ET trial
Abstract Number: 6500
Presenter: Dr. Ruben Mesa
Session: Hematologic Malignancies — Leukemia, Myelodysplastic Syndromes, and Allotransplant
Date: Monday, June 2, 2025
Time: 3:00 p.m. - 6:00 p.m. CDT

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About Essential Thrombocythemia
Essential thrombocythemia is a chronic, rare blood disorder that is the most common type of myeloproliferative neoplasm. Essential thrombocythemia is most often caused by genetic mutations that cause the bone marrow to produce too many platelets, which can obstruct blood flow and cause a stroke, heart attack or pulmonary embolism.

About BESREMi® (ropeginterferon alfa-2b-njft) in polycythemia vera (PV)
BESREMi is an innovative monopegylated, long-acting interferon. With its unique pegylation technology, BESREMi has a long duration of activity in the body and is aimed to be administered once every two weeks (or every four weeks with hematological stability for at least one year), allowing flexible dosing that helps meet the individual needs of patients.

BESREMi has orphan drug designation for the treatment of polycythemia vera (PV) in adults in the United States. BESREMi has been approved in more than 40 countries, with approval from the European Medicines Agency (EMA) in 2019, by the US Food and Drug Administration (FDA) in 2021, and by the Pharmaceuticals and Medical Devices Agency (PMDA) in Japan in 2023. It 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.

Please see full Prescribing Information, including Boxed Warning.

About PharmaEssentia
PharmaEssentia USA Corporation, located in Burlington, Massachusetts, is a subsidiary of PharmaEssentia Corporation (TWSE: 6446). PharmaEssentia Corporation headquartered in Taipei, Taiwan, is a global and rapidly growing biopharmaceutical innovator. Leveraging deep expertise and proven scientific principles, PharmaEssentia aims to deliver effective new biologics for challenging diseases in the areas of hematology, oncology, and immunology 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 PharmaEssentia 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, Taiwan.

For more information about PharmaEssentia USA, visit the website, LinkedIn or X (formerly Twitter).

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