PharmaEssentia Announces Publication of Phase 3 SURPASS-ET Results in *The Lancet Haematology*

Ropeginterferon alfa-2b Demonstrated Superior Efficacy and Favorable Safety Compared with Anagrelide in Hydroxyurea-Resistant or -Intolerant Essential Thrombocythemia with Leukocytosis

Anticipate FDA Submission to Support Ropeginterferon alfa-2b (BESREMi®) Label Expansion Before Year-End 2025

BURLINGTON, Mass, Nov. 24, 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 that positive results from its pivotal Phase 3 SURPASS-ET clinical trial (NCT04285086) have been published in *The Lancet Haematology*.

The paper, titled "Ropeginterferon alfa-2b in hydroxyurea-intolerant or hydroxyurea-refractory essential thrombocythaemia (SURPASS ET): a multicentre, open-label, randomised, active-controlled, phase 3 study," highlights the potential of ropeginterferon alfa-2b-njft as a new therapeutic option for patients with essential thrombocythemia (ET). ET is a chronic myeloproliferative neoplasm (MPN) characterized by uncontrolled platelet production and an elevated risk of blood clots, bleeding events and progression to more serious cancers. There have been no new treatments approved in the United States for ET since anagrelide in 1997, underscoring the need for new innovative therapies.

SURPASS-ET compared ropeginterferon alfa-2b with anagrelide in patients with ET with leukocytosis who were resistant or intolerant to hydroxyurea. Data showed that ropeginterferon alfa-2b achieved statistically superior responses, with 43% of patients demonstrating durable responses at months 9 and 12 (as defined by modified ELN criteria) compared with 6% of those receiving anagrelide.

Beyond the primary endpoint, ropeginterferon alfa-2b demonstrated more robust hematologic responses, greater symptom improvement, improved control of splenomegaly, fewer thromboembolic events and deeper molecular responses across key patient subgroups. Notably, treatment with ropeginterferon alfa-2b resulted in significant reductions in JAK2 V617F allele burden, an important indicator of potential disease-modifying activity in MPNs. The therapy was also well tolerated, with no major cardiac or neurological events and lower rates of significant adverse events and treatment discontinuations relative to anagrelide.

"The SURPASS-ET data are impressive and demonstrate not only durable clinical and symptomatic benefits with ropeginterferon alfa-2b, but also reductions in JAK2 V617F allele burden—an important marker associated with potential disease modification," said Ruben Mesa, MD, lead author of the publication, principal investigator of the SURPASS-ET trial and President of Advocate Health's Cancer National Service Line, which includes Atrium Health Levine Cancer Institute and

the Comprehensive Cancer Center at Atrium Health Wake Forest Baptist. “ET remains a challenging chronic disease, and patients who are resistant or intolerant to hydroxyurea have had few alternatives for sustained disease control. After nearly three decades without new therapeutic options, these findings represent a promising step forward for patients and clinicians.”

“We are encouraged to see the SURPASS-ET results recognized in a leading peer-reviewed journal,” said Ko-Chung Lin, PhD, Founder and Chief Executive Officer of PharmaEssentia. “Ropeginterferon alfa-2b-njft has already reshaped the treatment landscape for polycythemia vera, and the findings from this study further reinforce its potential to benefit patients across the MPN spectrum. We look forward to advancing our regulatory efforts to bring this therapy to individuals living with ET, supporting the potential to expand our commercialization efforts in this new indication in 2026, pending FDA approval.”

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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).

About Essential Thrombocythemia (ET)

Essential thrombocythemia is a rare blood disorder and type of myeloproliferative neoplasm (MPN). It is characterized by the bone marrow overproducing platelets. Patients with ET are at an increased risk of blood clots, abnormal bleeding and enlarged spleens. ET is often caused by genetic mutations such as a JAK2 genetic mutation.

About BESREMi® (ropeginterferon alfa-2b-njft)

Ropeginterferon alfa-2b-njft is currently FDA-approved and marketed as BESREMi® for the treatment of adults with polycythemia vera (PV). The Company plans to seek a ropeginterferon alfa-2b-njft label expansion to include ET and has submitted a sBLA with the U.S. FDA.

BESREMi® holds orphan drug designation in the United States for the treatment of polycythemia vera (PV) in adults. It has received regulatory approval in over 40 countries, including from the European Medicines Agency (2019), the U.S. Food and Drug Administration (2021), and the Pharmaceuticals and Medical Devices Agency in Japan (2023). The product was developed by

PharmaEssentia. PharmaEssentia retains full global intellectual property rights across all indications.

INDICATION
BESREMi® is indicated for the treatment of adults with polycythemia vera.

IMPORTANT SAFETY INFORMATION
WARNING: RISK OF SERIOUS DISORDERS
Interferon alfa products may cause or aggravate fatal or life-threatening neuropsychiatric, autoimmune, ischemic, and infectious disorders. Patients should be monitored closely with periodic clinical and laboratory evaluations. Therapy should be withdrawn in patients with persistently severe or worsening signs or symptoms of these conditions. In many, but not all cases, these disorders resolve after stopping therapy.

CONTRAINDICATIONS
Existence of or history of severe depression, suicidal ideation, or suicide attempt
Hypersensitivity to interferons or any inactive ingredients
Moderate or severe hepatic impairment
History or presence of active serious or untreated autoimmune disease
History of transplantation and receiving immunosuppressant agents

WARNINGS AND PRECAUTIONS
Patients exhibiting the following events should be closely monitored and may require dose reduction or discontinuation of therapy:

- Depression and Suicide: Monitor closely for symptoms and need for treatment.
- Endocrine Toxicity: Discontinue if endocrine disorders occur that cannot be medically managed.
- Cardiovascular Toxicity: Avoid use in patients with severe, acute or unstable cardiovascular disease. Monitor patients with history of cardiovascular disorders more frequently.
- Decreased Peripheral Blood Counts: Perform blood counts at baseline, every 2 weeks during titration, and at least every 3-6 months during maintenance treatment.
- Hypersensitivity Reactions: Stop treatment and immediately manage reaction.
- Pancreatitis: Consider discontinuation if confirmed pancreatitis
- Colitis: Discontinue if signs or symptoms of colitis
- Pulmonary Toxicity: Discontinue if pulmonary infiltrates or pulmonary function impairment
- Ophthalmologic Toxicity: Advise patients to have eye examinations before and during treatment. Evaluate eye symptoms promptly and discontinue if new or worsening eye disorders.
- Hyperlipidemia: Monitor serum triglycerides before BESREMi® treatment and intermittently during therapy and manage when elevated.
- Hepatotoxicity: Monitor liver enzymes and hepatic function at baseline and during treatment. Reduce dose or discontinue depending on severity.
- Renal Toxicity: Monitor serum creatinine at baseline and during therapy. Discontinue if severe renal impairment develops.
- Dental and Periodontal Toxicity: Advise patients on good oral hygiene and to have regular dental examinations.
- Dermatologic Toxicity: Consider discontinuing if clinically significant dermatologic toxicity.
- Driving and Operating Machinery: Advise patients to avoid driving or using machinery if they experience dizziness, somnolence, or hallucination.

Please see full Prescribing Information, including Boxed Warning.

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