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# NEW ROPEGINTERFERON ALFA-2B DATA SUGGEST ALTERNATE DOSING SCHEDULE MAY ACHIEVE GREATER AND QUICKER COMPLETE HEMATOLOGIC AND MOLECULAR RESPONSES IN POLYCYTHEMIA VERA

**JUNE 30, 2023, TAIPEI –** **PharmaEssentia Corporation** (TPEx:6446), a leading fully integrated biopharmaceutical company in Taiwan, today announced the publication of new results from a Phase 2 clinical study with ropeginterferon alfa-2b (marketed as BESREMi®) for the treatment of patients with polycythemia vera (PV). This study, which was conducted in China, demonstrated the efficacy and tolerability of ropeginterferon alfa-2b using an alternate dosing regimen that has a higher starting dose and a more rapid dose titration as compared to current U.S. label dosing. The publication, titled "*A new dosing regimen of ropeginterferon alfa-2b is highly effective and tolerable: findings from a phase 2 study in Chinese patients with polycythemia vera*," was published in *Experimental Hematology & Oncology* and co-authored by PharmaEssentia researchers.

PV is the most common myeloproliferative neoplasm (MPN) and a long-term, potentially life-threatening disease with limited approved treatment options. Patients with PV are at an increased risk of developing thromboembolic events due to increased blood cell counts and have a long-term risk of progression to myelofibrosis or transformation to acute myeloid leukemia.[1] Per current label dosing, the recommended starting dose of ropeginterferon alfa-2b is 100 µg, with dose increases of 50 µg every two weeks until hematologic parameters are stabilized (up to a maximum dose of 500 µg).[2] The intention of this study was to assess whether ropeginterferon alfa-2b treatment at a starting dose of 250 µg, followed by 350 µg two weeks later and then 500 µg from week 4 onwards could achieve faster and improved clinical efficacy within 24 weeks of treatment with acceptable tolerability. The study included 49 patients with PV with resistance or intolerance to hydroxyurea. Key findings included:

- The complete hematologic response (CHR) rate at week 24 (61.2%) was notably higher than that at 12 months previously observed in the PROUD-PV study and a Phase 2 study by Edahiro et al. (43.1% and 51.7%, respectively), both of which used the current labeled dose titration schedule.[3,4]
- 41 out of 48 patients who completed the study[i] (85.4%) saw a reduction in *JAK2*$^{V617F}$ allele burden.

"The study shows that using this dosing regimen of ropeginterferon alfa-2b can help achieve desired clinical outcomes earlier for patients living with PV," said Dr. Albert Qin, Chief Medical Officer of PharmaEssentia and one of the authors of the publication. "We were encouraged to also see higher CHR rates at treatment week 24. In addition, we observed a decrease in the *JAK2*$^{V617F}$ allele burden from baseline, showing the potential of ropeginterferon alfa-2b to help reduce the risk of disease progression over time."

Ropeginterferon alfa-2b was generally well-tolerated in this study. Adverse events (AEs), which were mostly mild or moderate, were reported in 48 out of 49 patients. The most common AEs

[i] Only 48 patients completed the Phase 2 study as one patient withdrew.

with an incidence ≥ 10% included an increase in alanine aminotransferase (ALT) and aspartate aminotransferase (AST) with the majority being grade 1 or grade 2.

Long-term treatment and follow-up of the patients in the study are planned to assess progression-free and overall survival.

**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. PV may result in cardiovascular complications such as thrombosis and embolism, and often transforms 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.[5]

**About BESREMi (ropeginterferon alfa-2b-njft)**
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 treatment of polycythemia vera (PV) in the United States. The product was approved by the European Medicines Agency (EMA) in 2019, in the United States in 2021, and has also received approval in Taiwan, South Korea and most recently, Japan. 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. The company retains full global intellectual property rights for the product in all indications.

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

**Please see accompanying full Prescribing Information, including Boxed Warning.**

**About PharmaEssentia**
PharmaEssentia (TPEx: 6446), headquartered in Taipei, Taiwan, is a leading fully integrated biopharmaceutical company in Taiwan. Leveraging deep expertise and proven scientific principles, PharmaEssentia 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 2000 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.

**Forward Looking Statement**
This press release may contain forward looking statements, including statements regarding the clinical benefits to be derived from ropeginterferon alfa-2b and potential new indications or labeling for ropeginterferon alfa-2b. 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 risks and uncertainties related to the initiation, timing, progress and results of clinical trials and regulatory submissions. 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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[3] Gisslinger H, Klade C, Georgiev P, Krochmalczyk D, Gercheva-Kyuchukova L, Egyed M, et al. Ropeginterferon alfa-2b versus standard therapy for polycythaemia vera (PROUD-PV and CONTINUATION-PV): a randomized, non-inferiority, phase 3 trial and its extension study. Lancet Haematol. 2020;7:e196–208.
[4] Edahiro Y, Ohishi K, Gotoh A, Takenaka K, Shibayama H, Shimizu T, et al. Efficacy and safety of ropeginterferon alfa-2b in Japanese patients with polycythemia vera: an open-label, single-arm, phase 2 study. Int J Hematol. 2022;116:215–27.
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