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PHARMAESSENTIA INITIATES PHASE 3B TRIAL OF ROPEGINTERFERON ALFA-2B-NJFT INVESTIGATING NEW DOSING REGIMEN FOR PATIENTS WITH POLYCYTHEMIA VERA (PV)

Single-arm trial will evaluate an accelerated dosing schedule

May 3, 2023, 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 first patients are now being dosed in ECLIPSE PV, a Phase 3b clinical study evaluating an accelerated dosing schedule for ropeginterferon alfa-2b-njft using a prefilled syringe for the treatment of adults with polycythemia vera (PV).

Ropeginterferon alfa-2b-njft (marketed as BESREMi®) was approved by the U.S. Food and Drug Administration in November 2021 as a treatment for adults with PV.[1] PV is a rare, chronic and life-threatening blood cancer caused by a mutation in hematopoietic stem cells in the bone marrow, resulting in the overproduction of red blood cells, white blood cells and platelets. Individuals with PV are at risk for serious health problems, including blood clots, stroke and heart attack.[2,3] Without proper management, this debilitating cancer can progress into myelofibrosis and other malignancies, including acute myeloid leukemia.[4]

“This therapy represents an important addition to the treatment arsenal for PV in the U.S., and clinical data supports its use across a broad range of patients regardless of their treatment history,” said John Mascarenhas, M.D., professor of medicine, hematology, and medical oncology at the Icahn School of Medicine at Mount Sinai in New York. “This new study is addressing an important therapeutic and clinical question regarding whether treatment utilizing accelerated dosing leads to a more rapid hematologic and molecular response, indicating potential disease modifying activity and long-term disease control.”

The study will evaluate an accelerated dosing schedule for ropeginterferon alfa-2b-njft compared to the current labeled dosing. The primary endpoint is the proportion of patients achieving a CHR, defined as hematocrit <45% for at least 3 months since last phlebotomy, platelets $\leq 400 \times 10^9$/L, leukocytes $\leq 10 \times 10^9$/L, at 24 weeks of treatment. Approximately 100 adults with PV in the U.S. and Canada will be randomized to receive either the accelerated dosing (i.e., starting dose of 250 mcg, then 350 mcg at week 2, with a target optimal dose of 500 mcg at week 4, and then dosing will remain fixed at the highest tolerated dose for the remainder of the treatment period) or patients will receive the current labeled dosing (50 or 100 mcg starting dose with 50 mcg titration every 2 weeks). There is a 48-week study period followed by a 28-day safety follow-up. Those who respond to treatment will be eligible to participate in a long-term extension phase of the study.

“Our goal with this study is to deliver evidence on the potentially enhanced benefits of treating patients with BESREMi through this accelerated dosing schedule and to bring additional confidence to clinicians and patients in the utility of the treatment to manage this chronic cancer,” said Raymond Urbanski, M.D., Ph.D., U.S. Head of Clinical Development and Medical

Affairs. “We believe this study will deliver further insight into the potential of BESREMi to meet the needs of PV patients.”

More information on the study including eligibility criteria can be found by visiting www.eclipsepv.com or www.clinicaltrials.gov and searching for the trial identifier NCT05481151. Topline data from the trial are expected by 2024.

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 the treatment of polycythemia vera (PV) in adults in the United States. The product was approved by the European Medicines Agency (EMA) in 2019, in Taiwan in 2020, in South Korea and the United States in 2021, and has recently received approval in Japan. The drug candidate 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 Polycythemia Vera (PV)

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.[4]

About PharmaEssentia

PharmaEssentia (TPEx: 6446), headquartered in Taipei, Taiwan, is a rapidly growing, fully integrated global biopharmaceutical innovator. Leveraging proven scientific principles and deep expertise in commercializing medicines, PharmaEssentia aims to build upon its discovery-based innovation to deliver biologics for challenging diseases in hematology, oncology and immunology. With an approved product and a diversifying pipeline, PharmaEssentia strives to be an essential partner in cancer care by reshaping the treatment path for diseases with significant unmet medical needs. 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, and a new research and development facility in the Boston, Massachusetts, area.

For more information about PharmaEssentia USA, visit the website, LinkedIn or Twitter.

Forward Looking Statement

This press release may contain forward-looking statements. 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 our research and development programs, preclinical studies, 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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[1] BESREMi Prescribing Information. PharmaEssentia 2021.
[2] Mehta J, Wang H, Iqbal SU, Mesa R. Epidemiology of Myeloproliferative Neoplasms in the United States. *Leuk Lymphoma*. 2014 Mar;55(3):595-600.
[3] 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.
[4] 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 J*. 2015;5, e366; doi:10.1038/bcj.2015.95.