PharmaEssentia

PHARMAESSENTIA JAPAN FILES MARKETING AUTHORIZATION APPLICATION FOR ROPEGINTERFERON ALFA-2B FOR THE TREATMENT OF POLYCYTHEMIA VERA

April 27, 2022, Burlington, MA – PharmaEssentia Japan, the Japanese 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, announced that it has submitted a marketing authorization application to the Ministry of Health, Labour and Welfare (MHLW) for ropeginterferon alfa-2b for the treatment of adults with polycythemia vera (PV).

The application is based on a series of clinical development programs including a phase II clinical study in Japan (A19-201 study) and a global phase III clinical study (PROUD-PV study) and its extension study (CONTINUATION-PV study). The treatment received approval for the PV indication by the U.S. Food and Drug Administration in 2021, and was approved by the European Medicines Agency (EMA) in 2019 (brand name: BESREMi®).

“We congratulate our Japanese colleagues on this important milestone toward bringing ropeginterferon to the PV community in Japan,” said Meredith Manning, U.S. General Manager. “We believe strongly in our mission to introduce this next-generation therapeutic option to advance the care of PV, and are encouraged to see continued progress in reaching more patient communities around the world.”

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.[1]

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.

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[1] 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 Journal (2015) 5, e366; doi:10.1038/bcj.2015.95.

US-BSRM-2200046 03/2022