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PHARMAESSENTIA RECEIVES REGULATORY APPROVAL IN SOUTH KOREA FOR BESREMI (ROPEGINTEREON ALFA-2B) TO TREAT POLYCYTHEMIA VERA

Next-generation interferon now approved in Taiwan, Europe and South Korea; US regulatory decision expected in November 2021

October 14, 2021, Burlington, MA – 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 its South Korean subsidiary has received approval for BESREMi (ropeginterferon alfa-2b) for the treatment of polycythemia vera (PV) from the Ministry of Food and Drug Safety (MFDS).

"We are incredibly pleased to launch BESREMi, a next-generation interferon for people with PV in Korea," said Ko-Chung Lin, Ph.D., Co-Founder and Chief Executive Officer for PharmaEssentia. "We will actively collaborate with key stakeholders and medical leaders to make BESREMi available for the PV community in Korea."

BESREMi previously received regulatory approval in Taiwan and in the E.U. for the treatment of PV without symptomatic splenomegaly in adults; it received orphan drug designation from MFDS in July 2020. PharmaEssentia is also seeking approval for the PV indication in the U.S. and expects a decision by the U.S. Food and Drug Administration (FDA) in November 2021.

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. This condition may result in cardiovascular complications such as thrombosis and embolism, as well as transformation 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 Ropeginterferon alfa-2b

Ropeginterferon alfa-2b is a long-acting, mono-pegylated proline interferon aimed to be administered once every two weeks or longer. Ropeginterferon alfa-2b 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. Ropeginterferon alfa-2b was discovered and is manufactured by PharmaEssentia in its Taichung plant, which was cGMP certified by TFDA in 2017 and by EMA in January 2018.

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.

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