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PHARMAESSENTIA RESUBMITS APPLICATION TO THE U.S. FDA FOR ROPEGINTERFERON ALFA-2B-NJFT TO TREAT POLYCYTHEMIA VERA (PV)

May 14, 2021, Burlington, MA – PharmaEssentia USA Corporation, a subsidiary of Taiwan-based PharmaEssentia Corp. (TPEx: 6446), a global biopharmaceutical innovator leveraging deep expertise and proven scientific principles to deliver new biologics in hematology and oncology, today announced the resubmission of its Biologics License Application (BLA) to the U.S. Food and Drug Administration (FDA), seeking approval for ropeginterferon alfa-2b-njft for the treatment of polycythemia vera (PV), a rare blood cancer.

The resubmission follows receipt of a complete response letter in March, in which the FDA sought additional information about the administration format with the product. Importantly, no concerns were raised about the clinical profile of the product. Also noted were COVID-related restrictions that delayed the required pre-approval inspection of the company's manufacturing facility in Taiwan.

"We are confident that we have thoroughly addressed the information requests and look forward to engaging with the Agency throughout its review of our application, which we believe supports a positive profile for ropeginterferon alfa-2b-njft," said Meredith Manning, U.S. General Manager. "We remain steadfast in our goal to introduce a much-needed new therapeutic option for the U.S. PV community, fostering more modern approaches to care that can help reduce the risk of disease progression."

Ropeginterferon alfa-2b-njft has Orphan Drug designation for the treatment of PV in the United States. Marketed as Besremi® in Europe, the product was approved by the European Medicines Agency (EMA) in 2019. The molecule was invented and is manufactured by PharmaEssentia.

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 product already approved in Europe 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.

Forward Looking Statement

Some of the statements included in this press release, particularly those relating to the results of clinical trials, the clinical benefits to be derived from ropeginterferon alfa-2b-njft, regulatory

submissions and the timing of any such review, approvals, the commercial opportunity and competitive positioning, and any business prospects for ropeginterferon alfa-2b-njft, may be forward-looking statements that involve a number of risks and uncertainties. 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. Among the factors that could cause our actual results to differ materially are the following: acceptance of the BLA filing does not represent final evaluation of the adequacy of the data submitted in the BLA; whether the FDA will complete its review of the BLA on a timely basis; the risk that the FDA ultimately denies approval of the BLA; whether the FDA concurs with our interpretation of our phase 3 study results, supportive data, or the conduct of the studies; whether, ropeginterferon alfa-2b-njft, if approved, will be successfully launched and marketed; and other risk factors identified from time to time in our reports filed with any global securities regulator or agency. Any forward-looking statements set forth in this press release speak only as of the date of this press release. We do not undertake to update any of these forward-looking statements to reflect events or circumstances that occur after the date hereof. The information found on our website, and the FDA website, is not incorporated by reference into this press release and is included for reference purposes only.

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