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U.S. FDA ACCEPTS PHARMAESSENTIA'S BLA RESUBMISSION FOR ROPEGINTERFERON ALFA-2B-NJFT FOR THE TREATMENT OF POLYCYTHEMIA VERA (PV)

FDA assigns a new PDUFA action date of November 13, 2021

June 3, 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 that the United States Food and Drug Administration (FDA) has accepted the Company's resubmission of its Biologics License Application (BLA) seeking approval for ropeginterferon alfa-2b-njft for the treatment of polycythemia vera (PV), a rare blood cancer. The FDA has assigned a six-month review period for the resubmitted application and provided November 13, 2021 as the target Prescription Drug User Fee Act (PDUFA) action date.

"The FDA's acceptance of our resubmitted application for ropeginterferon alfa-2b-njft is a positive step forward and we will work actively with the Agency during its review," said Meredith Manning, U.S. General Manager. "We eagerly look forward to contributing to advances in care through a new therapeutic solution for this challenging rare blood cancer."

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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