

## **PHARMAESSENTIA PROVIDES U.S. REGULATORY UPDATE ON ROPEGINTERFERON ALFA-2B-NJFT FOR THE TREATMENT OF POLYCYTHEMIA VERA (PV)**

March 14, 2021, Burlington, MA – [PharmaEssentia Corporation](#) (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 U.S. Food and Drug Administration (FDA) has issued a complete response letter (CRL) for the company’s Biologics License Application (BLA) for ropeginterferon alfa-2b-njft for the treatment of polycythemia vera (PV), a rare blood cancer.

The rationale for the CRL was COVID-related travel restrictions, which delayed a required pre-approval inspection of the company’s manufacturing facility in Taiwan. The FDA also indicated a need for additional data about the administration format with the product. Importantly, no concerns were raised about the clinical profile of the product.

“We are confident that we can work with the Agency to address the requests highlighted in the response letter and resubmit in an expeditious manner,” said Meredith Manning, U.S. General Manager. “We remain fully committed to introducing ropeginterferon alfa-2b-njft to the U.S. PV community.”

Rpeginterferon 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) 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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