Biofrontera Inc. Announces FDA Approval of Biofrontera Pharma GmbH as a Contract Laboratory for Ameluz®

Significantly Improves Manufacturing Efficiency, Quality Control and Supply Reliability

WOBURN, Mass., April 13, 2022 (GLOBE NEWSWIRE) — Biofrontera Inc. (Nasdaq: BFRI), a biopharmaceutical company specializing in the commercialization of dermatological products, announced today that the U.S. Food and Drug Administration (FDA) has approved Biofrontera Pharma's cGMP laboratory in Leverkusen, Germany, as a contract laboratory for batch control and stability testing of Ameluz® (aminolevulinic acid hydrochloride gel, 10%). This recognition enables significant improvements in product manufacturing efficiency, quality control and reliability of supply.

The FDA cleared Biofrontera Pharma GmbH's laboratory to operate a method of impurity testing, which is a critical component of the gel's stability assurance. The clearance enables part of the necessary testing of production batches to be performed in the Leverkusen facility, thereby reducing dependence on third-party suppliers and the risk of production downtime and product delays. Previously, quality control was conducted entirely by contract manufacturers in collaboration with third-party providers.

"Impurity testing is extremely complex and one of the most important components of batch release and stability testing. To establish such a method at third-party suppliers could take a year or two, and several contract laboratories have already failed at establishing the specific methods we need for Ameluz®. Bringing this important function under the control of our licensor therefore strengthens quality control, reduces third-party dependence and enables transparency to identify opportunities for further developments," stated Hermann Lübbert, Executive Chairman of Biofrontera Inc.

"Under a license and supply agreement with Biofrontera AG, we have exclusive rights to market and sell Ameluz and the PDT-lamps BF-RhodoLED® and RhodoLED XL in the U.S. As our U.S. commercial sales build momentum, we appreciate the importance of optimizing for scale and ensuring commercial supply without compromising quality," stated Erica Monaco, Chief Executive Officer of Biofrontera Inc.

About Biofrontera Inc.

Biofrontera Inc. is a U.S.-based biopharmaceutical company commercializing a portfolio of pharmaceutical products for the treatment of dermatological conditions with a focus on PDT and topical antibiotics. The Company's licensed products are used for the treatment of actinic keratoses, which are pre-cancerous skin lesions, as well as impetigo, a bacterial skin infection. For more information, please visit www.biofrontera-us.com.

Forward-Looking Statements

Certain statements in this press release may constitute “forward-looking statements” within the meaning of the United States Private Securities Litigation Reform Act of 1995, as amended to date. These statements include, but are not limited to, statements relating to the expected trading commencement and closing dates. We have based these forward-looking statements on our current expectations and projections about future events, nevertheless, actual results or events could differ materially from the plans, intentions and expectations disclosed in, or implied by, the forward-looking statements we make. These risks and uncertainties, many of which are beyond our control, including, but not limited to, the impact of extraordinary external events, such as the current COVID-19 pandemic; any changes in the Company’s relationship with the Licensor; the Company’s ability to achieve and sustain profitability; whether the current global disruptions in supply chains will impact the Company’s ability to obtain and distribute its licensed products; changes in the practices of healthcare providers, including any changes to the coverage, reimbursement and pricing for procedures using the Company’s licensed products; the uncertainties inherent in the initiation and conduct of clinical trials; availability and timing of data from clinical trials; whether results of earlier clinical trials or trials of Ameluz® in combination with BF-RhodoLED® in different disease indications or product applications will be indicative of the results of ongoing or future trials; uncertainties associated with regulatory review of clinical trials and applications for marketing approvals; whether the market opportunity for Ameluz® in combination with BF-RhodoLED® is consistent with the Company’s expectations; whether the Company will be able to successfully complete the transition to a public company operating independently of Biofrontera AG; the Company’s ability to retain and hire key personnel; the sufficiency of cash resources and need for additional financing and other factors that may be disclosed in the Company’s filings with the SEC, which can be obtained on the SEC website at www.sec.gov. Readers are cautioned not to place undue reliance on the forward-looking statements, which speak only as of the date on which they are made and reflect management’s current estimates, projections, expectations and beliefs. The company does not plan to update any such forward-looking statements and expressly disclaims any duty to update the information contained in this press release except as required by law.

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