Biofrontera Inc. Announces Last Patient Out in Phase I Study to Evaluate Safety and Tolerability in Treating Actinic Keratosis Using 3 Tubes of Ameluz®

WOBURN, MA / ACCESSWIRE / April 26, 2023 / Biofrontera Inc. (NASDAQ:BFRI), a biopharmaceutical company specializing in the commercialization of dermatological products, today announced that that the last patient in a Phase I study to evaluate the safety and tolerability of Ameluz® – PDT for treatment of mild to severe actinic keratosis on the face and scalp in the expanded treatment field using 3 tubes of BF-200 ALA 10% gel (Ameluz) has now completed the study. This Phase 1 clinical study is being conducted by Biofrontera Bioscience GmbH, a wholly owned subsidiary of Biofrontera AG. Top line results from the study are expected in the fourth quarter of 2023.

“We are pleased to announce the completion of the last patient visit in this Phase I study, which represents an important advancement in the treatment of AK with Ameluz – PDT,” said Erica Monaco, Chief Executive Officer of Biofrontera, Inc. “We look forward to reviewing the top line results and anticipate that with FDA approval, AK treatments using 3 tubes of Ameluz can have benefits for both patients and physicians through treatment of a wider affected area while potentially requiring fewer office visits.”

About Actinic Keratosis

Actinic keratosis (AK) is the most common pre-cancerous skin lesion caused by chronic sun exposure that may, if left untreated, develop into life-threatening skin cancer called squamous cell carcinoma. AKs typically appear on sun-exposed areas such as the face, bald scalp, arms or the back of the hands. According to the Skin Cancer Foundation, in the U.S. AK affected approximately 58 million people in 2020 and an estimated 13 million AK treatments were performed.

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 photodynamic therapy (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, visit www.biofrontera-us.com and follow Biofrontera on LinkedIn and Twitter.

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 results of the Phase I study, the release of top line results and the potential benefits of AK treatments using 3 tubes of Ameluz® for both patients and physicians. 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 any extraordinary external events; any changes in Biofrontera Inc.'s (the "Company") relationship with its licensors; the ability of the Company's licensors to fulfill their obligations to the Company in a timely manner; 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; the Company's ability to comply with public company requirements; the Company's ability to regain compliance with Nasdaq continued listing standards, 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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