Biofrontera Inc. Announces Last Patient Enrolled in Phase 3 Clinical Study Evaluating Ameluz®-PDT for the Treatment of Basal Cell Carcinoma

Trial Results Expected in Mid-2024

WOBURN, MA / ACCESSWIRE / August 10, 2023 / Biofrontera Inc. (NASDAQ:BFRI) (the "Company"), a biopharmaceutical company specializing in the commercialization of dermatological products, announces that patient enrollment is now complete in the Phase 3 clinical study evaluating Ameluz®-PDT in combination with the BF-RhodoLED® lamp for the treatment of basal cell carcinoma (BCC). This study is being conducted by Biofrontera Bioscience GmbH.

"Completing patient enrollment in this Phase 3 clinical study is an important milestone in our strategy to expand the Ameluz® label beyond actinic keratosis (AK). As awareness about skin cancer increases, so does demand for non-surgical BCC treatments without ionizing radiation. According to the Skin Cancer Foundation, of the 5.4 million annual cases of non-melanoma skin cancer in the U.S., approximately 3.6 million, or 67%, are BCC. There is a significant unmet medical need for more effective, less invasive and cost-efficient therapies that treat BCC as well as underlying premalignancies. We look forward to sharing results from this Phase 3 study in mid-2024," said Hermann Luebbert, Chief Executive Officer and Chairman of Biofrontera Inc.

"In addition to treating individual lesions, Ameluz® is indicated by its prescribing information* for the lesion-directed and field-directed treatment of skin areas with multiple AKs. Superficial BCC is another, more severe form of neoplastic damage that such a field may carry, and inclusion into the label broadens the use of Ameluz® in field-directed treatment, starting a new chapter of PDT for non-melanoma skin cancer", he continued.

This randomized, double-blind, placebo-controlled study aimed at enrolling 186 patients at 19 U.S. sites. With 183 patients now treated, and four more patients screened and awaiting histological results and treatment, the clinical sites have been informed that the enrollment is complete. Each patient had one or more clinically and histologically confirmed superficial BCC. Patients receive one cycle of two PDTs (either Ameluz®-PDT or placebo-PDT) 1-2 weeks apart, which may be repeated after three months if required. The last assessment of the patient will take place three months after the final PDT cycle. The primary endpoint is the composite complete clinical and histological clearance of a main BCC lesion, which was selected at the beginning of the study. In addition, data on drug safety as well as secondary efficacy parameters of all BCCs will be evaluated. After completion of the trial, patients will be followed for an additional five years.

*_**For full prescribing information for Ameluz®, please see https://bit.ly/AmeluzPI**_

About Biofrontera Inc.

Biofrontera Inc. is a U.S.-based biopharmaceutical company commercializing a portfolio of products for the treatment of dermatologic 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 Biofrontera Inc.'s (the "Company") preliminary revenues for the three and six months ended June 30, 2023, expectations for revenue growth in 2023, the adoption of PDT and sBCC for the treatment of actinic keratoses by dermatologists, the achievements of our salesforce and the performance of the Company's new hires. 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 the Company's 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 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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