Biofrontera Inc. Announces Positive Results from Phase 1 Safety Study Evaluating Photodynamic Therapy with Three Tubes of Ameluz®

WOBURN, MA / ACCESSWIRE / August 28, 2023 / Biofrontera Inc. (NASDAQ:BFRI) (the "Company"), a biopharmaceutical company specializing in the commercialization of dermatological products, announces positive topline results from its non-randomized, open-label, multicenter Phase 1 study evaluating the safety and tolerability of 3 entire tubes of BF-200 ALA (Ameluz®) in the treatment of actinic keratosis (AK) on the face and scalp with photodynamic therapy (PDT) using the RhodoLED® XL lamp. Of the 100 patients treated in 9 participating clinical centers, the incidences of Treatment Emergent Adverse Events (TEAEs) were consistent with the TEAEs listed in the US prescribing information (US PI) that are based on studies with 1 tube. The treatment was generally well tolerated and TEAEs were as expected due to the therapeutic principle of photodynamic therapy. All TEAEs were transient. In most cases, they resolved within 1 to 4 days after PDT, but occasionally persisted for 1 to 2 weeks or in a few cases even longer, similar to the TEAEs observed after single-tube PDT. No Serious Adverse Events (SAEs), deaths or other clinically relevant AEs were reported during the study and no subject discontinued the study due to a TEAE.

With results demonstrating no additional safety or tolerability issues with 3 tubes, Biofrontera Inc. intends to present these findings to the U.S. Food and Drug Administration (FDA) during the fourth quarter of this year. This Phase 1 study, conducted by Biofrontera Bioscience GmbH, follows a maximal-usage pharmacokinetics study presented to the FDA in 2021, upon which the FDA requested another safety study focusing on transient side effects before amending the product information, which currently limits use to one tube of Ameluz® per treatment.

"The positive results demonstrated there were no additional safety risks in treatment of AK with three tubes of Ameluz compared to one tube. There are benefits of treatment with 3 tubes for both physicians and patients because of the ability to treat a wider affected area while potentially requiring fewer office visits. With the results of this study and the previously reported pharmacokinetics study, we expect the FDA to waive the restriction limiting treatment to 1 tube at a time, broadening the Ameluz® label for using up to 3 tubes. Ameluz® is the only PDT drug FDA approved for field-directed application, rendering the simultaneous application of up to 3 tubes particularly valuable," said Hermann Luebbert, Chairman and Chief Executive Officer of Biofrontera Inc.

Additionally, following Biofrontera Inc.'s recent announcement of completed patient enrollment in the Phase 3 clinical study evaluating Ameluz®-PDT in combination with the BF-RhodoLED® lamp for the treatment of basal cell carcinoma, all patients in screening at the time have now been randomized. The study is now treating 187 patients, which is one patient

more than agreed upon with the FDA. The last patient to complete the final assessment, which occurs three months after their final PDT, is expected in the first quarter of 2024.

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 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.

Contact:
LHA Investor Relations
Tirth T. Patel
212-201-6614
tpatel@lhai.com

# # #

SOURCE: Biofrontera Inc.

View source version on accesswire.com:
https://www.accesswire.com/777604/Biofrontera-Inc-Announces-Positive-Results-from-Phase-1-Safety-Study-Evaluating-Photodynamic-Therapy-with-Three-Tubes-of-AmeluzR