Biofrontera Inc. Announces First Patient Dosed in Pivotal Phase 3 Clinical Study Evaluating Ameluz®-PDT for the Treatment of Actinic Keratosis on the Extremities, Neck and Trunk

WOBURN, MA / ACCESSWIRE / January 9, 2023 / Biofrontera Inc. (Nasdaq:BFRI), a biopharmaceutical company specializing in the commercialization of dermatological products, today announced that the first patient has been dosed in a Phase 3 randomized, double-blind, vehicle-controlled, multicenter clinical study to evaluate the safety and efficacy of Ameluz® and BF-RhodoLED® XL in the field-directed treatment of actinic keratosis (AK) on the extremities, neck and trunk. This Phase 3 clinical study is being conducted by Biofrontera Bioscience GmbH, a wholly owned subsidiary of Biofrontera AG.

“Having recently kicked off this Phase 3 study with a meeting of clinical trial investigators, dosing the first patient is an important milestone in our clinical development strategy,” said Erica Monaco, Chief Executive Officer of Biofrontera Inc. “With AK affecting an estimated 58 million Americans and driving approximately 13 million treatments annually, there is large and growing demand for a highly effective therapy such as Ameluz-PDT to treat AK beyond the face and scalp. We look forward to expanding the addressable market for Ameluz-PDT.”

“Biofrontera Inc. is at the forefront of treating AK where Ameluz-PDT has demonstrated up to 91% total clearance on the face and scalp in prior clinical trials,” continued Ms. Monaco. “This Phase 3 clinical study supports our strategy to expand the label for Ameluz-PDT for use on the extremities, neck and trunk, and ultimately enables our leading therapy to help many more people who suffer from AK.”

Initially 11 clinical trial sites in the U.S. will participate, enrolling approximately 165 patients stratified by body region. This study utilizes Biofrontera’s new RhodoLED XL, a red-light lamp approved by the U.S. Food and Drug Administration (FDA) for use in PDT in combination with Ameluz® (Ameluz – PDT) for the treatment of mild-to-moderate actinic keratosis.

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.

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 clinical development strategy for Ameluz®, the potential to expand the label of Ameluz®, the addressable market and growing demand for Ameluz® and ongoing clinical trials conducted in collaboration with our licensing partner and the future impact of such trials on the market for Ameluz®. 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 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 complete the transition to a public company; 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:

Biofrontera Inc. Investor Relations
ir@bfinc.com

SOURCE: Biofrontera Inc.

View source version on accesswire.com:
https://www.accesswire.com/734502/Biofrontera-Inc-Announces-First-Patient-Dosed-in-Pivotal-Phase-3-Clinical-Study-Evaluating-AmeluzR-PDT-for-the-Treatment-of-Actinic-Keratosis-on-the-Extremities-Neck-and-Trunk