Biofrontera Inc. Announces FDA Filing of Supplemental New Drug Application for Ameluz® to Permit Up to Three Tubes Per Use

FDA has set a target action date of October 4, 2024

sNDA supported by two Phase 1 safety studies[1]
Aims at actinic keratosis (AK) field treatment with up to 3 tubes

An estimated 13 million treatments given each year for AK in the US[2]

WOBURN, MA / ACCESSWIRE / February 5, 2024 / Biofrontera Inc. (NASDAQ:BFRI) ("Biofrontera" or the "Company"), a biopharmaceutical company specializing in the commercialization of dermatologic products, today announced that the U.S. Food and Drug Administration (FDA) has issued a "*no filing review issues identified"* letter regarding the sNDA (supplementary New Drug Application) submitted by its licensor Biofrontera Bioscience GmbH to increase the maximally approved dosage from one to three tubes of Ameluz® per treatment. FDA has completed its filing review and will begin its substantive review of Biofrontera's communication.

"The studies supporting this application showed robust safety parameters for the simultaneous use of three tubes, with systemic and application site adverse events equivalent to those with one tube," stated Hermann Luebbert, Chief Executive Officer and Chairman of Biofrontera Inc. "Many patients have actinic keratoses over large surface areas and the ability to treat these pre-cancerous lesions in one office visit is more convenient for patients and more efficient for their dermatologists. Therefore, we believe this approval, if granted, will lead to increased use of Ameluz in the US" he continued.

The sNDA is supported by two clinical phase I studies investigating the safety of the application of three tubes of Ameluz®. The first study investigated the blood levels of 5-aminolevulinic acid, the active ingredient in Ameluz®, and its active metabolite protoporphyrine IX (PpIX), in 32 patients. Blood concentrations of these compounds were determined at 14 time points before and up to 10 hours after treatment in two groups of patients: 16 receiving photodynamic therapy (PDT) and three tubes of Ameluz on the face or scalp, and 16 receiving PDT and 3 tubes of Ameluz on other parts of the body. Further to a Type A meeting with the FDA in 2021, an additional safety trial with 100 patients receiving PDT with three tubes of Ameluz® was conducted. This data also formed part of the sNDA.

The studies showed that after application of three tubes the blood concentrations of the active ingredient and the metabolite are transiently increased but they were several magnitudes below those at which side effects are known to occur. The systemic and application site adverse events were similar to those observed with one tube of Ameluz®, with patients frequently experiencing a transient inflammatory response at the application site and pain during illumination that was managed by a cooling air stream.

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. In 2020 approximately 58 million people in the US were affected by AK and 13 million AK treatments were performed.[3]

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 the clinical development strategy for Ameluz®, the potential to expand the label of Ameluz®, 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 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 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 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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