Biofrontera Inc. Receives FDA Approval for New Formulation of Ameluz®

Patent Application Filed with Potential to Extend Ameluz® Protection to 2043

WOBURN, MA / ACCESSWIRE / October 10, 2023 / Biofrontera Inc. (NASDAQ:BFRI) ("Biofrontera" or the "Company"), a biopharmaceutical company specializing in the commercialization of dermatologic products, today announced that its licensor Biofrontera Bioscience GmbH has received approval from the U.S. Food and Drug Administration (FDA) for a new formulation of Ameluz® (aminolevulinic acid hydrochloride) for the treatment of actinic keratosis (AK). The new formulation is covered by the License and Supply Agreement between the two companies.

We anticipate that the new formulation, which will be implemented in all U.S. Ameluz® production beginning in 2024, will improve the safety profile of the topical gel by replacing propylene glycol, an ingredient common in semi-solid formulations, with ingredients already existing in Ameluz®. The improved Ameluz® formulation eliminates potential risks of propylene glycol due to the ingredient exhibiting allergic potential and reacting with other components, giving rise to contaminants accumulating over time.

"Receipt of FDA approval reflects Biofrontera's commitment to continued innovation and improving patient outcomes and experiences with photodynamic therapy (PDT) to treat AK. With a reengineered formulation of Ameluz®, Biofrontera is not only able to deliver a superior product with reduced risk of contaminants, but also potentially benefit from extended patent protection," stated Hermann Luebbert, Chief Executive Officer and Chairman of Biofrontera Inc.

Biofrontera Bioscience has filed a patent application to protect the new formulation given that the nanoemulsion without propylene glycol constitutes a novel invention. If granted, patent protection for Ameluz® could be extended until at least 2043.

"The use of PDT with Ameluz® (Ameluz®-PDT) and RhodoLED® lamps could be protected until 2040 by patents granted on the RhodoLED® lamps and the associated procedure. Patent protection for Ameluz® itself currently expires in 2028, after which protection in the U.S. would rely on the lamp and procedure patents in the combination approval. In addition to extending the overall patent life, a potential new patent on Ameluz® itself would provide considerably stronger protection," added Dr. Luebbert.

The license agreement between Biofrontera Bioscience GmbH and Biofrontera Inc. covers all

new developments and patents on Ameluz®, including the new formulation.

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 the effects and efficacy of the new formulation of Biofrontera Inc.'s (the "Company") licensed product Ameluz®, the reduced risk of contaminants, the potential extension of patent protection for Ameluz® and the benefits of a new patent 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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