Biofrontera Kicks Off US Clinical Study Program for Ameluz®

WOBURN, MA, Nov. 16, 2021 (GLOBE NEWSWIRE) — Biofrontera Inc. (Nasdaq: BFRI) (the "Company"), a biopharmaceutical company specializing in the commercialization of dermatological products, announced today the start of a clinical study program focused on optimizing and expanding the market positioning of its in-licensed FDA-approved prescription drug Ameluz® for photodynamic therapy (PDT) in the United States. Site initiations for two upcoming studies are currently in progress with patient recruitment to start before the end of the year. The studies are being initiated and overseen by Biofrontera AG, an affiliate of the Company.

Within the scope of the license and supply agreement (LSA) between Biofrontera Inc. and Biofrontera AG and its Germany-based subsidiaries (together the "Licensor"), the Company holds the exclusive rights to market and sell Ameluz® and the PDT-lamps BF-RhodoLED® as well as its successor model BF-RhodoLED XL in the United States. Under the terms of the LSA, Biofrontera Inc. acquires Ameluz® from the Licensor for a transfer fee. In exchange for the transfer fee paid for the in-licensed products, the Licensor ensures the manufacturing and the supply of the products as well as responsibility for certain other aspects such as regulatory approvals and quality assurance. In addition, the LSA calls for the Licensor to perform and finance an extensive clinical study program to expand the FDA-approval of Ameluz® in the U.S. market.

Site initiations for two upcoming studies are currently in progress, seven sites for the phase IIb study for the treatment of moderate-to-severe acne in adults as well as eight sites for the phase I safety study evaluating the safety of PDT with the simultaneous application of three tubes of Ameluz®. The latter trial comes on the back of a maximal-usage pharmacokinetics clinical study completed in early 2021. The results from that study were recently published on ClinicalTrials.gov and were presented to the FDA earlier this year. Following that meeting, the FDA requested another safety study focusing on transient application site effects before adding the use of three tubes in one session of PDT to the label. Along with an ongoing phase III study in the United States to evaluate Ameluz® in combination with PDT for the treatment of superficial basal cell carcinoma, which was initiated by the Licensor in 2018, the current site initiations mark the kick-off of the extensive study program under the terms of the LSA.

"We believe the clinical study program supporting the alignment of Ameluz® with the needs of patients and health care professionals is an important piece of the puzzle to reach our goal of establishing Ameluz® as the leading PDT drug for the treatment of actinic keratosis in the United States," states Erica Monaco, Chief Executive Officer of Biofrontera Inc. "The LSA is an important element of the interaction between Biofrontera Inc. and the Germany-based

Biofrontera companies. It provides Biofrontera Inc. with the freedom to grow separately of the success of Biofrontera AG. The recent IPO of Biofrontera Inc. aims at separating Biofrontera Inc. from Biofrontera AG, allowing it to mature and grow according to the needs of a U.S. company active in the U.S. pharmaceutical marketplace."

The Licensor is in the process of preparing further clinical studies in the United States according to the development program that was agreed upon with Biofrontera Inc. Under the LSA, Biofrontera Inc. will benefit from these studies and consequent approval expansions without participating in the cost beyond the transfer fee paid for Ameluz® and BF-RhodoLED®.

Ameluz® gel in combination with PDT using BF-RhodoLED® lamp, is currently indicated by the FDA for the lesion-directed and field-directed treatment of actinic keratoses of mild-to-moderate severity on the face and scalp.

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 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 expected trading commencement and closing dates. 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 the Licensor; the outcome of the Company's litigation with DUSA Pharmaceuticals, Inc., including the trial scheduled to begin at the end of November; the Company's ability to achieve and sustain profitability; whether the current disruptions in the supply chain 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 early clinical trials or trials in different disease indications will be indicative of the results of ongoing or future trials; whether results of the studies described above will be indicative of results for any future clinical trials and studies of

Ameluz® in combination with BF-RhodoLED®; 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; whether the Company will be able to successfully transition to a public company operating independently of Biofrontera AG; 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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