Biofrontera Inc. Enrolls First Subject in Phase 1 Safety Study Evaluating Photodynamic Therapy with Three Tubes of Ameluz®

WOBURN, Mass., Dec. 06, 2021 (GLOBE NEWSWIRE) — Biofrontera Inc. (Nasdaq: BFRI), a biopharmaceutical company specializing in the commercialization of dermatological products, announced today that the first subject has been enrolled in a Phase 1 study to evaluate the safety and tolerability of photodynamic therapy (PDT) for the treatment of actinic keratosis (AK) using three tubes of Ameluz® together with the company's BF-RhodoLED® XL lamp. This open-label study is being conducted at eight sites and will enroll 100 subjects with mild-to-severe AK on the face and scalp.

"Today's news marks an important step in our clinical program for optimizing the positioning of our flagship product Ameluz®," commented Erica Monaco, Chief Executive Officer of Biofrontera Inc. "The use of three tubes of Ameluz® enables treatment of larger surface areas such as for mild-to-severe AK on the face and scalp. Success with this study could significantly improve the competitiveness of Ameluz® in the U.S. and advance Biofrontera's goal of gaining market share for PDT as standard of care for treatment of AK."

The Phase 1 study follows a maximal-usage pharmacokinetics (PK) clinical study that was completed in early 2021. As announced in June, results from that PK study were presented to the U.S. Food and Drug Administration (FDA). The FDA subsequently requested another safety study focusing on transient adverse events before amending the product information, which currently limits use to one tube of Ameluz® per treatment.

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 the fields of photodynamic therapy (PDT) and topical antibiotics, Biofrontera currently commercializes the FDA-approved flagship drug Ameluz® in the United States. When used in combination with PDT and Biofrontera's BF-RhodoLED® lamp, Ameluz®-PDT is indicated for the treatment of actinic keratoses (AK), one of the most common precancerous skin conditions. Biofrontera also commercializes Xepi®, an FDA-approved drug for the treatment of impetigo. In collaboration with dermatologists, Biofrontera is fully committed to advancing treatment options and patient care. 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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