Biofrontera Inc. Announces Enrollment of First Subject in Phase 2b Clinical Trial Evaluating Ameluz® + BF-RhodoLED® in Moderate-to-Severe Acne

WOBURN, Mass., Dec. 13, 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 the Phase 2b study performed by Biofrontera Bioscience GmbH to evaluate the safety and efficacy of Ameluz® in combination with the red-light lamp BF-RhodoLED® for the treatment of moderate-to-severe acne with photodynamic therapy (Ameluz®-PDT).

"Ameluz®-PDT has the potential to improve treatment outcomes for millions of Americans with moderate-to-severe acne. This study is an important component of Biofrontera group's clinical development strategy that aims to expand the FDA-label of our licensed product Ameluz®. The inclusion of additional indications aims at unlocking its full therapeutic and market potential in the US," stated Erica Monaco, Chief Executive Officer of Biofrontera Inc.

The multicenter, randomized, double blind phase II study with four arms uses conventional Ameluz®-PDT and includes 126 adult patients suffering from moderate to severe acne, which will be treated with Ameluz®-PDT or placebo. The efficacy of Ameluz®-PDT will be tested with respect to incubation periods of one and three hours compared to placebo. The composite primary endpoint of the study is the absolute change in the number of inflammatory lesions and an improvement in symptoms. To ensure data consistency across all participating sites, the study will combine clinical assessments performed by the investigators conducting the study with a cutting-edge, FDA-approved, artificial intelligence analysis platform that will provide an automated lesion count along with a severity assessment. A total of seven sites are participating in the study.

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 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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