Biofrontera Inc. provides Update on Patient Recruitment for Phase III Study for the Treatment of sBCC with Ameluz®-PDT

WOBURN, Mass., Feb. 01, 2022 (GLOBE NEWSWIRE) — Biofrontera Inc. (Nasdaq: BFRI) (the "Company"), a biopharmaceutical company specializing in the commercialization of dermatological products, is pleased to provide an update on the patient recruitment for the phase III clinical study for the treatment of superficial basal cell carcinoma (sBCC) with Ameluz® photodynamic therapy (Ameluz®-PDT) in combination with the BF-RhodoLED® lamp in the U.S. To date, 70% of the planned 186 patients have been enrolled in the study. Patient recruitment for this study has been ongoing since 2018 with completion of patient recruitment anticipated by the end of 2022.

"Due to a demanding study protocol mandated by the FDA, the recruitment process has been taking a considerable amount of time and was additionally slowed down by the Covid pandemic, but has recently picked up again", said CEO Erica Monaco. "Following successful FDA approval, Ameluz® would be the only drug in the United States approved for the treatment of superficial BCC with PDT, which we expect to further increase the growth potential of our flagship product Ameluz® in the medium term. "

This randomized, double-blind and placebo-controlled study will include 186 patients at 12 study sites in the United States. Each patient will have one or more clinically and histologically confirmed superficial BCC. Patients will receive one cycle of two PDTs 1-2 weeks apart, which may be repeated after three months if required. The last assessment of the patients will take place three months after the last PDT cycle. After completion of the trial, Biofrontera will follow patients for an additional 5-year period. Each patient will be treated with Ameluz®-PDT or placebo-PDT. The primary study endpoint is the composite complete clinical and histological clearance of a main sBCC lesion, which will be selected at the beginning of the study. In addition, data on drug safety as well as secondary efficacy parameters of all sBCCs will be evaluated in the study.

According to the Skin Cancer Foundation, within the total of 5.4 million annual nonmelanoma skin cancers in the US, approximately 3.6 million skin cancer incidence are BCCs (source: https://www.skincancer.org/blog/our-new-approach-to-a-challenging-skin-cancer-statistic/)

This phase III clinical study, as well as two other clinical studies currently being performed by Biofrontera AG and its Germany-based subsidiaries (together the "Licensor"), focuses on optimizing and expanding the market positioning of the Company's in-licensed FDA-approved prescription drug Ameluz® for PDT in the United States. Within the scope of the license and supply agreement (LSA) between Biofrontera Inc. and the Licensor, the Company holds the exclusive rights to market and sell Ameluz® and the PDT-lamps BF-RhodoLED® as well as the

new RhodoLED® XL in the United States. Under the terms of the LSA, Biofrontera Inc. purchases 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.

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, the Company's estimated revenue for the fourth quarter and year ended December 31, 2021 and statements regarding the future performance of the Company, opportunities for market growth, objectives of management, strategic plans and future operations. The words "believe", "anticipate", "intend", "expect", "target", "goal", "estimate", "plan", "assume", "may", "will", "predict", "project", "would", "could" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. 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 and its evolving nature; any changes in the Company's relationship with its licensors; the outcome of the Company's litigation with DUSA Pharmaceuticals, Inc.,; 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 RhodoLED® lamps 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 and are also available on our website at www.biofrontera-us.com. 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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