Biofrontera Inc. Announces Notice of Allowance for U.S. Patent on Innovative Illumination Protocol

WOBURN, Mass., Dec. 02, 2021 (GLOBE NEWSWIRE) — Biofrontera Inc. (Nasdaq: BFRI), a biopharmaceutical company specializing in the commercialization of dermatological products, announced today that the United States Patent and Trademark Office (USPTO) has issued a Notice of Allowance for the U.S. patent application number 17/234,490, titled "Illumination for Photodynamic Therapy," that covers an innovative, pain-reducing illumination protocol for photodynamic therapy (PDT).

"This patented illumination protocol demonstrates Biofrontera's commitment to the patients' need for innovative treatments. The patent also strengthens Biofrontera's competitiveness for our FDA-approved combination product, Ameluz® together with our PDT-lamp BF-RhodoLED® and its successor model RhodoLED® XL in the U.S. by providing an opportunity to pursue label expansion to include more patient-friendly protocols," stated Erica Monaco, Chief Executive Officer of Biofrontera Inc.

The patent application claims a method for photodynamic therapy in which a dynamic and innovative illumination protocol is implemented. This protocol consists of changing illumination intensities combined in a predefined order with interruptions of the illumination to specifically modulate and reduce pain perception to the patient. The new illumination protocol aims at combining the high efficacy of Ameluz® with the flexibility of BF-RhodoLED® to modulate light for pain reduction to ultimately become a new standard-of-care in PDT.

Implementation of the protocol to Biofrontera's medical devices requires a software installation and can be rolled-out to both the BF-RhodoLED® and BF-RhodoLED® XL lamps. To include this illumination protocol in the U.S. prescribing information, Biofrontera Group, in accordance with pipeline development under the license and supply agreement (LSA) between Biofrontera Inc. and Biofrontera AG, will start a Phase 3 trial for the treatment of actinic keratoses on the face and scalp with 3 tubes of Ameluz® and the RhodoLED® XL lamp involving the new protocol in 2022.

Within the scope of the LSA between Biofrontera Inc. and Biofrontera AG and its Germany-based subsidiaries (together the "Licensor"), Biofrontera Inc. holds the exclusive rights to market and sell Ameluz® and the PDT-lamps BF-RhodoLED® as well as the advanced BF-RhodoLED® XL in the United States. Under the LSA, the Licensor holds the patents for the licensed products.

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 financial impact and benefits of the Company's recent initial public offering and private placement, the clinical developments involving the Company's licenses products and any other statements about future Expectations, prospects, estimates and other matters that are dependent on future events or developments. Statements containing the words "anticipate," "believe," "estimate," "expect," "intend," "may," "plan," "predict," "project," "target," "potential," "likely," "will," "would," "could," "should," "continue," and similar expressions constitute forward-looking statements. 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 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 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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