Biofrontera Inc. Announces FDA Orange Book Listing of U.S. Patent for BF-RhodoLED® XL, Extends Protection of Ameluz®-PDT Through October 2040

WOBURN, Mass., March 14, 2022 (GLOBE NEWSWIRE) — Biofrontera Inc. (Nasdaq: BFRI), a biopharmaceutical company specializing in the commercialization of dermatological products, announced today that the previously granted U.S. patent No. 11,235,169 (the '169 patent) for the BF-RhodoLED® XL illumination device is now listed in the U.S. Food and Drug Administration (FDA) publication "Approved Drug Products with Therapeutic Equivalence Evaluations," commonly known as the Orange Book.

BF-RhodoLED® XL is a red-light lamp approved by the FDA for use in photodynamic therapy (PDT) in combination with Ameluz® (Ameluz®-PDT) for the treatment of mild-to-moderate actinic keratosis. Inclusion of the '169 patent in the Orange Book provides Ameluz®-PDT with protection through October 2040.

The listing of a patent in the Orange Book is confirmation by the FDA that such patent protects an approved drug or drug-device combination and constitutes a hurdle for generic manufacturers who wish to launch a generic product. Should Biofrontera become aware of a generic product imitating the Ameluz®-PDT drug-device combination prior to the expiration of the '169 patent, the filing of a lawsuit would automatically trigger a 30-month stay on the sale of the generic product.

"The Orange Book listing is an endorsement by the FDA that the '169 patent covers our exclusively licensed approved drug-device combination and forestalls any potential generic competition until mid-2040. As previously announced two new patents related to the advanced BF-RhodoLED® XL lamp have recently been granted by the U.S. Patent and Trademark Office. Through our exclusive agreement with Biofrontera Pharma GmbH, our patent strategy is designed to strengthen our competitive advantage by enabling long-lasting protection for Ameluz®-PDT," commented Erica Monaco, Chief Executive Officer of Biofrontera Inc.

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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