New Data and Forecasts for the U.S. Skin Cancer Market Strongly Support the Commercial Opportunity for Biofrontera's Ameluz®

WOBURN, Mass., May 24, 2022 (GLOBE NEWSWIRE) — Biofrontera Inc. (Nasdaq: BFRI), a biopharmaceutical company specializing in the commercialization of dermatological products, views new data on skin cancer prevalence provided by the American Cancer Society[1], indicating approximately 3.4 million U.S. residents could be diagnosed with non-melanoma skin cancer (NMSC) in 2022, as strongly supportive of the commercial opportunity for the Company's flagship product Ameluz®. Additionally, a market survey report published earlier this month by ReportLinker[2], titled "Global Non-melanoma Skin Cancer Market 2022-2026," forecasts the global NMSC market will grow by more than $180 million during that period. The report identifies the increasing incidence of NMSC as a primary driver of market growth, forecasting a compound annual growth rate of 5.8% through 2026.

Ameluz® is utilized along with photodynamic therapy (PDT) provided by the Company's proprietary lamp devices to form Ameluz®-PDT. Ameluz®-PDT is approved by the U.S. Food and Drug Administration (FDA) for the treatment of pre-cancerous skin lesions known as actinic keratoses (AK) on the face and scalp. AK is caused by excessive sun exposure over many years and therefore found predominantly on sun-exposed parts of the body. When left untreated, AK can develop into potentially fatal squamous cell carcinoma (SCC), the second most common form of skin cancer.[3-5]

"With May being Skin Cancer Awareness Month, there is heightened awareness of the prevalence and associated risks of skin cancer, the most common and most preventable cancer in the United States. These updated data and forecasts cast light on the growing market opportunity for Ameluz® and its commercial prospects. Our flagship product, Ameluz®, and the RhodoLED lamp series are gaining significant recognition from clinicians nationwide as the prevalence of skin cancers, most of which are basal and squamous cell carcinomas, increases, and as PDT continues to gain market share from cryotherapy. Expanding PDT as a first-option treatment for AK, especially in patients with more than 15 lesions, is a large and growing opportunity for us," stated Erica Monaco, Chief Executive Officer of Biofrontera Inc.

"Our company's goal is to establish Ameluz® as the leading PDT drug for the treatment of AK in the United States, and leveraging the potential for future FDA approvals and label expansions is a key pillar of our growth strategy. Multiple clinical studies are ongoing by our licensor that are designed to broaden the addressable market and further strengthen the current market positioning of Ameluz®," added Ms. Monaco.

Ameluz® and the RhodoLED® lamps, through the license and supply agreement with Biofrontera AG, are developed further in the U.S. in three ongoing clinical studies:

1. Biofrontera AG is currently enrolling patients in a Phase 3 clinical study in the U.S. evaluating Ameluz®-PDT in combination with the BF-RhodoLED® lamp for the treatment of superficial basal cell carcinoma. This study is approximately 75% enrolled and will enroll a total of 186 patients.
2. Biofrontera AG is currently enrolling patients in a multicenter, randomized, double-blind Phase 2 clinical study evaluating the efficacy of Ameluz®-PDT for the treatment of moderate-to-severe acne. The primary endpoint is the change in number of inflammatory lesions and improvement in symptoms as assessed by the physicians conducting the study and, as an objective comparator, by an automated imaging system. This study enrolled its first patient in December 2021 and will enroll a total of 126 patients.
3. Biofrontera is currently enrolling patients in an open-label, multicenter Phase 1 study evaluating the safety and tolerability of Ameluz® for the treatment of AK located on the face and scalp together with the RhodoLED®-XL lamp. Each patient receives a field-directed treatment with the content of three tubes of Ameluz®, better enabling treatment of larger surface areas. This study enrolled its first patient in December 2021 and will enroll a total of 100 patients.

Biofrontera AG expects enrollment in the superficial basal cell carcinoma study to be completed by the end of 2022, and enrollment in the other two studies to be completed in the second half of 2022.

About Actinic Keratosis

Actinic keratosis (AK) is a superficial, potentially pre-cancerous skin lesion caused by chronic sun exposure that may, if left untreated, develop into life-threatening skin cancer called squamous cell carcinoma. AKs typically appear on sun-exposed areas such as the face, bald scalp, arms or the back of the hands. According to the Skin Cancer Foundation, in the U.S. AK affected approximately 58 million people in 2020 and an estimated 12.7 million AK treatments were performed. The most common treatment for AK is cryotherapy, with approximately 86% of the market. Topical drugs for the treatment of AK had a market share of about 12%, followed by photodynamic therapy (PDT) treatments with about a 2% share.

About Ameluz®

Ameluz® (aminolevulinic acid hydrochloride gel, 10%), Biofrontera’s flagship product, is FDA-approved for use in combination with the BF-RhodoLED® lamp for photodynamic therapy

(PDT) for the lesion-directed and field-directed treatment of actinic keratosis (AK) of mild-to-moderate severity on the face and scalp. Biofrontera's commercial focus is to improve the market positioning of Ameluz® to become the leading PDT drug for the treatment of AK, especially in patients with more than 15 lesions, and positioning Ameluz® as the number one treatment choice for patients with extended skin areas affected by AK. Ameluz® and Biofrontera's RhodoLED® lamp series are being further developed through ongoing clinical studies by Biofrontera's license and supply partner.

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 https://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 Company's business and marketing strategy, future operations and business, potential to expand the label of Ameluz®, market presence and position of Ameluz® and ongoing clinical trials conducted by our licensing partners and the future impact of such trials on the market for Ameluz®. 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 ability of the Company's licensors to fulfill their obligations to the Company in a timely manner; the Company's ability to achieve and sustain profitability; whether the current global disruptions in supply chains 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 earlier clinical trials or trials of Ameluz® in combination with BF-RhodoLED® in different disease indications or product applications will be indicative of the results of ongoing or future trials; 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; the Company's ability to complete the transition to a public company; 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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[2] ReportLinker.com – Global Non-melanoma Skin Cancer Market 2022-2026
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