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Biofrontera Inc. Announces 100 RhodoLED® XL Machines Now Placed in US Market

- Biofrontera started commercial distribution of the RhodoLED XL in June 2024 and has seen rapid uptake in the US market since launch.
- The RhodoLED XL is approved by the FDA in combination with Ameluz® (aminolevulinic acid hydrochloride) topical gel, 10% for photodynamic therapy (PDT) of actinic keratoses of mild-to-moderate severity on the face and scalp.
- Biofrontera's RhodoLED XL and BF-RhodoLED lamps deliver red light energy using long-lasting light-emitting diode (LED) arrays.

WOBURN, Mass., Dec. 23, 2024 (GLOBE NEWSWIRE) -- Biofrontera Inc. (Nasdaq: BFRI) ("Biofrontera" or the "Company"), a biopharmaceutical company specializing in the development and commercialization of photodynamic therapy (PDT), today announced that the 100th commercial RhodoLED® XL Lamp has now been installed in the US market.

The RhodoLED XL was approved by the FDA for use in combination with Ameluz® in 2022 and was launched in June of this year. Since then, it has seen rapid adoption by offices who had previously used Ameluz and those who are new to the product, with 100 now being installed since launch. The main difference between the company's existing BF-RhodoLED lamp and the new RhodoLED XL is the number of LED panels which allows a larger surface area to be illuminated during a single PDT treatment with Ameluz®.

"We are delighted that the RhodoLED XL Lamp has had such an enthusiastic reaction from dermatologists who perform PDT, with more than 10% of offices using Ameluz already installing one" said Dr Hermann Luebbert, CEO and Chairman of Biofrontera Inc. "It is remarkable to have placed this many in such a short span of time post launch, and our customers have been very complimentary about the level of service we have delivered both in the lead up to installation, and with the training and support afterwards," he continued.

After a three-month evaluation of the RhodoLED XL, Dr. Aaron Hoover of Front Range Dermatology, Colorado was so impressed with its performance that his practice decided to purchase not one but two units, including the 100th installed RhodoLED XL lamp. "We were thoroughly impressed by the lamp's robust yet elegant design, as well as its exceptional maneuverability and adjustability, which made it ideal for Photodynamic Therapy (PDT) treatments in our offices," Dr. Hoover explained. "The larger illumination area has significantly increased our patient throughput while also enhancing the overall quality of care and patient experience." Dr. Hoover also noted the high level of satisfaction among both staff and patients with the outcomes of using Ameluz PDT in conjunction with the RhodoLED XL. "Additionally, the Biofrontera team made the purchase and transition to the XL an entirely seamless process for us," he added.

"We were pleased to receive FDA approval for the use of up to 3 tubes of Ameluz® in one treatment in October of this year" stated Dr Luebbert. "With this capability and the larger illumination area of

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Biofrontera Inc. et al v. Sun Pharmaceutical et al

Sun Pharmaceutical's Exhibit 2046

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the RhodoLED XL our physicians can now treat a larger surface area on the face and scalp at one time which is efficient for the office and convenient for their patients” he concluded.

About Actinic Keratosis

AK is the most common 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. In 2020, approximately 58 million people in the US were affected by AK and 13 million AK treatments were performed.²

1. <https://www.skincancer.org/skin-cancer-information/basal-cell-carcinoma/>

2. <https://www.skincancer.org/skin-cancer-information/actinic-keratosis/>

About Biofrontera Inc.

Biofrontera Inc. is a U.S.-based biopharmaceutical company specializing in the treatment of dermatological conditions with a focus on PDT. The Company commercializes the drug-device combination Ameluz[®] with the RhodoLED[®] lamp series for PDT of AK, pre-cancerous skin lesions which may progress to invasive skin cancers. The Company performs clinical trials to extend the use of the products to treat non-melanoma skin cancers and moderate severe acne. For more information, visit www.biofrontera-us.com and follow Biofrontera on [LinkedIn](#) and [Twitter](#).

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. These statements include, but are not limited to, statements relating to Biofrontera's commercial opportunities and the commercial success of its licensed products. 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, include, but are not limited to: the impact of any extraordinary external events; 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 and/or RhodoLED XL 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 and/or RhodoLED XL is consistent with the Company's expectations; 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 Securities and Exchange Commission (the “SEC”), which can be obtained on the SEC's 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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