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Biofrontera Announces the Launch of a New, FDA-Approved Red Light Source, the RhodoLED® XL Lamp - BioSpace



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Biofrontera Announces the Launch of a New, FDA-Approved Red Light Source, the RhodoLED® XL Lamp

June 24, 2024 | 5 min read



Biofrontera Inc. (NASDAQ: BFR1), a biopharmaceutical company specializing in the commercialization of dermatologic products, is proud to announce the launch of its FDA-approved RhodoLED XL, a red light emitting LED lamp.

- 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 launched the commercial distribution of the RhodoLED XL on June 10, 2024, shipping the first three machines within 1 week of launch

WOBBURN, MA, June 24, 2024 (GLOBE NEWSWIRE) -- Biofrontera Inc. (NASDAQ: BFR1), a biopharmaceutical company specializing in the commercialization of dermatologic products, is proud to announce the launch of its FDA-approved RhodoLED XL, a red light emitting LED lamp.



Biofrontera RhodoLED XL®

This innovative device represents a significant advancement in the treatment of PDT with state-of-the-art engineering, robust but sleek construction and an intuitive user interface. It is designed to be simple to maneuver and able to accommodate various patient treatment positions in order to optimize ease of use.

Biofrontera's PDT drug, Ameluz®, is approved by the FDA in combination with either member of the RhodoLED lamp family. The introduction of the RhodoLED XL provides the option to illuminate a larger area in a single on-label Ameluz PDT treatment.

"We are delighted to introduce the RhodoLED XL lamp to the dermatology community in the US," said Dr. Hermann Luebbert, CEO of Biofrontera Inc. "This new device underscores our commitment to innovation and excellence, providing dermatologists with a powerful tool to deliver superior patient care. The XL lamp's advanced features and user-friendly design will undoubtedly set a new standard in photodynamic therapy."

In comparison to Biofrontera's existing lamp, the RhodoLED XL offers a larger illumination area with five panels compared to one, and additional features such as positioning sensors to ensure the patient receives the optimal energy delivery from the LED array.

Dr. Luebbert continued "I'm pleased to say we have already shipped three of these new devices to customers in our first week of launch and the response from dermatology organizations across the US has been very encouraging."

<https://www.biospace.com/biofrontera-announces-the-launch-of-a-new-fda-approved-red-light-source-the-rhodoled-xl-lamp>

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Sun-ITC-0174877

CX-1230.1

IPR2025-00287

Biofrontera Inc. et al v. Sun Pharmaceutical Industries, Inc.

Sun Pharmaceutical's Exhibit 2045

EX2045, Page 1



Cleaver Dermatology

Cleaver Dermatology, a renowned practice with offices in Missouri and Georgia, was the first to have the RhodoLED XL lamp installed.

"We are honored to be the first to integrate the XL lamp into our practice," said Dr. David Cleaver. "The advanced features and versatility of this device represent a considerable upgrade on what has been available until now and will allow us to provide our patients with the highest standard of care. In addition, we have been very pleased with the level of customer service that the team at Biofrontera has delivered."

To request information about the RhodoLED XL lamp, please visit <https://us.ameluz.com/contact-us>.

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 Inc.'s (the "Company") launch of the RhodoLED XL lamp, related commercial opportunities for the Company, and the commercial success of the Company's 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 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.

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 and follow Biofrontera on [LinkedIn](#) and [Twitter](#).



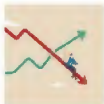
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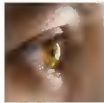
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