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Biofrontera Inc. Announces Patent for Propylene Glycol-Free Formula of Ameluz® (aminolevulinic acid HCl) Topical Gel, 10% Now Listed in FDA Orange Book

- Biofrontera received patent approval for the revised formulation of Ameluz® in April 2025, extending patent protection through to December 2043.
- The Orange Book is published by the U.S. Food and Drug Administration (FDA) and lists all approved prescription drug products, along with patent and exclusivity information.
- Inclusion signifies FDA recognition of the revised formulation's approved status and its intellectual property protection.

WOBURN, Mass., June 03, 2025 (GLOBE NEWSWIRE) -- Biofrontera Inc. (Nasdaq: BFRI), a biopharmaceutical company focused on the development and commercialization of photodynamic therapy (PDT), today announced the inclusion of the patent for its propylene glycol-free formulation of Ameluz® nanoemulsion gel in the US Food and Drug Administration's (FDA's) publication "Approved Drug Products with Therapeutic Equivalence Evaluations" (commonly known as the Orange Book).

The Orange Book is a key reference for healthcare providers, pharmacists, and payers and is the definitive source for identifying FDA-approved drug products. Inclusion of a drug in the Orange Book confirms that the FDA recognizes that the drug meets their rigorous standards for safety, efficacy, and quality. In addition, patents listed confer intellectual property protections which may include the drug's composition, formulation, or specific uses. Listing of the patent for the propylene glycol-free formulation of Ameluz® prevents generic competition as long as the patent is valid, which currently is December 2043.

The revised formulation, which eliminates propylene glycol—a well-known allergen for some patients[1]—demonstrates Biofrontera's continued commitment to innovation and patient-centric

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development. It offers a significant improvement for individuals who are sensitive to this excipient without compromising the treatment's effectiveness. The patent for the revised formulation of Ameluz® was issued on April 22, 2025, and lasts until December 8, 2043. The formulation itself was accepted by the FDA and has been in use since 2024.

"We are proud to announce the inclusion of the patent for our propylene glycol-free formula in the Orange Book," said Dr Hermann Luebbert, CEO and Chairman of Biofrontera Inc. "This recognition validates the differentiated profile of our propylene glycol-free formulation, offering physicians and patients a formulation that reduces the potential for allergic reactions while maintaining the efficacy of Ameluz® RhodoLED PDT."

References:

1. Jacob SE, et al. "Contact Allergy to Propylene Glycol: A Review." Dermatitis. 2008;19(3):157–163. https://pubmed.ncbi.nlm.nih.gov/18569104

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 to 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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