Biofrontera Inc. Completes Transfer of Ameluz® and RhodoLED® FDA approval and Associated Intellectual Property Portfolio

Ameluz® and RhodoLED® New Drug Application (NDA) and Investigational New Drug Application (IND) have successfully been transferred to Biofrontera Inc.
Assignment to Biofrontera Inc. of 11 granted US patents, 10 pending US patent applications and various trademarks associated with Ameluz® and the RhodoLED® Lamp Series has been applied for registration with the relevant authorities, including the US Patent Office (USPTO)
In addition, 19 international patent applications and/or registered designs for RhodoLED® lamps outside of the US were acquired and registration of the transfer has been initiated

WOBURN, Mass., Dec. 18, 2025 (GLOBE NEWSWIRE) — Biofrontera Inc. (Nasdaq: BFRI) ("Biofrontera" or the "Company"), a leader in photodynamic therapy (PDT) development and commercialization, today announced the completion of the transfer of the FDA approvals for Ameluz® and the RhodoLED® Lamp Series, including the NDA and the Investigational New Drug Application (IND), to Biofrontera. In addition, the Company has completed all necessary filings to transfer all US and some international intellectual property associated with Ameluz® and the RhodoLED® Lamp Series, including 11 granted US patents, 10 US patent applications, and 19 patent filings or registered designs outside of the US. The registration of the assignment to Biofrontera of all associated trademarks has also been initiated. These asset transfers were secured, in part, by an $11.0 million investment recently reported by the Company.

With the NDA and IND transfers effective as of December 17, 2025, Biofrontera now assumes full control of the Ameluz® NDA and IND, enabling the Company to manage ongoing and future clinical development activities independently, and to take full responsibility for all aspects of manufacturing and marketing Ameluz® and the RhodoLED® lamps in the US. The patent and trademark transfers further strengthen Biofrontera's intellectual property portfolio and market position in the US.

"This achievement represents the next important milestone in the transformative arrangement we initiated in June 2025," said Dr. Hermann Luebbert, CEO and Chairman of Biofrontera. "By consolidating control of Ameluz's US regulatory filings and its robust patent portfolio, we are positioned to drive operational efficiencies, optimize R&D expenditures, swiftly pursue new indications, and continue refining our RhodoLED® lamp platform – to meet and exceed the evolving needs of clinicians and patients."

About Biofrontera Inc.

Biofrontera 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 Actinic Keratosis, pre-cancerous skin lesions which may progress to invasive skin cancers[1]. 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 X.

References

1 https://www.skincancer.org/skin-cancer-information/actinic-keratosis/

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 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 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; the impact of any extraordinary external events; 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 products; changes in the practices of healthcare providers, including any changes to the coverage, reimbursement and pricing for procedures using the Company's products; 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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