

Last Patient Completes Biofrontera's Phase 1 Pharmacokinetics Study of Ameluz® for Treatment of Actinic Keratoses on the Trunk and Extremities

- Phase 1 Maximal-use Phase 1 study evaluated pharmacokinetic (PK) profile following application of 3 tubes of Ameluz® over treatment area of 240 cm²
- Completion of this study marks a key milestone towards a planned summer 2026 FDA submission for FDA approval for the use of Ameluz® on all non-face and scalp areas

WOBURN, Mass., Dec. 04, 2025 (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 the completion of the final patient visit in its Phase 1 pharmacokinetic (PK) study of Ameluz® (aminolevulinic acid hydrochloride) gel, 10%, for the treatment of mild to moderate actinic keratoses (AKs) on the neck, trunk and extremities (peripheral body areas). The last patient visit took place on 24 November 2025.

Data from this study, together with results from Biofrontera's recently completed Phase 3 clinical trial, will form the basis of a planned supplemental New Drug Application (sNDA) to the U.S. Food and Drug Administration (FDA) seeking to expand the Ameluz® label to include the treatment of AKs on all peripheral body areas. Actinic keratoses commonly occur on sun-exposed areas across the body and may progress to squamous cell carcinoma if left untreated. Expanding Ameluz®'s current FDA approval for use beyond the face and scalp would address a critical unmet need in dermatology.

This open-label Phase 1 study assessed the PK profile of 5-aminolevulinic acid (ALA) and its metabolite protoporphyrin IX (PpIX) during Ameluz®-PDT of the upper extremities, neck or trunk using the BF-RhodoLED® XL lamp. Under maximal use conditions, three tubes of Ameluz® were applied to a treatment area of approximately 240 cm². Seventeen patients received one PDT treatment and blood samples were taken over the 10 hours following the application of Ameluz® to assess the systemic exposure to ALA and PpIX.

“We are delighted to reach this important clinical milestone” said Dr. Hermann Luebbert, CEO and Chairman of Biofrontera Inc. “Completion of this Phase 1 study is a key step toward expanding the use of Ameluz® to treat Actinic Keratoses on the extremities, neck and trunk. If approved this label extension would not only provide meaningful benefits for patients but would be an immense step forward toward our vision to become market leaders in the field of PDT in dermatology.”

Dr. Ted Lain, board-certified dermatologist, Chief Medical Officer of Sanova Dermatology,

Executive Director for the Austin Institute for Clinical Research (AICR) and a key contributor to the Phase 1 study stated “Ameluz® PDT has already proven to be a valuable option for the treatment of AKs on the face and scalp. We see many patients who have these lesions on other areas of the body, and I look forward to potentially having this as an approved option for my patients.”

Pending positive outcomes of this trial and the corresponding Phase III study, the company plans to submit a supplemental New Drug Application (sNDA) to the Food and Drug Administration (FDA) in the Summer of 2026.

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.¹

1. <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 to severe acne. For more information, visit www.biofrontera-us.com and follow Biofrontera on LinkedIn and X.

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 impact of any extraordinary external events; the ability of the Company’s manufacturing partners to fulfill their obligations to the Company in a timely manner; the

Company's ability to achieve and sustain profitability; whether any 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; 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.

Investor Relations Contact:

Ben Shamsian

Lytham Partners

646-829-9701

shamsian@lythampartners.com

