Biofrontera Inc. Announces Database Lock of Phase 1 Pharmacokinetics Study of Ameluz® for Actinic Keratoses on Trunk and Extremities

- Phase 1 maximal-use pharmacokinetics (PK) study completed in support of planned U.S. label expansion
- Data to complement previously announced positive Phase 3 efficacy results on extremities, neck and trunk
- Supplemental NDA submission for extremities, neck and trunk indication expected in Q3 2026

WOBURN, Mass., Feb. 17, 2026 (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 database of its Phase 1 PK study evaluating Ameluz® (aminolevulinic acid hydrochloride) topical gel for the treatment of mild to moderate actinic keratoses (AKs) on neck, trunk and extremities was locked on February 11, 2026.

The Phase 1, non-randomized, open-label study assessed systemic exposure to 5-aminolevulinic acid (ALA) and its metabolite protoporphyrin IX (PpIX) during photodynamic therapy (PDT) with Ameluz® in combination with the red-light BF-RhodoLED® XL lamp. The study was designed to investigate the pharmacokinetics of 5-aminolevulinic acid (ALA) and protoporphyrin IX (PpIX) under maximal use conditions during and after treatment with 3 entire tubes of Ameluz® applied to an approximately 240 cm^2 treatment field.

Seventeen patients received a single PDT treatment with Ameluz®. Plasma concentrations of ALA and PpIX were then measured for a 10-hour period following application.

Together with the Company's previously announced positive Phase 3 clinical results evaluating Ameluz® PDT for mild to moderate AKs on the extremities, neck and trunk, the PK data are intended to support a supplemental New Drug Application (sNDA) to the U.S. Food and Drug Administration (FDA) for expansion of the current label. This submission is expected in the third quarter of 2026 and aims at extending the label from the currently approved indication of an up to 60 cm^2 treatment field with AK on the face and scalp to an AK treatment field of up to 240 cm^2 on other body parts.

"This data base lock represents another important milestone in our clinical program," said Hermann Luebbert, CEO and Chairman of Biofrontera Inc. "The PK data from this study, together with the positive Phase 3 results we recently announced, are designed to support expansion of Ameluz® PDT beyond the current indication of AK on the face and scalp. If approved, this will enable treatment of broader, high-burden AK fields on additional sun-

exposed body areas, further strengthening Ameluz®'s clinical positioning and long-term growth potential."

About Actinic Keratosis

AK is the most common pre-cancerous skin lesion caused by chronic sun exposure that may develop into life-threatening skin cancer called squamous cell carcinoma. AKs typically appear on sun-exposed areas such as the face, bald scalp, decollete, 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 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[5]. 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 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 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 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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