Biofrontera Announces Positive Results in Phase 3 Study of Ameluz® PDT for Actinic Keratoses on the Extremities, Neck, and Trunk, Meeting Primary Endpoint

- Study findings met its primary endpoint and showed highly statistically significant superiority for Ameluz® vs. vehicle gel ($p<0.0003$)
- Actinic keratosis (AK) is the most common skin condition diagnosed by US dermatologists[1]
- If left untreated, AK may progress to squamous cell carcinoma[2,3]

WOBURN, Mass., Feb. 09, 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 positive and statistically significant top-line results from its Phase 3 clinical trial evaluating Ameluz® PDT with the red-light LED (RhodoLED®) platform for the treatment of mild to moderate actinic keratoses (AKs) on the extremities, neck, and trunk.

The multicenter, randomized, double-blind, vehicle-controlled Phase 3 study evaluated the efficacy and tolerability of field-directed Ameluz® PDT compared with vehicle PDT in patients with AKs located on the extremities, neck, and trunk. The study enrolled 172 patients, randomized 4:1 to receive Ameluz® gel or vehicle gel, respectively.

The study was designed to assess treatment of increasing field sizes through the application of one, two, or three tubes of Ameluz® over areas of approximately 80, 160, or 240 cm^2, applied either continuously or in patches, followed by PDT using a RhodoLED® XL or BF-RhodoLED® lamp. Patients received one PDT treatment, with a second PDT treatment administered at Week 12 if any AK lesions remained. Patients are being followed for approximately one year after their final PDT treatment.

The primary endpoint was "subject complete clearance rate," defined as the percentage of patients with complete clearance of all treated AK lesions 12 weeks after the last PDT treatment.

Ameluz® PDT demonstrated highly statistically significant superiority over vehicle PDT for the primary endpoint. In the Full Analysis Set (FAS), complete clearance was achieved in 45.6% of patients treated with Ameluz® PDT (62/136), compared with 16.7% of patients treated with vehicle PDT (6/36) ($p < 0.0003$). In the Per Protocol Set (PPS), complete clearance rates were 53.2% (58/109) for Ameluz® PDT versus 22.2% (6/27) for vehicle PDT ($p < 0.001$).

Key secondary outcomes further supported the efficacy of Ameluz® PDT. The percentage of AK lesion clearance 12 weeks after the last PDT was 73.1% in the FAS and 80.3% in the PPS. Subject complete clearance rates by anatomical location were 38.5% (FAS) and 46.5% (PPS) on the extremities, and 74.1% (FAS) and 78.3% (PPS) on the neck and trunk.

In addition to efficacy, Ameluz® PDT demonstrated favorable cosmetic outcomes and high patient satisfaction. Investigators rated the aesthetic appearance of treated skin as "good" or "very good" in 75.2% of patients, while 70.9% of patients reported similar assessments. Consistent with these results, 86.3% of patients indicated they would choose PDT again for future treatment.

"These results represent a critical milestone in our clinical program," said Hermann Luebbert, CEO and Chairman of Biofrontera Inc. "These data support Ameluz®'s potential to treat broader, high-burden AK fields beyond the face and scalp, significantly expanding its potential clinical use across multiple sun-exposed body areas, underscoring the potential to expand Ameluz®'s addressable market beyond the face and scalp. If approved, this label expansion would provide meaningful benefit to patients with actinic keratoses on the extremities, neck, and trunk and represent an important step forward in advancing our vision to establish leadership in photodynamic therapy."

Nathalie Zeitouni, Professor of Dermatology at the University of Arizona College of Medicine – Phoenix and Adjunct Professor of Oncology at Roswell Park Comprehensive Cancer Center, and coordinating investigator of the study, commented: "Ameluz® PDT is already a valuable treatment option for actinic keratoses on the face and scalp. Many patients present with lesions on other areas of the body, and these data support the potential for Ameluz® PDT to expand treatment options for physicians and their patients."

Based on these positive Phase 3 results, Biofrontera plans to submit a supplemental New Drug Application (sNDA) to the U.S. Food and Drug Administration in the third quarter of 2026.

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[3]. 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. *J Clin Aesthet Dermatol.* 2022;15(5):E82-E86
2. *Cancer.* 2009;115(11):2523-2530
3. *Dermatol Surg.* 2007;33(9):1099-1101

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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