

## **Biofrontera Submits Supplemental New Drug Application to FDA to Expand Ameluz® Red Light PDT to Actinic Keratoses on the Full Body**

**Submission seeks to extend the Ameluz® label beyond the face and scalp to treatment fields of up to approximately 240 cm<sup>2</sup> on the rest of the body, with an adjusted illumination protocol**

WOBURN, Mass., Oct. 08, 2026 (GLOBE NEWSWIRE) — Biofrontera Inc. (NASDAQ: BFRI) (“Biofrontera” or the “Company”), a biopharmaceutical company specializing in the development and commercialization of photodynamic therapy (PDT) in dermatology, today announced that it has submitted a supplemental New Drug Application (sNDA) to the U.S. Food and Drug Administration (FDA) to expand the indication for Ameluz® (aminolevulinic acid hydrochloride) topical gel, 10%, in combination with PDT using the RhodoLED® lamp series, to include mild-to-moderate actinic keratoses (AKs) on the extremities, neck and trunk.

Ameluz® PDT is currently FDA approved for AKs on the face and scalp and, since September 2026, for superficial basal cell carcinoma (sBCC). If approved, the new indication would make Ameluz® with red light the only PDT approved in the U.S. for AKs on full body.

Hermann Luebbert, Chief Executive Officer and Chairman of Biofrontera, said: “This submission is the next step in converting our clinical program into label expansions. Coming only weeks after FDA approval of Ameluz® in combination with RhodoLED® red light for superficial basal cell carcinoma, it reflects our strategy of broadening the clinical utility of our red-light PDT platform. Many patients present with AKs well beyond the face and scalp. If approved, this expansion would allow dermatologists to treat these patients with the same Ameluz® product and the BF-RhodoLED® lamps already installed in their practices.” He continued, “Our revenue growth of 12% for the full year 2025 and about 25% for the first half of 2026 demonstrates the increasingly strong market positions of our products. New FDA approvals like that for sBCC and the one just submitted for AKs on the entire body are expected to accelerate revenue growth even further.”

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: “In my practice I see many patients with AKs well beyond the face and scalp: on the arms, legs, neck, chest and back. Treatment options for these areas are limited, and that remains a real unmet need. If approved, extending Ameluz® PDT to the extremities, neck and trunk would give dermatologists a field-directed option for these patients, and I look forward to having it available.”

The submission is supported by a multicenter, randomized, double-blind, vehicle-controlled Phase 3 trial in 172 patients with AKs on the extremities, neck and trunk, and by a Phase 1 maximal-use pharmacokinetics (PK) study. In the Phase 3 trial, which evaluated 4 to 15 AK lesions in treatment fields of approximately 80, 160 and 240 cm<sup>2</sup>, using one to three tubes of Ameluz<sup>®</sup>, 45.6% of patients treated with Ameluz<sup>®</sup> PDT achieved complete clearance of all treated AK lesions 12 weeks after the last PDT, compared with 16.7% of patients treated with vehicle PDT (p<0.0003, Full Analysis Set). In the study, patients received one PDT treatment, with a second PDT treatment administered at Week 12 if any AK lesions remained. Patients are to be followed for approximately one year after their final PDT treatment.

In addition to efficacy, Ameluz<sup>®</sup> 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.

The sNDA also includes an adjusted illumination protocol, for which approval is being sought for all RhodoLED<sup>®</sup> lamps and all indications, intended to improve patient tolerability of the illumination. The light is ramped up to full intensity, held for a few minutes, and then cycled on and off until the full light dose of 37 J/cm<sup>2</sup> is delivered within 15 minutes in total. PDT-related pain is known to increase with treatment field size; in the new study, pain during illumination with this protocol was no higher than in a comparable Ameluz<sup>®</sup> PDT study in which treatment fields were four times smaller.

Under standard FDA procedures, the agency conducts a filing review within 60 days of receipt of an sNDA to determine whether the application is sufficiently complete to permit a substantive review. The Company will continue to provide an updates.

AK is the most common pre-cancerous skin lesion and is caused by chronic sun exposure; if left untreated, AKs may progress to squamous cell carcinoma. AKs typically appear on sun-exposed areas such as the face and bald scalp, but also on other sun-exposed areas of the body. In 2020, approximately 58 million people in the U.S. were affected by AK and 13 million AK treatments were performed.<sup>1</sup>

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

## **About Biofrontera Inc.**

Biofrontera Inc. is a U.S.-based biopharmaceutical company commercializing a portfolio of pharmaceutical products for the treatment of dermatological conditions with PDT. The Company’s products are used for the treatment of AKs on the face and scalp, which are pre-

cancerous skin lesions, and superficial basal cell carcinoma, and are in development for additional indications. For more information, visit [www.biofrontera-us.com](http://www.biofrontera-us.com) and follow Biofrontera on LinkedIn and X.

## **Investor Contact**

Ben Shamsian  
Lytham Partners  
646-829-9701  
[shamsian@lythampartners.com](mailto:shamsian@lythampartners.com)

## **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. All statements, other than statements of historical facts, in this press release, including statements regarding our strategy, future operations, regulatory process, future financial position, future revenue, projected costs, prospects, plans, objectives of management and expected market growth, are forward-looking statements. The words “believe”, “anticipate”, “intend”, “expect”, “target”, “goal”, “estimate”, “plan”, “assume”, “may”, “will”, “predict”, “project”, “would”, “could” and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. You should read this press release and any documents referenced herein completely and with the understanding that our actual future results may be materially different from what we expect. While we have based these forward-looking statements on our current expectations and projections about future events, we may not actually achieve the plans, intentions or expectations disclosed in or implied by our forward-looking statements, and you should not place undue reliance on our forward-looking statements.

These forward-looking statements are subject to risks, uncertainties and assumptions about us and accordingly, 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: our ability to achieve and sustain profitability; our ability to compete effectively in selling our products; our ability to expand, manage and maintain our direct sales and marketing efforts, including our ability to obtain the financing to develop our marketing strategy, if needed; changes in our relationship with our manufacturing partners and the possible impact of tariffs; our ability to manufacture our products; our ability to adequately protect our intellectual property and operate the business without infringing upon the intellectual property rights of others; our actual financial results may vary significantly from forecasts and from period to period; our estimates regarding anticipated operating losses, future revenues, capital requirements and our needs for additional financing; market risks regarding

consolidation and group purchasing organizations (“GPOs”) in the healthcare industry; the willingness of healthcare providers to purchase our products if coverage, reimbursement and pricing from third-party payors for our products, or procedures using our products significantly declines; our ability to market, commercialize, achieve market acceptance for and sell our products; the fact that product quality issues or product defects may harm our business; any claims brought against the Company, including but not limited to product liability claims, claims of patent infringement, or claims challenging the validity of our intellectual property; our ability to maintain compliance with The Nasdaq Stock Market, LLC continued listing standards; our ability to comply with the requirements of being a public company; the progress, timing and completion of research, development and preclinical studies and clinical trials for our products; our ability to obtain and maintain the regulatory approvals necessary for the marketing of our products in the United States; and other factors that may be disclosed in the Company’s filings with the Securities and Exchange Commission (“SEC”), which can be obtained on the SEC website at [www.sec.gov](http://www.sec.gov). Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures or investments that we may make. We do not assume any obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law. Any forward-looking statements speak only as of the date on which they are made, and we undertake no obligation to publicly update or revise any forward-looking statements to reflect events or circumstances that may arise after the date of this press release, except as required by applicable law. Investors should evaluate any statements made by us in light of these important factors.

