Biofrontera Announces FDA Approval of Ameluz® Red Light PDT for the Treatment of Superficial Basal Cell Carcinoma

Ameluz used in conjunction with the RhodoLED lamp becomes the first and only photodynamic therapy approved in the United States to treat a skin cancer, creating an additional growth opportunity for Biofrontera's photodynamic therapy platform

WOBURN, Mass., Sept. 14, 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 the U.S. Food and Drug Administration (FDA) has approved the Company's supplemental New Drug Application (sNDA) for Ameluz® (aminolevulinic acid hydrochloride) topical gel, 10%, in combination with photodynamic therapy using the BF-RhodoLED® lamp series, for the treatment of superficial Basal Cell Carcinoma (sBCC) in adults[1].

With this approval, Ameluz becomes the first and only PDT drug approved by the FDA for the treatment of a skin cancer, and the only topical PDT in the United States indicated to treat both a pre-cancerous skin condition, actinic keratosis (AK), and a skin cancer. The sBCC indication expands the addressable market for Ameluz and strengthens its position in medical dermatology. This label expansion also furthers Biofrontera's strategy of broadening the clinical utility of its Red-Light PDT platform. Hermann Luebbert, Chief Executive Officer and Chairman of Biofrontera, stated: "FDA approval of Ameluz for superficial basal cell carcinoma is a defining milestone for Biofrontera. Ameluz is now the first and only photodynamic therapy approved in the United States to treat a skin cancer, which sets our platform apart in medical dermatology and gives dermatologists an effective, non-surgical option for a very common tumor. This approval reflects years of disciplined investment in the clinical development of Ameluz, and the latest stage in the ongoing expansion of our PDT platform." He added "We are planning an official launch of the sBCC indication late in the fourth quarter of 2026 through the first quarter of 2027 with our existing commercial organization and installed lamp base. We believe the approval represents a further driver of long-term growth for our existing customers. It also gives new Dermatology practices a reason to purchase a RhodoLED lamp and begin to use Ameluz PDT, expanding our overall installed base." This new indication utilizes the same topical product (Ameluz) and the same red-light device as the Company's AK indication, so our existing customers will be able to rapidly adopt this new treatment option.

Basal cell carcinoma (BCC) is the most common skin cancer in the United States, with approximately 3.6 million cases diagnosed annually, according to the Skin Cancer Foundation. Published estimates suggest that the superficial subtype accounts for

approximately 15%-20% of BCC cases, or an estimated 540,000 to 720,000 sBCC cases annually in the U.S.[2]. Superficial BCC lesions can be up to several cm in diameter and are frequently located on the trunk and extremities and often present as multiple lesions, for which non-surgical, tissue-sparing treatment options are limited.

The approval is supported by a multicenter, randomized, double-blind, vehicle-controlled Phase 3 trial in 187 adults with histologically confirmed sBCC. The primary endpoint was a composite of both clinical and histological complete response of a main target lesion 12 weeks after the start of the last PDT cycle. This rigorous target was achieved in 66% of subjects treated with Ameluz PDT (95/145) compared with 5% of subjects treated with placebo-PDT (2/42). Histological clearance of the main target lesion was seen in 76% of Ameluz PDT treated patients versus 19% with Placebo-PDT, and 83% of Ameluz-treated subjects achieved complete clinical clearance of all target lesions compared with 21% for Placebo-PDT. The most common adverse reactions were application-site reactions consistent with the known safety profile of Ameluz PDT.

Dr. M. Shane Chapman, MBA, board certified dermatologist, Professor and Founding Chair, Department of Dermatology, Dartmouth Hitchcock Medical Center and the Dartmouth Geisel School of Medicine, and a key contributor to the Phase 3 study added “For many patients with superficial basal cell carcinoma – those with multiple lesions, lesions in cosmetically sensitive locations, or for whom surgery would not be preferred – treatment options have been limited. This FDA approval for Ameluz® and the RhodoLED gives us a rigorously studied, non-surgical option that we can deliver in our office. As someone who has worked with PDT for many years, I see this as a meaningful expansion in the use of this treatment.”

[1] Ameluz Prescribing information (https://www.accessdata.fda.gov/drugsatfda_docs/label/2026/208081s040lbl.pdf)

[2] Scrivener Y, Grosshans E, Cribier B. Variations of basal cell carcinomas according to gender, age, location and histopathological subtype. Br J Dermatol. 2002;147(1):41-47

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 photodynamic therapy (PDT). The Company’s products are used for the treatment of actinic keratoses, 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 and follow Biofrontera on LinkedIn and X.

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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. 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.

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