Biofrontera Announces FDA Filing Acceptance of Supplemental New Drug Application for Ameluz® PDT in Superficial Basal Cell Carcinoma

- Prescription Drug User Fee Act (PDUFA) target action date set for September 28, 2026
- If approved, Ameluz® would be the first and only PDT photosensitizer indicated for the treatment of superficial Basal Cell Carcinoma (sBCC) in the US
- BCC is the most common skin cancer in the US with 3.6 million cases diagnosed annually[1]

WOBURN, Mass., Feb. 11, 2026 (GLOBE NEWSWIRE) — Biofrontera Inc. (Nasdaq: BFRI) ("Biofrontera" or the "Company"), a biopharmaceutical company specializing in the commercialization and development of photodynamic therapy (PDT), today announced that the U.S. Food and Drug Administration (FDA) has completed its filing review and accepted filing of the Company's supplemental New Drug Application (sNDA) for Ameluz® (aminolevulinic acid hydrochloride) topical gel used in combination with the RhodoLED® red-light lamp series for the treatment of sBCC. The FDA identified no filing deficiencies and assigned a PDUFA target action date of September 28, 2026.

If approved, this new indication would represent a significant clinical expansion of the Ameluz® PDT platform beyond its existing FDA approval for treatment of actinic keratosis. It would also further validate Biofrontera's PDT approach, which combines Ameluz®'s nanoemulsion technology with red-light illumination designed to penetrate deeper into tissue compared with shorter wavelengths of light such as green and blue, enabling treatment of lesions extending into deeper skin layers.

Basal cell carcinoma is the most common cancer in the U.S., with approximately 3.6 million cases diagnosed annually[1], and published estimates suggest that 10-25% of these cases are of the superficial subtype[2,3,4]. Current treatment options often rely on surgical or destructive approaches, which may not be appropriate or preferred for all patients.

"We are proud of the investments we continue to make in this specialty. This milestone represents an important step forward in our strategy to expand the clinical utility of Ameluz® and reinforce photodynamic therapy as a versatile platform in dermatology," said Dr. Hermann Luebbert, Chief Executive Officer of Biofrontera. "The FDA's acknowledgement of no filing deficiencies in our sNDA reflects the strength of the data package and allows us to move forward with confidence toward a potential new indication that addresses a meaningful unmet medical need."

If approved, Ameluz® PDT for the treatment of sBCC would offer dermatology providers and

their patients a non-invasive treatment option aligned with real-world practice needs. Biofrontera believes this indication has the potential to meaningfully expand the addressable market for Ameluz® and strengthen the Company's position in medical dermatology.

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.

References

1. https://www.skincancer.org/skin-cancer-information/basal-cell-carcinoma/
2. Cameron MC et al, *J. Am. Acad. Dermatol.* 2019;80(2):303-317
3. Cameron MC et al., *J. Am. Acad. Dermatol.* 2019;80(2):321-339
4. Marzuka AG and Book SE. *Yale J Biol Med*. 2015;88(2):167-179

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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