Biofrontera Inc. Announces Data Base Locks for Two Clinical Studies Supporting Key Data and Regulatory Milestones

- **Database locks for studies on actinic keratosis (AK) and acne vulgaris achieved on January 5, 2026**
- **Data generated will support key regulatory milestones for Ameluz PDT in both indications**
- **AK and acne are the two most commonly diagnosed skin disorders in the US[1]**

WOBURN, Mass., Jan. 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), today announced the successful database lock of two clinical studies evaluating Ameluz® PDT, marking an important milestone ahead of several anticipated data and regulatory events in 2026.

The databases for the treatment phase of the Company's Phase 3 clinical study evaluating Ameluz® PDT for the treatment of actinic keratosis (AK) on the extremities, neck and trunk as well as its Phase 2 clinical study evaluating the treatment of moderate to severe acne vulgaris were successfully locked on January 5, 2026.

All data from participants that is collected throughout each study is captured in a specific database. Locking the database enables unblinding and statistical analysis of the study results in accordance with the pre-specified study endpoints. Biofrontera expects data for both studies to be available in February of this year.

Actinic keratosis and acne vulgaris are the two skin disorders most commonly diagnosed by dermatologists in the US[1], with tens of millions of patients impacted.

"Despite the prevalence of AK and acne vulgaris, a large unmet need still exists for the treatment of these common skin conditions. An in-office treatment could significantly improve the compliance rate compared to other therapies for each of these disorders. Growing concerns about antibiotic resistance, systemic safety, and treatment burden have led dermatologists to look at different approaches to prolonged oral antibiotic and isotretinoin use for the treatment of acne[2]. Together with the large number of AKs appearing on areas of the body other than the face and scalp we believe these two indications have the potential to increase the use of Ameluz PDT substantially if approved," commented Prof. Hermann Luebbert, Biofrontera's CEO.

Pending positive outcomes of the Phase 3 AK study, the company plans to submit a supplemental New Drug Application (sNDA) to the U.S. Food and Drug Administration (FDA) in

Summer of 2026 to expand the approved use of Ameluz® PDT for AK beyond the face and scalp. Results from the Phase 2 acne vulgaris study are expected to be presented to the FDA in early Q3 2026 and are intended to provide the basis of a future Phase 3 program, with the goal of achieving approval for Ameluz® PDT in this indication.

Together with the submission in December 2025 of the Company's sNDA for the treatment of superficial Basal Cell Carcinoma (sBCC) with Ameluz® PDT, these milestones support Biofrontera's strategy to expand the clinical utility of its PDT platform and advance additional growth opportunities.

For further information on the two studies, please see Biofrontera's press releases[3,4] from September 16, 2025, and August 25, 2025. The 1-year follow-up phase of the phase III study on AK is still ongoing, but not required for FDA approval of the indication.

References

1. Peck et al., J Invest Dermatol; Vol 142; (8), S60
2. Del Rosso JQ et al., J Clin & Aesthet Dermatol. 2019; 12(6):30-41; Habeshian KA, Cohen BA. Current Issues in the Treatment of Acne Vulgaris. Pediatrics. 2020 May;145(Suppl 2):S225-S230; Leyden JJ, J Eur Acad Dermatol Venereol. 2001;15 Suppl 3:51-5.
3. https://investors.biofrontera-us.com/full-news/?qm-storyId=7016033192978791
4. https://investors.biofrontera-us.com/full-news/?qm-storyId=7994141858240250).

About Actinic Keratosis

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

5. https://www.skincancer.org/skin-cancer-information/actinic-keratosis/

About Acne Vulgaris

Acne vulgaris is the most common skin condition in the United States, affecting an estimated 50 million people each year[1]. Although often associated with adolescence, it persists into adulthood, impacting approximately 40% of adults[2]. The condition ranges from mild blackheads and whiteheads to severe inflammatory forms such as nodules and cysts, which can cause permanent scarring and have profound effects on mental health and self-esteem[3]. Current U.S. guidelines recommend topical therapies, oral antibiotics, and isotretinoin for moderate to severe acne . However, these treatments are frequently limited by significant

systemic side effects, driving demand for safer and more effective alternatives. The U.S. acne treatment market, valued at $5.7 billion in 2024 and projected to grow at a 5.3% CAGR, reflects this unmet need . More than 55% of spending is currently directed to oral antibiotics and isotretinoin , underscoring the reliance on systemic therapies and the opportunity for novel treatment approaches.

About Biofrontera Inc.

Biofrontera Inc. 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 AK, pre-cancerous skin lesions which may progress to invasive skin cancers. 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 Twitter.

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 impact of any extraordinary external events; the Company’s ability to achieve and sustain profitability; whether any 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 the coverage, reimbursement and pricing for procedures using the Company’s products; 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; 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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