Biofrontera Inc. Reports Positive Phase 2b Results Supporting Further Development of Ameluz® Photodynamic Therapy for moderate to severe Acne Vulgaris

Phase 2b study demonstrated greater reductions in inflammatory acne lesions with Ameluz® PDT versus vehicle

3-hour incubation regimen identified as the most promising protocol for further clinical development

Acne vulgaris represents a promising potential future indication for Ameluz®, significantly broadening the Company's dermatology pipeline

WOBURN, Mass., March 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 results of its Phase 2b clinical trial evaluating Ameluz® (aminolevulinic acid HCL) topical gel, 10% PDT for the treatment of moderate to severe acne vulgaris (AV).

The multicenter, randomized, double-blind study compared Ameluz® and vehicle gel using two incubation times (1 hour and 3 hours) prior to illumination with the BF-RhodoLED® lamp. Participants received one tube of Ameluz® or vehicle gel applied to the entire face, followed by incubation and illumination with the red light. Up to three PDT treatments were administered at one-month intervals, and patients were followed up for two months after receiving the final PDT treatment.

The study had co-primary endpoints, one of which looked at the relative reduction in inflammatory lesion counts. The other required an improvement of at least two grades on a 5-point modified Investigator Global Assessment (mIGA) scale and that the patient was rated "clear" or "almost clear" (score 0 or 1).

Clinical results

Greater improvements in both inflammatory lesion counts and mIGA scores were observed with Ameluz® vs. vehicle with the 3-hour incubation regimen, identifying this as the most promising protocol for further clinical investigation in acne vulgaris.

In the 3-hour per-protocol population, the Ameluz group achieved a 57.97% reduction in inflammatory lesions (n=20), compared with 36.51% (n=14) in the corresponding vehicle group. For the mIGA analysis, 25% of the Ameluz treated patients met this co-primary

endpoint with 21.4% of the vehicle patients achieving the same outcome.

Reductions in absolute lesion counts further supported the efficacy of the 3-hour regimen. The values for inflammatory, non-inflammatory and total lesion reductions were 19.7, 23.1 and 42.7 with Ameluz vs. 15.4, 16.5 and 31.9 with vehicle.

Safety, Tolerability and Patient Satisfaction

Ameluz® PDT demonstrated a favorable safety profile consistent with previously reported photodynamic therapy experience. The most frequently reported treatment-related adverse events were burning sensation and pruritus, both of which were generally mild to moderate in severity.

In addition, the average pain scores during the 3-hour incubation PDT treatments were modest, with the values in the Ameluz group ranging from 3.4 to 3.8, and from 2.0 to 2.1 with vehicle on an 11-point scale.

Participants reported high overall satisfaction with PDT treatment. Of the patients who underwent the 3-hour Ameluz incubation, 85.7% said they would choose PDT again and 71.4% of them rated their esthetic outcome as “good” or “very good”.

Medical Need for Moderate to Severe Acne

Acne vulgaris is one of the most common dermatologic conditions in the US, affecting millions of patients and representing a large treatment market. It may lead to permanent scarring and can carry a significant psychosocial burden, including reduced self-esteem and depression.

Current treatment options include topical therapies requiring long-term daily treatment, and systemic antibiotic and oral isotretinoin which may have significant safety considerations. Additionally, increasing antibiotic resistance continues to drive interest in alternative treatment approaches.

As an in-office physician-administered procedure, photodynamic therapy may offer dermatologists an alternative treatment option with a high rate of compliance and that avoids patients having to undergo chronic systemic exposure.

“We are thrilled to reach this crucial milestone in our clinical program”, said Dr. Hermann Luebbert, CEO and Chairman of Biofrontera Inc. “The results of this Phase 2b study show promising reductions of inflammatory, non-inflammatory and total lesions with Ameluz® PDT after 3-hour incubation, as well as an improvement in the mIGA.

The successful completion of this study brings us a step closer to potentially offering an effective and well tolerated treatment option for patients with moderate to severe acne

vulgaris. Expanding the potential indications for Ameluz® demonstrates our commitment to the development of PDT and would further strengthen our dermatology franchise."

Mitchel P. Goldman, MD, FAAD, Medical Director of Cosmetic Laser Dermatology, Board Member of Platinum Dermatology Partners and the coordinating investigator of the study, expressed enthusiasm about its' potential impact for the treatment of acne vulgaris. "Ameluz® PDT has shown encouraging potential for the treatment of moderate to severe acne vulgaris. We see many patients who suffer from this condition, still relying on treatment regimens that often come with a high burden for the patients. The possibility of expanding the use of Ameluz® to treat those patients with PDT is promising for physicians and our patients."

The Company plans to present these Phase 2b data to the U.S. Food and Drug Administration (FDA) in Q3 2026 to discuss potential next steps to develop Ameluz® PDT for the treatment of acne vulgaris.

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[1]. 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.

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; 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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