Biofrontera
Experts in dermatology

News Release

Excellent long-term outcome with field treatment of actinic keratosis with Ameluz®

- 12-month follow-up data of the trial CT007 confirms the sustained efficacy of Ameluz®
- Added benefit of an anti-aging effect that is increasing for 12 months

Leverkusen, Germany, 22 September 2015 – Biofrontera (FSE/AIM:B8F), the biopharmaceutical company focusing on sun-induced skin cancer, announces that preliminary long-term results of the Phase III trial for photodynamic field therapy of actinic keratosis in combination with Biofrontera's PDT lamp BF-RhodoLED® show excellent long term results for patients. This data is a key component in the FDA approval process of Ameluz® and BF-RhodoLED® and will be included in the safety update for the FDA which is due 120 days after submission.

In October 2014 Biofrontera announced the excellent clearance rates in field treatment and the significant improvement in skin complexion shortly after the last treatment with Ameluz® (see announcement of 2 October 2014).

All patients treated within the scope of the trial were further monitored by the trial doctors for one year after the last treatment. The aim of this continued patient observation was to analyze the sustainability of Ameluz®'s pharmaceutical action in terms of efficacy, safety and cosmetic outcome.

During the trial entire fields of actinic keratoses on the face or scalp were treated with Ameluz® in combination with the BF-RhodoLED®. 61.8% of patients were completely cleared from all actinic keratoses after the first treatment cycle with Ameluz®. Patients with remaining lesions received a repeated field treatment, resulting in complete clearance of all actinic keratoses in 90.9% of patients.

The new trial data now confirms that one year later 63.3% of the completely cleared patients are still free of symptoms, which reinforces the previous excellent results of the long-term efficacy obtained with Ameluz® spot therapy.

An added benefit is the progressive improvement of skin complexion in patients treated with Ameluz®. Measuring parameters such as roughness, dryness and flakiness of the skin revealed continuous improvement of the skin surface quality, which one year after the treatment was even more pronounced than after 3 or 6 months. Prior to the PDT with Ameluz® only 14.8 % of patients did not display an impaired skin surface. Twelve weeks after the last PDT already 63% no longer had such impairments. This improvement increased even further to 72.2% of patients after one year. Similar results were obtained for pigmentation disorders. Prior to PDT hyperpigmentation was observed in 59.3%, hypopigmentation in 46.3%, and irregular pigmentation in 48.1% of patients. Twelve weeks after the Ameluz® field therapy these numbers decreased to 42.6%, 29.6% and 29.6%, and improved even further to 24.1%, 11.1% and 18.5%, respectively, within one year.

These results demonstrate the impressive sustainability of the skin rejuvenation effect provided by the photodynamic therapy with Ameluz®, and that the induced repair processes are active over the course of at least 12 months. Patients thus sustainably benefit from both

complete clearance of actinic keratoses as well as the accompanying skin rejuvenation.

It is the first time that data on the aesthetic effect of PDT have been collected during a pivotal Phase III trial. The results emphasize the important role of PDT with Ameluz® and BF-RhodoLED® and affirm that this therapy clearly stands out from many other treatment options.

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Background:

Biofrontera Group (FSE/AIM: B8F, ISIN DE0006046113) is a biopharmaceutical company specialising in the development, sale and distribution of drugs and medical cosmetics for the care and treatment of skin diseases. Biofrontera's most important product is **Ameluz®**, a prescription drug which is approved in Europe for the treatment of mild and moderate actinic keratosis (superficial skin cancer) with photodynamic therapy (light therapy). Biofrontera is the first German pharmaceutical start-up company to obtain centralised approval for a drug it has developed itself. The company also plans for Ameluz® to be approved for basal cell carcinoma and is currently preparing for approval in other countries, especially in the largest pharmaceutical market in the world, the United States.

The company also markets the Belixos® dermatological range of cosmetics. Belixos® products, a cream, a gel and a scalp tonic, contain combinations of active substances extracted from plants, relieve itching and redness and are used for the regenerative care of chronic skin conditions such as atopic dermatitis or psoriasis. The Belixos® Protect, a daily skincare for sun-damaged skin, complements this dermo-cosmetic line. All products are available through Amazon.

The Biofrontera Group was established in 1997 by Prof. Dr Hermann Lübbert, the Chairman of the company's Management Board, and has its headquarters in Leverkusen, Germany.
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