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Experts in dermatology

News Release

Biofrontera delivers excellent results from the Phase III study for field therapy of actinic keratosis for publication

- **Excellent clearance rates with 90.9% of patients cleared from all actinic keratoses**
- **Details of skin quality assessment illustrate strong skin rejuvenation effect**

Leverkusen, 06 May 2015 – Biofrontera AG (AIM/FSE: B8F), the biopharmaceutical company focussing on sun induced skin cancer, has prepared a scientific publication about the results of the multi-centre, placebo-controlled phase III study for field therapy of actinic keratosis using the combination of Biofrontera's prescription drug Ameluz® and PDT-lamp BF-RhodoLED®. Field therapy involves treating entire fields on the face or scalp covered with mild to moderate actinic keratosis with photodynamic treatment (PDT) with an entire tube of Ameluz® in combination with Biofrontera's PDT-lamp BF-RhodoLED®. Preliminary results of the phase III trial were first published in October 2014 and comprise a key component of the clinical program executed for the approval of Ameluz® in the US.

With 90.9% of all patients fully cleared from all actinic keratoses, the combination of Ameluz® and BF-RhodoLED® provided excellent efficacy. After a maximum of two treatments clearance of the non-hyperkeratotic Olsen Grade I lesions[1] reached 99.1%, that of the moderately hyperkeratotic Olsen Grade II lesions 91.7%. Completely eliminating all Olsen Grade I lesions is of particular importance since up to 63.8% of all squamous cell carcinomas originate from the less suspicious Olsen Grade I lesions[2].

The cosmetic outcome of the treatment was assessed by the clinical investigators without taking the removal of the keratotic lesions into consideration. All tested parameters improved significantly during the treatment. The number of patients left without skin roughness, dryness, and scaliness increased from 14.8% to 63% after Ameluz® treatment. Patients without hyperpigmentation or hypopigmentation increased from 40.7% to 57.4% and 53.7% to 70.4%, respectively. Mottled pigmentation, including both hyper- and hypopigmentation within the treatment area, decreased from 48.1% of the patients to 29.6% of the patients, respectively. Before treatment, 22.2% of the patients displayed mild scarring, which after treatment was reduced to 14.8% of the patients. Atrophic skin tissue was apparent in 31.5% of the patients before, and in 16.7% of the patients after treatment.

The study is an important component of the application that is currently prepared by Biofrontera to obtain approval for Ameluz® and BF-RhodoLED® in the USA. No other phase III trial applying PDT in the field-directed approach has ever been conducted, rendering Biofrontera's study an important contribution to the field. The application for approval in the USA is expected to be made by the end of Q2, and approval is anticipated 12 months after application.

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For Biofrontera's strategically evenly important study in Basal Cell Carcinoma the number of enrolled patients is now sufficient for a statistical power of greater than 90%, and Biofrontera's request for completion of patient recruitment is currently evaluated by the responsible federal agency.

Commenting on findings of the study, CEO Prof. Hermann Lübbert said: "Field therapy with PDT should be the standard of care for patients with multiple actinic keratoses because of the extremely high efficacy rates, the potent skin rejuvenation effect documented in this study, and the potential to prevent new neoplastic lesions. The latter effect will be documented further during the ongoing follow-up phase of the study, but the fact that no patient presented with new tumours in the treatment field after Ameluz® treatment, while one patient with new lesions was in fact present in the twice smaller placebo group, may, even though not statistically relevant, indicate the prophylactic effect of field therapy using Ameluz® PDT."

References:

1. Olsen EA, Abernethy ML, Kulp-Shorten C et al. A double-blind, vehicle-controlled study evaluating masoprocol cream in the treatment of actinic keratoses on the head and neck. J Am Acad Dermatol 1991; 24:738–43.

2. Fernandez-Figueras MT, Carrato C, Saenz X, Puig L, Musulen E, Ferrandiz C, et al. Actinic keratosis with atypical basal cells (AK I) is the most common lesion associated with invasive squamous cell carcinoma of the skin. J Eur Acad Dermatol Venereol. 2014.

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Enquiries, please contact:

Biofrontera AG	+49 (0) 214 87 63 2 0
Prof. Hermann Lübbert, Chief Executive Officer	press@biofrontera.com
Thomas Schaffer, Chief Financial Officer	www.biofrontera.com
IR Germany: Brainwell Asset Solutions	+49 (0) 152 08931514
Jürgen Benker	
Nomad and Broker: Shore Capital	+44(0) 20 7408 4090
Bidhi Bhoma / Toby Gibbs	
IR UK: Seton Services	+44(0) 20 7603 6797
Toni Vallen	
Financial PR: Gable Communications	+44(0) 20 7193 7463
John Bick / Justine James	+44 (0)7872 061007

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The **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 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. At the moment, Belixos® cream, gel and scalp tonic 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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