Biofrontera
Experts in dermatology

News Release

Patient recruitment started in phase III study for field-therapy of actinic keratosis

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Leverkusen, Germany, 14. October 2013 – Biofrontera AG (B8F) announced today that first patients were included in its clinical phase III study for field treatment of actinic keratosis. Actinic keratoses commonly occur in larger areas damaged by excess UV exposure, most frequently the forehead, bald scalp or cheeks. Thus, treatment is often required for the entire skin area rather than just individual lesions. In the study, Ameluz® is specifically tested for the treatment of larger areas in combination with Biofrontera's PDT lamp BF-RhodoLED®. In addition to eradicating all actinic keratoses, the general cosmetic result plays an important role. The strong skin rejuvenating effect of PDT is broadly discussed in the dermatologic literature.

The results of the study will complement the data from the previous phase III studies presented for Ameluz® registration. The study is performed on 84 patients. Two thirds of the patients will be treated by photodynamic therapy with Ameluz® and one third with a placebo medication. The study is performed at 7 German medical centers under the medical coordination of Prof. Dr. Uwe Reinhold, Bonn. The treatment entails the application of the entire 2 g tube of Ameluz® or placebo onto the affected skin area, followed by a 10-minute red light illumination 3 hours later. The cure rate is determined after 12 weeks and the treatment repeated once if required.

In addition to expanding the European approval of Ameluz® on field therapy, the results of the study are of relevance to approval in the United States and will be included in the registration package. Registration of Ameluz® in the United States, the largest pharmaceutical market in the world, will more than double the sales potential.

Prof. Hermann Lübbert, CEO of Biofrontera AG, commented: "Patient recruitment is anticipated to be completed by the end of the year, and we

expect the final results of the study in the summer of 2014. The filing in the United States can thus proceed as planned. We are convinced that this study will confirm the very positive results of the previous phase III studies."

Actinic keratoses are the third most frequent reason for visiting a dermatologist's office in the United States. Five million new cases of actinic keratosis occur each year in Europe. This superficial skin cancer develops initially in the form of single, small lesions, usually in the face or on the patient's head, and spreads further in sun-exposed areas such as the nose, forehead or cheeks. In about 10% of the patients at least one lesion crosses the basal membrane and progresses to a potentially hazardous squamous cell carcinoma. Since this event cannot be predicted, an effective treatment of the entire field containing multiple actinic keratoses is required.

Background
Ameluz® was approved by the European Commission as a first-line therapy for the treatment of mild and moderate actinic keratosis on the face and scalp in December 2011. Clinical studies have shown the highest cure rates of actinic keratosis ever reported in Phase III studies with prescription drugs. The product is a photosensitizing agent used in photodynamic therapy (PDT). Actinic keratosis is mostly seen in fair-skinned people on skin areas that have had long-term sun exposure. The condition affects about 10% of the entire Caucasian population world-wide. About 5-20% of patients with actinic keratosis lesions develop malignant and potentially fatal squamous cell carcinomas.

About Biofrontera AG
Biofrontera Pharma GmbH is a wholly-owned subsidiary of Biofrontera AG. The Biofrontera group aims at attending and treating the skin, recognizing the aesthetic needs of a person's visual reflection. Biofrontera is listed at the regulated market of the Frankfurt stock exchange under the symbol B8F and the ISIN number DE0006046113.*www.biofrontera.com*

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