Biofrontera
Experts in dermatology

News Release

Biofrontera Receives Label Expansion for Ameluz® in Europe to Include Field Cancerization

Leverkusen, Germany, September 16, 2016 – Biofrontera AG (FSE: B8F), the specialist for the treatment of sun-induced skin cancer, today announced that the European Commission has issued marketing authorization for an expanded label indication for the Company's topical prescription drug Ameluz® to include field cancerization, significantly expanding the potential market opportunity.

In July 2016, the Committee for Medicinal Products for Human Use (CHMP) issued a positive assessment regarding Biofrontera's label expansion submission. The updated label now states that Ameluz® may be used to treat mild to moderate AK on the face and scalp and field cancerization, entire skin areas infiltrated by tumor cells and entailing several AKs. Such sun-damaged skin areas also benefit from skin rejuvenation triggered by PDT, which improves over at least 12 months after treatment. These skin rejuvenation effects are now also included in the approved product information of Ameluz®.

"We are pleased with the European Commission's decision to grant the expanded label indication for Ameluz® to include field cancerization. Treatment of larger skin regions is the most appropriate and recommended method for treating sun-damaged skin areas with AK. Inclusion of the skin rejuvenation resulting from PDT into the official product information documents an additional benefit of the treatment with our product", commented Prof. Dr. Hermann Lübbert, CEO of Biofrontera. "In line with our commercial development initiatives following U.S. FDA approval of Ameluz® for lesion- and field-directed treatment earlier this year, this label expansion in the EU will enable more patients the opportunity for treatment, further increasing the market potential for Ameluz® in Europe."

Approval of the indication field cancerization is based on the Company's pivotal Phase III trial conducted in Germany. The 86-patient study assessed field-directed treatment using combination Ameluz® and medical lamp BF-RhodoLED® for photodynamic therapy against placebo. The study demonstrated that 91% of patients treated were completely cleared after a maximum of two treatments, compared to only 22% complete clearance in patients treated with the placebo. After one year, full clearance was sustained in more than 90% of the AKs treated with Ameluz®.

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About Biofrontera

Biofrontera Group (FSE: B8F, ISIN DE0006046113) **Biofrontera** is a biopharmaceutical company specializing in the development, sale and distribution of drugs, medical devices and medical cosmetics for the care and treatment of skin diseases. Biofrontera's lead product is Ameluz®, a prescription drug which was initially approved and marketed in Europe and is now also approved in the U.S. in combination with its medical lamp BF-RhodoLED® for photodynamic therapy (PDT) treatment (light therapy) of mild and moderate actinic keratosis, a precursor to squamous cell carcinoma. Biofrontera is the first German pharmaceutical start-up company to obtain centralized EU and now U.S. approval for a medical device/drug it has developed itself.

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 Belixos® products are available in Europe 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.

For more information, visit **www.biofrontera.com**

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