Biofrontera
Experts in dermatology

News Release

European Commission provides unlimited approval for Ameluz®

Leverkusen, Germany, November 29, 2016 – Biofrontera AG (FSE: B8F), the specialist for the treatment of sun-induced skin cancer, today announced that the European Commission has provided an unlimited approval for Ameluz®, Biofrontera's prescription drug for the treatment of mild to moderate Actinic Keratosis on the face and scalp and Field Cancerization. In their decision, the European Commission followed a recommendation by the European Medicines Agency (EMA).

In the centralized European procedure, new medicines initially obtain the approval for five years, after which drug efficacy and safety are thoroughly re-evaluated by the EMA. If, following five years of experience with the new medicine in practical use, the efficacy / safety relationship is still considered positive, the EMA may recommend unlimited extension of the approval. The final decision is taken by the European Commission, which has now been taken for Ameluz®.

In the review process, the high efficacy, safety and the excellent cosmetic outcome of Ameluz® PDT as well as the superiority in the treatment of mild to moderate AK on the face and scalp compared to comparator Metvix were supported by the agency.

"With their positive assessment, the EMA has confirmed the high medical value of the treatment of AK and field cancerization with Ameluz®. With its high efficacy and excellent cosmetic outcome Ameluz®-PDT has been ranked as first-line therapy for these forms of skin cancer. The confirmation by the European commission strengthens Biofrontera's market position in Europe. Along with the recent capital raises of together about EUR 20 mln, which demonstrate the strong support of our major shareholders for Biofrontera's international marketing strategy, Biofrontera has reached another important milestone and strengthened its position as a company and in the market," commented Prof. Hermann Luebbert, Biofrontera's CEO.

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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 most important product is Ameluz®, a prescription drug which was initially approved and marketed in Europe and is now also approved in the US for the treatment of mild and moderate actinic keratosis, a precursor to squamous cell carcinoma, with photodynamic therapy (light therapy). Biofrontera is the first German pharmaceutical start-up company to obtain centralized EU and now US 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, a scalp tonic and acute roll-on, 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.

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

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