Biofrontera
Experts in dermatology

Press Release

European Medicines Agency recommends indication expansion of Ameluz® for treatment of basal cell carcinoma (BCC)

- **Approval by the European Commission expected in the next few weeks**
- **Increased market potential for Ameluz® particularly in hospitals**

Leverkusen, Germany, December 20, 2016 – Biofrontera AG (FSE: B8F), the specialist for the treatment of sun-induced skin cancer, today announced that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has issued a positive opinion with respect to Biofrontera's submission for label extension for its topical prescription drug Ameluz®. The extended approval will include the treatment of superficial and/or nodular basal cell carcinoma unsuitable for surgical treatment due to possible treatment-related morbidity and/or poor cosmetic outcome in adults. Based on the positive opinion, Biofrontera anticipates that the European Commission will issue formal approval within the coming weeks, significantly expanding the European market opportunity for Ameluz®. This will greatly extend the market opportunity for Ameluz®.

The approval for BCC allows Biofrontera to increase its efforts in placing the medicine in hospitals, where BCC is treated more frequently than AK. Dermatologists are predominantly based in hospitals in many European healthcare systems, and the new indication will be most relevant for those markets.

BCCs are the most common invasive tumors in humans and account for 50-80% of all invasive skin cancers. Around 30% of all Caucasians develop at least one BCC in their lifetime, and cases are increasing rapidly worldwide due to elevated exposure to UV light. Surgical removal of BCCs is the most frequent treatment currently used, but this can result in clearly visible scarring. The treatment with photodynamic therapy (PDT) is an alternative particularly for thin BCCs, and gives rise to excellent cosmetic results.

As a prerequisite for the approval of BCC Biofrontera had conducted a pivotal phase III trial with a total of 278 patients. The trial was conducted under the clinical supervision of Prof. Colin Morton (UK) and Prof. Markus Szeimies (Germany) and was carried out at 27 clinical trial centers in the UK and Germany. The results of the trial have been available since January 2016 and formed the basis for the application for approval extension. Efficacy and safety of Ameluz® were compared with that of Metvix®, a medication already approved in the EU for the treatment of BCC. The results confirmed the company's positive expectations. Non-aggressive (superficial and nodular) BCCs with a thickness of up to 2 mm were included in the trial. Ameluz® achieved the complete eradication of all BCCs in 93.4% of the patients, compared to 91.8% with Metvix®. There were greater differences in the case of thicker BCCs. With Ameluz®, 89.3% of the nodular carcinomas were completely removed, compared to only 78.6% with Metvix®. Additionally, after 12 months the recurrence rates were higher for Metvix® than for Ameluz® thereby increasing the distance between Ameluz® and Metvix®.

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"We are very pleased with the CHMP's favourable review regarding the label extension for Ameluz®, another important validation of the qualities of Ameluz®," commented Prof. Dr. Hermann Lübbert, CEO of Biofrontera. "We now look forward to the positive decision by the European Commission, which will allow us to expand our sales and marketing efforts by promoting basal cell carcinomas throughout Europe together with our marketing partners. This represents another important milestone in our strategic efforts to expand the market penetration of Ameluz® und to increase the product's revenue potential."

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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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