Biofrontera
Experts in dermatology

News Release

FDA completes Biofrontera's Ameluz® NDA mid-cycle review

Leverkusen, Germany, 26 January 2016 - Biofrontera (FSE/AIM: B8F), the biopharmaceutical company focusing on sun-induced skin cancer, has today announced recent progress on the ongoing approval process for Ameluz® and BF-RhodoLED® in the USA. FDA has now completed its mid-cycle review of the Ameluz® NDA (new drug application). The review resulted in no additional requests for material nor were any additional review issues highlighted.

Ameluz® is a prescription drug used in combination with Biofrontera's proprietary lamp, BF-RhodoLED®, as a photodynamic therapy (PDT) to treat actinic keratosis. Ameluz® is currently approved in the EU and Switzerland. With European sales continuously growing, an approval in the USA would create a significantly larger market opportunity for Biofrontera. The US market opportunity for Ameluz® and BF-RhodoLED® is particularly promising since PDT for actinic keratosis is a fully reimbursed Medicare procedure, which is not generally the case in Europe.

"The results of the mid-cycle review support our expectations. With this potential hurdle behind us, we do not anticipate any major delays and we look forward to FDA completing its review in the spring", commented Prof. Hermann Luebbert, CEO of Biofrontera."

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Background:

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, 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 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.

www.biofrontera.com

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