Biofrontera
Experts in dermatology

News Release

Biofrontera completes final steps ahead of FDA New Drug Application in the USA

- **Drug Master File for the active substance 5-ALA acknowledged by the FDA**
- **Biofrontera Pharma GmbH registered as medical device manufacturer**
- **Successful migration to a pharmacovigilance database which complies with FDA requirements**
- **Connectivity test and guidance compliant test submission of dossier achieved**

Leverkusen, 22 June 2015 – Biofrontera AG (AIM/FSE: B8F), the biopharmaceutical company focussing on sun induced skin cancer, has completed the final steps ahead of its imminent NDA submission of its prescription drug Ameluz® and its PDT-lamp BF-RhodoLED® to the Food and Drug Administration (FDA) in the USA.

Ahead of the FDA submission the final step was to submit the Drug Master File for the active substance, which was provided to the FDA several weeks ago and has now been acknowledged by the FDA. Further, Biofrontera Pharma GmbH has been registered as manufacturer of the BF-RhodoLED® lamp. Our pharmacovigilance database, a database used to maintain and report all information about drug safety and mandatory for every pharmaceutical company, was migrated to an FDA compliant database. As part of the final preparations, the team has successfully performed a guidance compliant test submission of the dossier and also tested the electronic connection between Biofrontera and the FDA Electronic Submission Gateway.

“Having come so far in the run up to the FDA submission, it is essential to test the final processes in order for the submission to be processed seamlessly and to ensure all the initial requirements are adhered to in order for the file to be accepted by the FDA. We are now preparing the final documents and expect to make the submission shortly.” said Prof. Hermann Luebbert, CEO of Biofrontera.

Ends

Pressemitteilung

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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 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. At the moment, Belixos® cream, gel and scalp tonic 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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