Biofrontera
Experts in dermatology

Press release

Further progress in international approval processes of Biofrontera's Ameluz®

- **Successful filing of waivers in the US**
- **Ameluz® applied for registration in Switzerland**

Leverkusen, 26 November 2014 - Biofrontera (FSE / AIM: B8F), the specialist for sun-induced skin cancer, has taken important steps towards further international approvals of Ameluz®. As part of the approval process for Ameluz® in the US, Biofrontera had discussed with the FDA to submit the "Pediatric Waiver" and the "User Fee Waiver" before submitting the complete registration dossier. These filings have now occurred. An approved Pediatric Waiver avoids the obligation for conducting studies with children. The User Fee Waiver is given to small enterprises and allows them to apply for their first drug approval without the need to pay further FDA fees, which would otherwise amount to the payment of fees by Biofrontera of in excess of US$2 million. Previously Biofrontera had obtained a similar status by the European Medicines Agency.

In Switzerland, the Company's licensing partner, Louis Widmer SA has, in collaboration with Biofrontera, submitted the registration dossier of Ameluz® to the local health authorities, the Swissmedic. After a technical validation of the application the authority has now accepted Ameluz® for registration, by which the next step of the approval process was initiated. Within the scope of the authorization procedure, Swissmedic assesses the quality, safety and efficacy of the drug on the basis of the comprehensive scientific documentation submitted, and approves the information provided to healthcare professionals and patients.

Prof. Dr. Hermann Lübbert, CEO of the Biofrontera: "In a close cooperation between Louis Widmer and Biofrontera the European drug approval dossier has been adapted to the Swiss regulations. In Switzerland Biofrontera's drug for photodynamic treatment of actinic keratosis will, as in all other European countries, be marketed under the brand name Ameluz®. The market authorization in Switzerland will represent another important milestone in the international expansion of the business with Ameluz®. The application of the two waivers is another important step within the scope of the US registration process."

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Background:

The **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® contains a combination of active substances extracted from plants, relieves itching and redness and is used for the regenerative treatment of chronic skin conditions such as atopic dermatitis or psoriasis. At the moment, Belixos® is available as a cream and scalp tonic.

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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