

## FDA grants small business waiver

Leverkusen, Germany, 23 December 2015 - Biofrontera (FSE/AIM: B8F), the biopharmaceutical company focusing on sun-induced skin cancer, announces that FDA has granted a small business waiver which exempts Biofrontera from a US\$ 2.34 million application fee (PDUFA fee) for its ongoing drug application for Ameluz®.

Such a waiver is usually granted to companies that file their first new drug application with FDA and that do not exceed certain size criteria. Biofrontera meets these criteria but, as previously announced, as FDA had not processed the waiver application at the time the NDA was filed, Biofrontera paid the fee in June 2015. Following the granting of the waiver, the US\$ 2.34 million PDUFA fee is now expected to be repaid shortly.

Hermann Lübbert, CEO of Biofrontera AG, commented: "This is good news for our company and its balance sheet shortly before Christmas. We are pleased that FDA has accepted our application for a waiver and we are now able to reclaim the PDUFA fee."

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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.

## News Release

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](http://www.biofrontera.com)**

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