

## **News Release**

# Israel Ministry of Health Approves Biofrontera's Ameluz® for treatment of actinic keratosis

- Marks third marketing approval of Ameluz<sup>®</sup> worldwide
- Ameluz® was approved for marketing in Israel by partner Perrigo Israel
- Validates data demonstrating efficacy, safety and quality of Ameluz<sup>®</sup>

**Leverkusen, Germany, April 13, 2016** – Biofrontera AG (FSE: B8F), the specialist for sun-induced skin cancer, today announced that the Israel Ministry of Health (IMOH) has granted marketing registration approval of Ameluz® for the photodynamic treatment of actinic keratosis (AK). The approval follows the regulatory agency's comprehensive examination of the safety, efficacy and quality and critical assessment of Ameluz®. This marks the third approval of Ameluz® worldwide, enabling further international commercialization. Israel will be the 13<sup>th</sup> country in which Ameluz® is commercially available.

Biofrontera's Israeli marketing partner, Perrigo Israel Agencies LTD, received the marketing authorization for Ameluz® last week, and will now launch Ameluz® on the Israeli market in the coming months.

Prof. Hermann Lübbert, CEO of Biofrontera AG commented: "Approval by the Israel Ministry of Health marks another important milestone for Biofrontera as we execute against our plan to expand the commercialization of Ameluz® internationally. The IMOH's decision to approve registration of Ameluz® validates the data within the marketing registration package demonstrating the efficacy, safety and quality of the product, and furthermore allows dermatologists in Israel to prescribe the medication to their patients with confidence. Ameluz® represents a unique and non-invasive treatment for AK before it advances to skin cancer and we look forward to working with a strong partner such as Perrigo in making Ameluz® available to dermatologists and their patients in Israel."

### **Ends**

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#### **About Biofrontera**

**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.

#### For more information, visit www.biofrontera.com

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