

News Release

Ameluz® has passed first stage in approval process in Israel

Leverkusen, 11 August 2014 – Biofrontera (AIM/FSE:B8F), the European biopharmaceutical company, announces that its licensee Perrigo Company plc has filed the marketing approval dossier with the Ministry of Health in Israel (IMOH). After a preliminary review, IMOH has accepted Ameluz[®] for registration and issued a preliminary registration number, in order for the full review process to now start. The underlying exclusive license with Perrigo Israel Agencies Ltd., a subsidiary of Perrigo Company plc, to market Ameluz[®] and BF-RhodoLED[®] in Israel was signed earlier this year (see press release of 6 January 2014).

The Perrigo dermatology team is the leading dermatology sales team in Israel. In a very short time, through a close collaboration between Biofrontera and Perrigo, the European approval dossier was adapted to the rules in Israel and all relevant documentation for the filing in Israel was collected. With the acceptance of the dossier by IMOH, we expect to obtain approval in Israel next year. Biofrontera's prescription drug Ameluz[®], for the treatment of actinic keratosis with photodynamic therapy, will be marketed in Israel under the same name.

Prof. Hermann Lübbert, Chief Executive Officer of Biofrontera commented: "Perrigo has enabled Biofrontera to accelerate its international development. The Board is delighted that we will have the opportunity to start marketing Ameluz[®] in this new territory next year. Perrigo has the leading dermatology sales team in Israel and we are confident of a strong start to the launch of Ameluz[®] in this new market."

In addition to the marketing approval application, the elaborate process for pricing and reimbursement required in Israel was recently initiated with the National Health Basket Committee, which is responsible for ensuring that with completion of the approval process the price and the eligibility for reimbursement are determined.



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Notes to Editors:

Biofrontera AG (AIM/FSE: B8F, ISIN DE0006046113) is a biopharmaceutical company specialising in the development and distribution of dermatological drugs and medical cosmetics for the treatment and care of skin diseases. Biofrontera's main product is **Ameluz**[®], a prescription drug approved for use in Europe for the treatment of mild to moderate Actinic Keratosis (superficial skin cancer) by photodynamic therapy (light therapy). Biofrontera is the first small German pharmaceutical company to receive a centralized approval for a drug developed in-house. The Company is looking to further develop Ameluz[®] for use in Basal Cell Carcinoma and is currently progressing through regulatory approvals to sell the product in other territories, in particular the largest pharmaceutical market, the USA.

In addition, the Company markets the **Belixos**[®] cosmetic series with plant extracts, currently available in cream and liquid formulations which offer nurturing and regenerating effects for people suffering from pruritus, dry skin or chronic ailments such as eczema or psoriasis.

Biofrontera group was founded in 1997 by Prof. Dr. Hermann Lübbert, the CEO, and is headquartered in Leverkusen, Germany.

www.biofrontera.com

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