Biofrontera
Experts in dermatology

News Release

FDA determines May 10, 2016 as PDUFA* date for Ameluz®

- 74-day letter received from FDA
- No potential review issues were identified in filing review
- FDA to provide interim report with suggested labelling by 30 March 2016
- PDUFA* action date is 10 May 2016

Leverkusen, Germany, 2 October 2015 – Biofrontera (FSE/AIM:B8F), the biopharmaceutical company focusing on sun-induced skin cancer, announces that it has received the 74-day letter from the Food and Drug Administration (FDA) in the approval process of Ameluz® in the USA. In its filing review, FDA did not identify any potential review issues and set the PDUFA date, the day of the approval letter, to 10 May 2016. Thus, FDA intends to use two months less than in most drug approvals for its review process.

FDA will now enter into its substantive review, which is expected to take six months. By 30 March 2016, FDA will release its interim report that will include suggested labelling and, if necessary, any post marketing commitment requests. Final labelling and potential commitments will be agreed upon between FDA and Biofrontera between 30 March 2016 and 10 May 2016. The suggested timing is based on the assumption that FDA does not identify any major issues during its substantive review.

Commenting on this milestone, Prof. Hermann Luebbert, CEO of Biofrontera said: “The choice of 10 May 2016 as PDUFA date is great news. FDA has not made use of their maximum 12-month review period, thereby potentially reducing time-to-market by two months”.

** PDUFA – Prescription Drug User Fee Act*

Ends

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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, 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

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