Biofrontera
Experts in dermatology

News Release

Biofrontera AG: Pre-NDA meeting scheduled with FDA for the approval of Ameluz® and BF-RhodoLED®

- **pre-NDA-Meeting scheduled by FDA for 8 October 2014**
- **Briefing Book submitted**

Leverkusen, Germany, 21 August 2014 – Biofrontera (AIM/FSE:B8F), the European biopharmaceutical company, announces that the US Food and Drug Administration (FDA) has scheduled the pre-NDA (New Drug Application) meeting for 8 October 2014. The pre-NDA meeting represents an important step in Biofrontera registering its medicinal product Ameluz® in combination with its medical device BF-RhodoLED® in the USA since it is the last opportunity to obtain direct feed-back to the dossier by the FDA prior to filing.

Ameluz® is a prescription drug approved in Europe by the European Medicines Agency (EMA) for the treatment of mild to moderate actinic keratosis on the face or scalp. BF-RhodoLED® is a CE-marked red light LED lamp used in combination with Ameluz® in photodynamic therapy (PDT). Both products are by now sold in most major European markets. Biofrontera is in the process of preparing the filing for approval in the US. In a first meeting with the FDA (see press release on 23-07-2012) the FDA requested some additional studies. In the meantime, Biofrontera has performed two phase I trials and one phase III study (the results of which are expected by the end of September or early October) to satisfy all requirements of the FDA. Biofrontera has also submitted an elaborate Briefing Book to the FDA which will serve as a guide to introduce all major elements of the dossier as well as discuss remaining questions.

Hermann Luebbert, CEO of Biofrontera commented: "*We are looking forward to the opportunity to discuss our dossier for the combination of Ameluz® and BF-RhodoLED® with the FDA. Since we have addressed all requests that the FDA had in the last meeting, we are confident that our data package will now satisfy all the requirements for filing. Whilst we had hoped for an earlier meeting, this delay will not influence the rest of our time table of filing the final dossier by the end of Q1 2015.*"

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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

This press release contains forward-looking statements based on the currently held beliefs and assumptions of the management of Biofrontera AG, which are expressed in good faith and, in their opinion, reasonable. Forward-looking statements involve known and unknown risks, uncertainties and other factors, which may cause the assumptions expressed or implied in this press release to be faulty. Given these risks, uncertainties and other factors, recipients of this document are cautioned not to place undue reliance on the forward-looking statements. Biofrontera AG disclaims any obligation to update these forward-looking statements to reflect future events or developments.