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News Release

Biofrontera submits New Drug Application for Ameluz® to FDA

- **Comprehensive dossier filed with FDA on Friday**
- **FDA 'Acceptance to file' response within next 60 days**
- **Submission represents outstanding milestone, achieved by very few biotech companies worldwide**

Leverkusen, Germany, 13 July 2015 – Biofrontera AG (AIM/FSE: B8F), a biopharmaceutical company focusing on sun induced skin cancer, has completed a major milestone by submitting a New Drug Application ('NDA') to the US Food and Drug Administration ('FDA') for its combination prescription drug Ameluz® and medical device BF-RhodoLED®. The combination of both products shall be applied in photodynamic therapy in the USA.

Unlike the US which requires combination approval, Ameluz® and BF-RhodoLED® were listed under separate filings in the EU. Ameluz® was granted marketing authorization by the European Medicines Agency ('EMA') in December 2011 for the treatment of mild and moderate actinic keratosis on the face and scalp. Biofrontera's PDT lamp BF-RhodoLED® was approved as a medical device in the EU.

The FDA combination drug and device application is extremely complex and required additional phase III testing prior to submission. The phase III actinic keratosis field therapy study with the drug/light combination reported complete clearance in over 90% of treated patients, along with a strong skin rejuvenation effect. The filing also includes results from two additional Phase III studies as well as results from two drug safety studies requested by the FDA. The comprehensive dossier was submitted to FDA on Friday July 10th. It comprises of more than 1,000 text files and documents, covering more than 50,000 pages, and data sets representing a multiple of these.

Biofrontera has been in close dialogue with FDA since July 2012 in order to prepare the NDA in coordination with the authority. The positive review during the pre-NDA meeting in October 2014 gives the company great confidence in the application.

According to US guidelines FDA has 60 days to respond as to whether the application will be accepted ('acceptance to file'). During this initial review period, FDA confirms completeness of the application and upon 'acceptance to file' FDA conducts a thorough review that is normally completed within 9-12 months after submission. FDA provides a mid-term review about six month after 'acceptance to file', which could provide a strong indication that approval will be granted.

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Prof. Hermann Lübbert, CEO of Biofrontera commented: “A New Drug Application in the US, in particular a combination drug/medical device submission, is a huge endeavour and it involves every single employee in our small company. Worldwide, only very few small biotech companies have accomplished such a milestone with an in-house developed drug. We believe we delivered excellent clinical data and are therefore very confident in our application. If approved, this product will generate outstanding growth potential for Biofrontera as well as a significant increase in shareholder value.”

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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 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. At the moment, Belixos® cream, gel and scalp tonic 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.

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