Biofrontera
Experts in dermatology

News Release

Biofrontera Announces NDA Progress Update for BF-200 ALA

- **FDA issued suggested labeling for BF-200 ALA for treatment of actinic keratosis (AK)**
- **FDA has not requested any further data**
- **NDA on track**

Leverkusen, Germany, April 4, 2016 – Biofrontera AG (FSE: B8F), the specialist for sun-induced skin cancer, today announced an update on the latest progress of its New Drug Application (NDA) for lead product BF-200 ALA, which is currently being reviewed by the U.S. Food and Drug Administration (FDA). The FDA has issued the proposed labeling for BF-200 ALA, the Company's prescription drug for the treatment of mild to moderate actinic keratosis (AK) on the face and scalp. Biofrontera anticipates finalizing the labeling of BF-200 ALA with the FDA over the next few weeks to adequately reflect the drug's efficacy and safety indications.

As a part of FDA's review, Biofrontera is addressing the additional questions posed by the regulatory agency regarding the quality management system and Biofrontera's photodynamic therapy lamp, which is used in conjunction with and activates the topically-applied BF-200 ALA. The Company anticipates these questions to be resolved in the coming days. In addition, the FDA has not made Biofrontera aware of any major issues or deficiencies with the submitted NDA, nor have they raised any major issues during their inspections of Biofrontera's clinical sites or partnered manufacturing facilities. The only inspection still pending is that of Biofrontera's medical device manufacturing facility, which FDA has announced for early May.

"We are extremely encouraged by the FDA's initially suggested labeling and look forward to working with them closely to finalize this important step as we prepare for the U.S. launch of BF-200 ALA," said Prof. Hermann Lübbert, CEO of Biofrontera AG. "We have been pleased with the efficiency and seamlessness of the NDA process and strongly believe we will be able to adequately address any additional inquiries that the FDA may raise as the May PDUFA date nears. BF-200 ALA represents a unique product that will assist those suffering from actinic keratosis that can eventually progress to skin cancer."

Ends

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About Biofrontera

Biofrontera Group (FSE: B8F, ISIN DE0006046113) is a biopharmaceutical company specializing 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 BF-200 ALA, a prescription drug approved in Europe under the name of Ameluz® 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 centralized 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 of BF-200 ALA 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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