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Experts in dermatology

News Release

Biofrontera Initiates Phase III Trial of Ameluz® in Combination with Daylight-PDT

- **First patient dosed this week**
- **To compare daylight photodynamic therapy with Ameluz® versus Metvix® for treatment of mild to moderate actinic keratosis**
- **EU study with 8 sites to evaluate approximately 50 patients**
- **Primary endpoint to determine total lesion clearance rate after 12 weeks**

Leverkusen, Germany, June 30, 2016 – Biofrontera AG (FSE: B8F), the specialist for the treatment of sun-induced skin cancer, today announced the first patient treatment in a Phase III clinical trial to evaluate the safety and efficacy of Ameluz® in combination with daylight photodynamic therapy (PDT) in comparison with Metvix® for the treatment of mild to moderate actinic keratosis (AK).

The head-to-head, randomized, observer-blinded, multi-center study in the European Union (EU) will include a total of eight sites in Spain and Germany and enroll approximately 50 patients, with 3 to 9 mild to moderate AK lesions (Olsen grade 1 and 2) in each of two comparable treatment areas on the face and/or scalp. For an intra-patient comparison of the treatments, each patient will receive daylight-PDT with Ameluz® on one side and with Metvix® on the other side of the face or scalp. The assignment of sides will be random. The last patient is expected to conclude treatment by year end 2016.

“Following U.S. FDA approval of Ameluz® for actinic keratosis, we are looking forward to identifying potential additional effective applications of our technology,” commented Prof. Dr. Hermann Lübbert, CEO of Biofrontera. “Daylight PDT offers a convenient and painless alternative to PDT with a specialized lamp. In daylight PDT the topical medication is activated by exposure to natural or artificial daylight, which among other benefits saves physician office visit time for the patient. A label extension to include daylight PDT would allow Biofrontera to compete directly with self-applied topical drugs and the cryotherapy market. We are excited to begin this late-stage trial to determine additional methods of effectively treating patients with superficial skin cancer.”

The study’s primary endpoint is to determine the total lesion clearance rate per patient’s side, which will be assessed 12 weeks after treatment. Secondary endpoints will include the evaluation of safety and secondary efficacy parameters. The study will be co-led by Susana Puig, MD, PhD, Research Director at the Biomedical Research Institute August Pi I Sunyer (IDIBAPS) and a professor at the University of Barcelona, as the coordinating investigator in Spain, and Professor Dr. Thomas Dirschka, founder of the private dermatology practice Centro Derm, as the coordinating investigator in Germany.

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Ameluz® was granted marketing authorization by the European Medicines Agency (EMA) in December 2011 for the treatment of mild and moderate AK on the face and scalp and currently has established sales in 13 countries. The Company received marketing approval from the U.S. Food and Drug Administration (FDA) for its combination topical prescription drug Ameluz® and medical device BF-RhodoLED® in May 2016, for lesion- as well as field-directed treatment of mild to moderate AK on the face and scalp.

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About Biofrontera

Biofrontera Group (FSE: B8F, ISIN DE0006046113) **Biofrontera** is a biopharmaceutical company specializing in the development, sale and distribution of drugs, medical devices and medical cosmetics for the care and treatment of skin diseases. Biofrontera's lead product is Ameluz®, a prescription drug which was initially approved and marketed in Europe and is now also approved in the U.S. in combination with its medical lamp BF-RhodoLED® for photodynamic therapy (PDT) treatment (light therapy) of mild and moderate actinic keratosis, a precursor to squamous cell carcinoma. Biofrontera is the first German pharmaceutical start-up company to obtain centralized EU and now U.S. approval for a medical device/drug it has developed itself.

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 Belixos® products are available in Europe 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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