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News Release

Biofrontera Announces U.S. FDA Approval of Ameluz® and Activating BF-RhodoLED® Device for Treatment of Actinic Keratosis

- **Outstanding success for a small European biotech company**
- **Marks fourth marketing approval of Ameluz® worldwide**
- **Expands international commercialization efforts**
- **Validates safety and efficacy data from three pivotal studies**

Leverkusen, Germany, May 11, 2016 – Biofrontera AG (FSE: B8F), the specialist for the treatment of sun-induced skin cancer, today announced that the U.S. Food and Drug Administration (FDA) has granted approval of its combination topical prescription drug Ameluz® (BF-200 ALA) and medical device BF-RhodoLED® for photodynamic therapy (PDT) treatment of mild to moderate actinic keratosis (AK) on the face and scalp. The approval covers lesion-directed as well as field-directed treatment and follows thorough review of the Company's New Drug Application (NDA), which was submitted in July 2015.

This marks an outstanding accomplishment for a start-up company that is rarely seen in European companies of comparable size. It is the fourth marketing approval of Ameluz® worldwide and further validates the comprehensive safety and efficacy data from the Company's three pivotal multi-center clinical trials, which were conducted in the European Union (EU) and collectively evaluated 779 patients with four to eight mild to moderate AK lesions. The compelling results obtained from these studies demonstrate that Ameluz® is significantly superior to the standard of care, with a complete patient response rate of 91% when paired with BF-RhodoLED® PDT lamp. Additionally, Ameluz® has exhibited positive long-term effects with low recurrence over the course of 12 months and in a pivotal phase III trial performed on entire treatment fields, it demonstrated long-lasting skin rejuvenation effects in sun-damaged but asymptomatic skin regions.

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. BF-RhodoLED® was approved as a medical device in the EU in November 2012.

Ameluz® in combination with BF-RhodoLED® light treatment is an innovative alternative to existing PDT for AK, which is characterized by lesions caused by frequent and prolonged exposure to the sun's ultraviolet rays. Typically, AK lesions occur on the face, scalp, lips, arms and hands, often resulting in the formation of rough, scaly and discolored skin patches. AK affects more than 58 million people in the U.S. alone, which, if left untreated can develop into squamous cell carcinoma (SCC), a potentially fatal skin disease with rapidly growing incidence. According to S3-guidelines, the highest level of treatment guidelines, multiple AKs should be treated in a field-directed approach, and Ameluz is the first PDT drug with field-directed treatment covered in the label.

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Biofrontera expects commercial launch of Ameluz® and BF-RhodoLED® in the U.S. by September 2016. The Company established a U.S. subsidiary in 2015 to build the infrastructure necessary to commence U.S. operations and initiate sales and marketing activities. The Company is currently hiring personnel in preparation for the product launch.

“We are extremely pleased with the FDA’s decision to approve Ameluz® and BF-RhodoLED® for the treatment of actinic keratosis. We expect early adoption from dermatologists as we showcase the response rates of guideline compatible field treatment, which is not covered by the label of competing technology,” commented Prof. Dr. Hermann Luebbert, CEO of Biofrontera. “The U.S. represents a large and growing market opportunity for the Company and we have been eagerly preparing for the U.S. launch of Ameluz®. We are excited about our growth prospects in the U.S., Europe, and other regions around the world and we look forward to expanding the indication for Ameluz® to basal cell carcinoma first in the EU, followed by the U.S.”

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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 most important product is Ameluz®, a prescription drug which was initially approved and marketed in Europe and is now also approved in the US for the treatment of mild and moderate actinic keratosis, a precursor to squamous cell carcinoma, with photodynamic therapy (light therapy). Biofrontera is the first German pharmaceutical start-up company to obtain centralized EU and now US 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 products are available through Amazon.

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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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