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Experts in dermatology

Press Release

Biofrontera Accelerates Production of BF-RhodoLED® Lamps to Prepare for U.S. Commercial Launch

- **First shipment from Biofrontera's own manufacturing site to U.S.**
- **Combination of Ameluz® and activating BF-RhodoLED® lamp received FDA approval in May 2016 for photodynamic therapy treatment of actinic keratosis**

Leverkusen, Germany, August 26, 2016 – Biofrontera AG (FSE: B8F), the specialist for the treatment of sun-induced skin cancer, today announced the Company accelerated activity at its production facility in Leverkusen, Germany to prepare for the U.S. commercial launch of its combination topical prescription drug Ameluz® (BF-200 ALA) and the accompanying BF-RhodoLED® lamp for the lesion-directed and field-directed photodynamic therapy treatment (PDT) of mild to moderate actinic keratosis (AK) on the face and scalp.

The first shipment of the BF-RhodoLED® lamps to the U.S. was in August for instalment ahead of the Ameluz® launch. The new established and certified 9,580 ft^2 (890 m^2) facility can currently produce up to 30 lamps per week, with the ability to increase capacity to meet market demand.

"Following FDA approval earlier this year, we are eager to begin the commercial rollout of Ameluz® in the U.S., one of the largest markets for AK with approximately 58 million Americans[1] living with the precancerous condition," commented Prof. Dr. Hermann Lübbert, CEO of Biofrontera. "Ensuring dermatologists have the BF-RhodoLED® lamp installed in their offices along with the appropriate training is critical to a successful commercial launch of Ameluz®."

The photodynamic treatment with Ameluz® and BF-RhodoLED® received FDA approval in May 2016, following three pivotal multi-center clinical trials evaluating a total of 779 patients. Data revealed a complete patient response rate of 91% when Ameluz® was paired with the BF-RhodoLED® lamp. In addition, patients showed a low recurrence after 12 months, and the therapy demonstrated long-lasting skin rejuvenation effects in sun-damaged but asymptomatic skin regions. According to S3-guidelines, multiple AKs should be treated in a field-directed approach. Ameluz® is the first PDT drug with field-directed treatment included on the US label. For Europe the approval is also in process and a positive opinion of the European Medicines Agency (EMA) has been obtained to include treatment of field cancerization in the European product information.

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References

1. Skin Cancer Foundation http://www.skincancer.org/skin-cancer-information/actinic-keratosis

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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, a scalp tonic and acute roll-on, 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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