Biofrontera
Deep in dermatology

News release

Biofrontera announces 1-year follow-up results for its phase III study of photodynamic therapy for actinic keratosis on the extremities and trunk/neck

Leverkusen, Germany, January 14, 2020 – Biofrontera AG (NASDAQ: BFRA; Frankfurt Stock Exchange: B8F) (the "Company"), an international biopharmaceutical company, today announced follow-up results for its Phase III clinical study evaluating the safety and efficacy of photodynamic therapy (PDT) with Ameluz® and the BF-RhodoLED® lamp for the treatment of actinic keratosis (AK) on the extremities, trunk and neck. After 12 months, the overall lesion recurrence rates were 14.1% after Ameluz® treatment, compared to 27.4% after placebo treatment in the Full Analysis Set (FAS; 11.7% vs. 24.6% in the Per Protocol Set, respectively).

"I am not aware of another pivotal clinical study showing similarly high clearance rates and low recurrence rates for the pharmaceutical treatment of actinic keratoses in the periphery," commented Biofrontera's CEO Prof. Hermann Luebbert. "With an overall lesion clearance rate of 77% one year after treatment, Ameluz® has once again demonstrated its unreached clinical efficacy."

The multi-center, randomized, double-blind, intra-individual study included 50 patients at six study sites in Germany, each with four to ten clinically confirmed AK lesions in comparable areas on the right and left side of the extremities and/or trunk/neck. Mild, moderate and severe actinic keratoses were treated with one or, if at least one lesion on each patient's side persisted after three months, two PDT applications. Each PDT consisted of the application of Ameluz® on one side of the patient, and an identically looking, feeling and smelling placebo gel on the other side. PDT illumination with 10 minutes of red light using the BF-RhodoLED® lamp followed after a 3-hour incubation with occlusion. The final examination of the patients took place three months after the last PDT. This clinical study phase was followed by a follow-up phase of up to one year after the last PDT, in which recurrence rates and numbers of new AKs and skin tumors were determined.

The results for the primary regulatory endpoint, demonstrating that Ameluz® was superior ($p<0.0001$) to placebo based on its mean total lesion clearance rate of 86% compared to 33% for placebo had been published in a Biofrontera press release on March 20, 2019.

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The following table represents the treatment outcome after 3 months and the recurrence rates during one year after the last PDT (FAS).

Endpoints (all FAS)	**Ameluz®** **Fully cleared lesions after 3 months**	**Placebo** **Fully cleared lesions after 3 months**	**Ameluz®** **12-month recurrence**	**Placebo** **12-month recurrence**
Lesions per patients' side (overall)	86.0%	32.9%	14.1%	27.4%
Lesions per patients' side - extremities	83.5%	27.1%	16.2%	34.3%
Lesions per patients' side – neck/trunk	96.0%	55.5%	6.7%	10.7%
Mild lesions per patients' side (overall)	88.3%	37.3%	14.0%	39.2%
Moderate lesions per patients' side (overall)	84.3%	27.2%	11.6%	18.6%
Severe lesions per patients' side (overall)	71.4%	42.9%	20.0%	66.7%

Of the patients who were cleared of all AK lesions 3 months after treatment (67.3%), 62.5% overall and 60.9% of the patients treated on extremities (placebo 66.7% and 66.7%, respectively) remained fully cleared up to one year after the last PDT. No new AKs and only one basal cell carcinoma (BCC) skin tumor were identified in the treatment area after one year whereas outside the treatment area 6 AKs or skin tumors (BCC, squamous cell carcinoma) where identified.

-End-

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About Biofrontera:

Biofrontera AG is a biopharmaceutical company specializing in the development and sale of dermatological drugs and medical cosmetics.

The Germany-based company, with almost 200 employees worldwide, develops and markets innovative products for the care, protection and treatment of the skin. The company's lead product is the combination of Ameluz®, a topical prescription drug, and medical device BF-RhodoLED® for the photodynamic therapy of certain superficial skin cancers and their precursors. Ameluz® has been marketed in the EU since 2012 and in the United States since May 2016. In addition, the company markets the prescription medication Xepi™ for the treatment of impetigo in the United States. In the EU, the company also sells the dermocosmetics series Belixos®, which offers specialized care for damaged or diseased skin.

Biofrontera is the first German founder-led pharmaceutical company to receive a centralized European and a US approval for a drug developed in-house. The Biofrontera Group was founded in 1997 by the current CEO Prof. Dr. Hermann Lübbert and is listed on the Frankfurt Stock Exchange (Prime Standard) and on the US NASDAQ.www.biofrontera.com.

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