Biofrontera
Deep in dermatology

News release

European Medicines Agency recommends indication expansion of Ameluz® for treatment of actinic keratoses on the extremities and trunk/neck

Leverkusen, Germany, February 3, 2020 – Biofrontera AG (NASDAQ: BFRA; Frankfurt Stock Exchange: B8F) (the "Company"), an international biopharmaceutical company, announced today that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has issued a positive opinion with respect to Biofrontera's submission for label extension for its topical prescription drug Ameluz®. The extended approval will include photodynamic therapy (PDT) of mild and moderate actinic keratoses (AK) on the extremities and trunk/neck.

In addition, the results of the follow-up phase of the clinical comparative study for daylight PDT with Ameluz® and Metvix® will be included in the product information (SmPC). The recurrence rate 12 months after a single daylight PDT with Ameluz® (lesion clearance rate after 3 months 79.8%, after 12 months recurrence of 19.5% of the initially no longer diagnosed lesions) was significantly lower than with Metvix® (clearance rate after 3 months 76.5%, recurrence rate after 12 months 31.2%).

Based on the positive opinion, Biofrontera anticipates that the European Commission will issue formal approval within the coming weeks, again significantly expanding the European market opportunity for Ameluz®.

"We are very pleased with the EMA's positive opinion on the approval for label extension. Our excellent results in the treatment of AK on all parts of the body again confirm the excellent efficacy of PDT with Ameluz®", says Prof. Dr. Hermann Lübbert, CEO of Biofrontera AG, "We are now waiting for the final decision of the European Commission, which will allow us to expand our marketing activities in the coming months to the treatment of actinic keratoses on the extremities and trunk/neck. The label extension is a further step in our strategic efforts to exploit the full market potential of Ameluz®."

For the respective US-label extension, the U.S. Food and Drug Administration (FDA) has requested a further study a few days ago, aiming to increase the number of patients treated on different parts of the body. Biofrontera has already started planning the requested study in the USA, which is expected to start as soon as possible.

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For the approval of Ameluz® for the treatment of mild and moderate actinic keratoses on the extremities and trunk/neck Biofrontera has thus far conducted one phase III clinical trial with a total of 50 patients. The multi-center, randomized, double-blind, intra-individual study included six study centers in Germany, where patients with four to ten clinically confirmed AK lesions in comparable areas on the right and left side of the extremities and/or trunk/neck were treated. The final evaluation of the patients for determination of the study's primary endpoint took place three months after the last PDT. The clinical study phase was then followed by a follow-up phase of twelve months after the last PDT, in which recurrence rates and/or numbers of new AKs and skin tumors were determined. The primary regulatory endpoint, published on March 20th, 2019, showed that Ameluz® was significantly superior (p<0,0001) to placebo based on its mean total lesion clearance rate of 86% compared to 33% for placebo. Significant superiority of Ameluz® was also demonstrated for all secondary parameters. After 12 months, the overall lesion recurrence rates were 14.1% after Ameluz® treatment, compared to 27.4% after placebo treatment (see press release published on January 14th, 2020).

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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

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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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