Biofrontera
Deep in dermatology

News release

European Commission approves use of Ameluz® for the treatment of actinic keratosis on extremities and trunk/neck

Leverkusen, Germany, March 10, 2020 – Biofrontera AG (NASDAQ: BFRA; Frankfurt Stock Exchange: B8F) (the "Company"), an international biopharmaceutical company, today announced that the European Commission has approved the use of Biofrontera's prescription drug Ameluz® in combination with photodynamic therapy (PDT) for the treatment of actinic keratosis (AK) on the extremities and trunk/neck. In addition, the results of the follow-up phase of the clinical study comparing daylight PDT with Ameluz® and Metvix® were included in the product information (SmPC). With a recurrence rate of 19.5%, Ameluz® showed lower recurrence rates after 12 months than Metvix with 31.2%.

"We are very pleased about the extended label now approved for Ameluz® in the EU. Our outstanding results in the treatment of AK on all body regions confirm the excellent efficacy of PDT with Ameluz®", says Prof. Dr. Hermann Lübbert, CEO of Biofrontera AG. "We expect that the extension of the approval will further strengthen the market positioning of Ameluz® in Europe".

The approval of the label extension by the European Commission followed a positive opinion issued by the European Medicines Agency (EMA) (see press release dated February 3, 2020) and was based on the results of one phase III clinical trial with a total of 50 patients. The multi-center, randomized, double-blind, placebo-controlled, intra-individual study included six study centers in Germany, where patients with four to ten clinically confirmed AK lesions each in comparable areas on the right and left side of the extremities and/or trunk/neck were treated. Patients were treated with Ameluz on one randomly selected side, the other side was treated with placebo. If lesions remained on both sides of the body, the PDT was repeated three months later. 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

Biofrontera AG
Hemmelrather Weg 201 I D-51377 Leverkusen, Germany
Phone: +49 214 87632-0 I Telefax: +49 214 87632-90
info@biofrontera.com I www.biofrontera.com

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Ameluz® treatment, compared to 27.4% after placebo treatment (see press release dated January 14th, 2020).

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Enquiries, please contact:	
Biofrontera AG	+49 (0) 214 87 63 2 0
Thomas Schaffer, Chief Financial Officer	ir@biofrontera.com
IR UK: Seton Services	+44(0) 20 7729 0805
Toni Vallen	
IR and PR US: The Ruth Group	
IR: Tram Bui	+1 646-536-7035
PR: Kirsten Thomas	+1 508-280-6592

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.

Biofrontera AG
Hemmelrather Weg 201 I D-51377 Leverkusen, Germany
Phone: +49 214 87632-0 I Telefax: +49 214 87632-90
info@biofrontera.com I www.biofrontera.com