Biofrontera
Deep in dermatology

**News release**

# Biofrontera provides clinical development updates

**Leverkusen, Germany, February 19, 2020** – Biofrontera AG (NASDAQ: BFRA; Frankfurt Stock Exchange: B8F) (the "Company"), an international biopharmaceutical company, today provides an update on its clinical developments.

On February 3, 2020, the Company announced that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) issued a positive opinion with respect to our submission for the Ameluz® label extension 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 comparison study for daylight PDT with Ameluz® and Metvix® will be included in the product information (SmPC). Based on the positive opinion received from the CHMP, the Company anticipates that the European Commission will issue formal approval towards the end of the first quarter of 2020.

Biofrontera has also entered into discussions with the U.S. Food and Drug Administration (FDA) for approval in the U.S. of a label extension to include the treatment of AK on the extremities and trunk/neck. The FDA provided positive and constructive feedback requesting additional clinical trials in order to approve expanded indications for Ameluz® on additional areas of the body. The study protocol is currently being prepared for review by the FDA and commencement of patient recruitment is planned for the second half of 2020.

In addition, after consultation with the FDA, Biofrontera has initiated a pharmacokinetics study (PK study) testing the safety of PDT with three tubes of Ameluz®. The purpose of this phase I study is to obtain pharmacokinetic profiles after Ameluz®-PDT in subjects with actinic keratosis in an expanded treatment field located on the face/scalp or in the periphery. Furthermore, subjects' safety and tolerability during and after treatment will be assessed. The program provides for patient recruitment to last 3-5 months and for completion of this phase I study to be in the third quarter of 2020. The data from this study is expected to establish a basis to obtain coverage and reimbursement approval by governments, insurance companies and other third-party payors for the use of several tubes of Ameluz® in conjunction with a newly developed lamp for PDT of larger peripheral body regions.



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Biofrontera is currently working to develop a new PDT lamp, the “BF-RhodoLED-XL”, which would allow the use of Ameluz® on larger surfaces of the body. The schedule provides for submission of the application with the FDA in the second half of 2020.

With respect to the letter of intent between Biofrontera and Maruho Co. Ltd. regarding a possible indication expansion of Ameluz® for acne as well as the expansion of commercializing Ameluz® into parts of Asia and Oceania (see ad hoc-release on March 19, 2019), Biofrontera has prepared a development plan for the indication extension of Ameluz® to acne and requested FDA to comment on the plan. FDA has in the meantime provided feedback regarding the design of the required clinical trials, such that the trial program is ready to be initiated shortly.

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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.




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Supervisory board: Dr. Ulrich Granzer (Chairman) I Jürgen Baumann (Vice-Chairman)
Executive board: Prof. Dr. rer. nat. Hermann Lübbert (CEO) I Thomas Schaffer (CFO)
**Commercial register:** Handelsregister Köln I **Register number:** HR B 49717 (AG)
**VAT-identification number according to § 27 a UStG VAT act:** DE 812374102

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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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