

News release

Biofrontera receives FDA approval for upscaling of batch size for Ameluz® production

Leverkusen, Germany, January 8, 2019 – Biofrontera AG (NASDAQ: BFRA; Frankfurt Stock Exchange: B8F) (the “Company”), an international biopharmaceutical company, today announced that the U.S. Food and Drug Administration (FDA), and earlier the European Medicines Agency (EMA), have approved the upscaling of the batch size for the production of Ameluz® to 35 kg from previously 7 kg.

“The approval for a 5-fold increase in batch size ensures a secure supply of Ameluz® to meet the growing demand for Ameluz® in all regions. Scaling the manufacturing process by significantly increasing the batch size also allows for a substantial improvement of our gross margin,” explains Prof. Dr. Hermann Lübbert, CEO of Biofrontera. “We have reached another milestone of operational success, which answers to the overall success story of Ameluz®.”

The FDA-approval is effective January 3, 2019. The FDA defines a batch as a specific quantity of a drug that is intended to have uniform character and quality, within specified limits, and is produced according to a single manufacturing process in the same cycle of manufacture.

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About Biofrontera:

Biofrontera AG is an international biopharmaceutical company specializing in the development and commercialization of a platform of pharmaceutical products for the treatment of dermatological conditions and diseases caused primarily by exposure to sunlight that results in sun damage to the skin. Biofrontera's approved products focus on the treatment in the U.S. and Europe of actinic keratoses, which are skin lesions that can sometimes lead to skin cancer, as well as the treatment of certain forms of basal cell carcinoma in the European Union. American Depositary Shares representing Biofrontera's ordinary shares are listed on the NASDAQ Capital Market under the symbol "BFRA", and Biofrontera's ordinary shares are listed in the Frankfurt Stock Exchange (B8F, ISIN: DE0006046113). Information is also available at www.biofrontera.com.

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Forward Looking Statements:

Certain statements in this press release are forward-looking within the meaning of the Private Securities Litigation Reform Act of 1995 regarding the public offering and the intended use of proceeds from the offering. These statements may be identified by the use of forward-looking words such as "anticipate," "believe," "forecast," "estimate" and "intend," among others. Such forward-looking statements are based on the currently held beliefs and assumptions of the management of Biofrontera AG, which are expressed in good faith and, in their opinion, reasonable. Forward-looking statements involve known and unknown risks, uncertainties and other factors, which may cause the actual results, financial condition, performance, or achievements of the Company, or industry results, to differ materially from the results, financial condition, performance or achievements expressed or implied by such forward-looking statements. These risks, uncertainties and other factors are set forth in the Registration Statement on Form F-1 filed with the SEC, including in the section "Risk Factors," and in future reports filed with the SEC. Given these risks, uncertainties and other factors, prospective investors are cautioned not to place undue reliance on these forward-looking statements. The Company does not undertake an obligation to update or revise any forward-looking statement.

Biofrontera AG

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Christoph Dünwald (CCO) | Thomas Schaffer (CFO)
Commercial register: Handelsregister Köln | **Register number:** HR B 49717 (AG)
VAT-identification number according to § 27 a UStG VAT act: DE 812374102