

### **News release**

# **Biofrontera implements new Falsified Medicines Directive**

**Leverkusen, Germany, February 11, 2019** – Biofrontera AG (NASDAQ: BFRA; Frankfurt Stock Exchange: B8F) (the "Company"), an international biopharmaceutical company, has implemented all necessary safety measures defined in the new Commission Delegated Regulation (EU) 2016/161 to fight medicine falsifications. Since the Regulation came into force on February 9, 2019, only prescription drugs for human use with the safety features of the Commission Delegated Regulation (EU) 2016/161 may be released for marketing. Product batches released before February 9, 2019 may still be sold.

"The implementation of the Falsified Medicines Directive throughout the pharmaceutical supply chain will contribute to one thing in particular: the safety of prescription drugs. The safety standard is already at a very high level in Germany, but is being driven even further by the EU-wide laws," explains Prof. Dr. Lübbert, CEO of Biofrontera AG. "With the new Regulation, a further and significantly higher hurdle has now been created for drug counterfeiters. Patients will now be even better protected against counterfeit drugs of low quality or incorrect dosage of active substances".

The Commission Delegated Regulation (EU) 2016/161 essentially provides for the introduction of two security features. A unique identifier in form of a serialized number combined with a product code, batch number and expiry date make each package unique and individually identifiable. A so-called "anti-tampering device" protects the outer packaging against manipulation and allows verification of whether the packaging has been tampered with before the first use.

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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 <a href="https://www.biofrontera.com">www.biofrontera.com</a>.



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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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