Biofrontera
Experts in photodynamic therapy

News release

Expansion of indication treatment for Ameluz®: Biofrontera completes patient recruitment for Phase III Trial

- **Following the inclusion of the last patient, the phase III trial with Ameluz® for photodynamic therapy of actinic keratoses on the extremities and torso/neck is on track to be completed in the first quarter of 2019.**
- **50 patients at 6 sites in Germany have been enrolled.**
- **Filing for approval anticipated for Q3 2019.**

Leverkusen, Germany, July 26, 2018 – Biofrontera AG (NASDAQ: BFRA; Frankfurt Stock Exchange: B8F), an international biopharmaceutical company, has completed enrollment in another phase III trial with Ameluz®. The study investigates the safety and efficacy of conventional photodynamic therapy (PDT) with Ameluz® and the BF-RhodoLED® lamp for the treatment of actinic keratoses (AK) on the extremities as well as the torso and neck.

"Our goal is to allow patients to treat actinic keratoses and field cancerization on the entire body," explains Prof. Dr. Hermann Lübbert, CEO of Biofrontera: "Patients with actinic keratoses on their face and scalp, most likely have other severely affected areas of the body that are exposed to the sun, such as the hands, cleavage and neckline. Following successful approval, Ameluz® would be the only PDT drug in Europe and the USA that can be used to treat actinic keratoses of all degrees of severity on the extremities, as well as the torso and neck. The study is therefore another important milestone in increasing the competitiveness of Ameluz® in both Europe and the USA".

The multi-center, randomized, double-blind, intra-individual study included 50 patients located at six study sites in Germany, each with four to ten AK lesions in comparable areas on the right and left side of the extremities and/or torso/neck. Mild, moderate and severe actinic keratoses are treated with one or two PDT treatments. The last examination of the patients will take place three months after the last PDT treatment. The end of the clinical study phase is followed by a follow-up phase of twelve months after the last PDT. The results of the clinical trial phase are expected in the first quarter of 2019. Applications for the extension of marketing authorizations are to be submitted to the European Medicines Agency (EMA) and the US Food and Drug Administration (FDA) by the third quarter of 2019.

Each patient in the trial will be treated with Ameluz®-PDT on one side and a placebo-PDT on the other side of the extremities or torso/neck. The assignment of the sides is random. The primary

endpoint of the study is efficacy in terms of complete healing of the lesions. In addition, safety and secondary efficacy parameters are evaluated.

Actinic keratoses are changes of the skin that manifest themselves as non-healing redness with a rough surface on typical sunlight-exposed skin areas. They mainly occur in people over 50. The main risk factor for the development of actinic keratoses is long-term exposure to the sun, whether at work or during leisure activities. Actinic keratoses can develop into squamous cell carcinoma, the second most common, possibly malignant skin tumor, and thus has to be treated constantly. The number of annual treatments of actinic keratoses is estimated at over 12 million In the USA alone, and at over 2 million in the EU.

-END-

For enquiries, please contact:	
Biofrontera AG	+49 (0) 214 87 63 2 0
Thomas Schaffer, Chief Financial Officer	press@biofrontera.com
IR Germany: Brainwell Asset Solutions	
Jürgen Benker	+49 (0) 152 08931514
IR UK: Seton Services	
Toni Vallen	+44 (0) 207 224 8468
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 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.

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
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