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Experts in photodynamic therapy

News Release

Biofrontera starts patient recruitment for U.S. Phase III Trial Evaluating Ameluz® / BF-RhodoLED® for Superficial Basal Cell Carcinoma

- **Enrollment of 186 patients at 12 study sites in the U.S. started**
- **Phase III trial completion for photodynamic therapy of superficial basal cell carcinoma expected in first half of 2020**
- **Filing for approval with the FDA anticipated in second half of 2020**

Leverkusen, Germany, September 26, 2018 – Biofrontera AG (NASDAQ: BFRA; Frankfurt Stock Exchange: B8F), an international biopharmaceutical company, today announced that patient enrollment started for its U.S. phase III trial for Ameluz® for the treatment of superficial basal cell carcinoma (BCC). The study investigates the safety and efficacy of conventional photodynamic therapy (PDT) with Ameluz® in combination with the Company's BF-RhodoLED® lamp. The U.S. Food and Drug Administration (FDA) has, after intensive assessment, agreed with the protocol of the study.

"The commencement of the patient recruitment for our phase III trial for the treatment of superficial BCC represents another significant milestone as we seek to expand the market opportunity of Ameluz® in the U.S. In consultation with the FDA, we plan to apply for approval for this indication with this single phase III trial conducted in the U.S." commented Prof. Dr. Hermann Lübbert, CEO of Biofrontera AG. "After potential FDA approval, Ameluz® would be the only PDT drug in the U.S. that can be used to treat superficial BCC. Through PDT with Ameluz®, we want to offer patients and physicians a treatment option with high efficacy and excellent cosmetic results".

This randomized, double-blind and placebo-controlled study will include 186 patients at 12 study sites in the United States. Each patient will have one or more clinically and histologically confirmed superficial BCC. Patients will receive one cycle of two PDTs 1-2 weeks apart, which may be repeated after three months if required. The last assessment of the patients will take place three months after the last PDT cycle. After completion of the trial, Biofrontera will follow patients for an additional 5-year period.

Each patient will be treated with Ameluz®-PDT or placebo-PDT. The primary study endpoint is the composite complete clinical and histological clearance of a main BCC lesion, which will be

selected at the beginning of the study. In addition, data on drug safety as well as secondary efficacy parameters of all BCCs will be evaluated in the study.

The clinical trial results are expected in the first half of 2020. Biofrontera anticipates FDA submission of the approval supplement of Ameluz® for superficial BCC during the second half of 2020.

Basal cell carcinomas are the most common locally invasive skin tumors worldwide and are classified as non-melanoma skin cancers. They typically develop on skin areas exposed to sunlight, but rarely form metastases (<1 in 10,000 tumors)[1]. BCC occurs mainly in Caucasian people at the age of forty and older. The main risk factor for the development of BCC is long-term UV exposure, be it for work or leisure activities, and a patient's tendency to sunburn. The number of affected patients has risen dramatically in recent years with an annual increase of 3-10%[2]. In the U.S. alone, the number of newly diagnosed cases of BCC is estimated at over 4 million per year[3].

Sources:

[1] LeBoit PB, G.; Weedon, D.; Sarasin, A. Pathology and Genetics of Skin Tumours. World Health Organization Classification of Tumours. 2006.

[2] Roozeboom MH, Arits AH, Nelemans PJ, Kelleners-Smeets NW. Overall treatment success after treatment of primary superficial basal cell carcinoma: a systematic review and meta-analysis of randomized and non-randomized trials. Br J Dermatol. 2012;167(4):733-56.

[3] https://www.skincancer.org/skin-cancer-information/basal-cell-carcinoma

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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.

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 statements.

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