Biofrontera
Experts in dermatology

News release

Biofrontera reports further positive results from the phase III trial with Ameluz® for photodynamic therapy of actinic keratoses on the extremities and trunk/neck

Leverkusen, Germany, April 16, 2019 – Biofrontera AG (NASDAQ: BFRA; Frankfurt Stock Exchange: B8F) (the "Company"), an international biopharmaceutical company, today reports positive results for the secondary endpoints of its Phase III clinical trial evaluating the safety and efficacy of conventional photodynamic therapy (PDT) with Ameluz® in combination with the BF-RhodoLED® lamp for the treatment of actinic keratoses (AK) on the extremities or trunk/neck. Patients were treated with Ameluz® on one side of the body and with a placebo gel on the other side.

In line with the result for the primary endpoint of the study (see ad hoc report dated March 20, 2019), which showed a mean lesion clearance rate per patient's side of 86% for Ameluz® compared to 33% for placebo, significant superiority of Ameluz® was demonstrated for all secondary parameters investigated. Even if mild AKs were ignored and only moderate AKs were considered, mean lesion clearance rates per patient's side were 84% with Ameluz® compared to 27% with placebo. In patients treated on the extremities, mean lesion clearance rates per patient's side were also 84% with Ameluz® compared to 27% with placebo. Mean lesion clearance rates in the area trunk/neck were even higher. Furthermore, the comparison parameter "patient complete clearance" also emphasized the superiority of Ameluz®: 67% of the patients' sides were completely cleared 12 weeks after the last PDT compared to 12% of the placebo-treated sides. All of the results were statistically highly significant. Thus, all secondary endpoints also confirm the high superiority of Ameluz® over the control group.

"It is generally accepted in dermatology that actinic keratoses of the trunk and extremities are particularly difficult to treat. Once we have received the approval both in Europe and the U.S., our excellent results for the treatment of these body regions will make Ameluz® stand out even more compared to alternative forms of therapy," explained Prof. Dr. Hermann Lübbert, CEO of Biofrontera AG.

These results support the primary endpoint data for the applications to the European Medicines Agency (EMA) and U.S. Food and Drug Administration (FDA), which Biofrontera plans to submit during the third quarter of 2019.

The multi-center, randomized, double-blind, intra-individual study included 50 patients at six study sites in Germany, each with four to ten clinically confirmed AK lesions in comparable areas on the right and left side of the extremities and/or trunk/neck. Mild, moderate and severe actinic keratoses were treated with one or two PDT treatments. The final examination of the patients took place three months after the last PDT treatment. The clinical study phase is now followed by a follow-up phase

of twelve months after the last PDT, in which recurrence rates and/or numbers of new AKs and skin tumors are determined.

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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 statement.