Biofrontera
Experts in dermatology

News Release

Biofrontera announces full results of Phase III clinical trial evaluating BF-200 ALA for treatment of basal cell carcinoma (BCC)

- Regulatory endpoint achieved
- European approval of BF-200 ALA for treatment of BCC expected in Q4 2016
- European sales increase anticipated for BF-200 ALA

Leverkusen, Germany, March 04, 2016 - Biofrontera AG (FSE: B8F), the specialist for sun-induced skin cancer, today announced the full results of its Phase III clinical trial evaluating BF-200 ALA for the treatment of basal cell carcinoma (BCC) that demonstrate the study met its regulatory endpoints. The analysis fully confirmed the preliminary results, which were initially reported on January 28th 2016.

Results of the EU multi-center study confirm that 93.4% of patients treated with BF-200 ALA were cleared of all BCCs, compared to only 91.8% of patients treated with the comparator treatment, methyl aminolaevulinate (MAL) photodynamic therapy, which is marketed as Metvix® or Metvixia®. In the study, 281 patients with 1 to 3 non-aggressive BCCs, including both superficial and nodular BCC subgroups, up to a thickness of 2 mm were treated. The analysis of the individual BCCs yielded a complete clearance rate of 94.6% after treatment with BF-200 ALA, compared to 92.9% with MAL (all values refer to the per protocol group). A stronger deviation of efficacy between the two drugs became apparent in thicker tumors. While 96.4% of tumors between 0 and 1 mm thickness were completely removed by treatment with BF-200 ALA (95.7% MAL), the value decreased in 1-2 mm tumors to 72.7% with BF-200 ALA and 66.7% with MAL. 89.3% of nodular BCCs, a subgroup of non-aggressive BCCs, were completely cleared with BF-200 ALA in comparison to only 78.6% with MAL.

In addition, treatment with BF-200 ALA resulted in an excellent cosmetic outcome. In 60.0 % of patients treated with BF-200 ALA, skin aesthetic appearance was strongly improved and rated by study physicians as very good to excellent, compared to only 48.6 % of patients treated with MAL. To evaluate these characteristics, various skin parameters had been qualified by the study physicians and graded by the severity of skin damage. The improvement of each parameter was documented and included in the analysis. An unsatisfactory result without cosmetic improvement was observed in 17.1% of BF-200 ALA patients and 18.9 % of patients treated with MAL.

“These are excellent results for the treatment of an infiltrating skin cancer, which we anticipate will aid in obtaining European labeling extension of BF-200 ALA for basal cell carcinoma potentially in Q4 of this year, which goes beyond the initial approval in actinic keratosis (AK) obtained in 2011. These results clearly demonstrate the high efficacy of PDT with BF-200 ALA’s to destroy BCC tumor tissue across a range of tumor thicknesses without the formation of scar tissue and instead the promotion of skin regeneration for positive aesthetic outcomes. EMA

approval of BF-200 ALA in BCC will significantly expand the market potential of BF-200 ALA in the EU", said Prof. Hermann Lübbert, CEO of Biofrontera AG.

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About Biofrontera

Biofrontera Group (FSE/AIM: B8F, ISIN DE0006046113) is a biopharmaceutical company specializing in the development, sale and distribution of drugs and medical cosmetics for the care and treatment of skin diseases. Biofrontera's most important product is BF-200 ALA, a prescription drug approved in Europe under the name of Ameluz® for the treatment of mild and moderate actinic keratosis (superficial skin cancer) with photodynamic therapy (light therapy). Biofrontera is the first German pharmaceutical start-up company to obtain centralized approval for a drug it has developed itself. The company also plans for Ameluz® to be approved for basal cell carcinoma and is currently preparing for approval of BF-200 ALA in other countries, especially in the largest pharmaceutical market in the world, the United States.

The company also markets the Belixos® dermatological range of cosmetics. Belixos® products, a cream, a gel and a scalp tonic, contain combinations of active substances extracted from plants, relieve itching and redness and are used for the regenerative care of chronic skin conditions such as atopic dermatitis or psoriasis. The Belixos® Protect, a daily skincare for sun-damaged skin, complements this dermo-cosmetic line. All products are available through Amazon.

The Biofrontera Group was established in 1997 by Prof. Dr Hermann Lübbert, the Chairman of the company's Management Board, and has its headquarters in Leverkusen, Germany.

For more information, visit **www.biofrontera.com**

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