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Experts in photodynamic therapy

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Ad-hoc Release pursuant to Art. 17 MAR

Biofrontera receives 12-month follow-up results of the Phase III trial for daylight PDT

Leverkusen, Germany, 23 January 2018 (18:15 CET) – Biofrontera AG (FSE: B8F), the specialist for the treatment of sun-induced skin cancer, today announces 12-month follow-up results from its Phase III clinical trial for daylight PDT. The study for the treatment of actinic keratosis (AK) was conducted in direct comparison with the competitor product Metvix®. In only a single daylight PDT, a thin layer of Ameluz® was applied to one side of the head and Metvix® to the other side of the head, with the treatment sides randomly distributed. Afterwards, patients went outside within 30 minutes and were exposed to direct daylight for 2 hours.
The primary clinical endpoint, the pairwise comparison of complete removal of AK lesions after one PDT, displayed that an average of 79.8% of the lesions were no longer clinically visible 3 months after Ameluz® treatment, and 76.5% after Metvix® treatment. After 12 months, 19.9% of the lesions that had previously been completely removed with Ameluz® reappeared; with Metvix®, 31.6% of the lesions were recurrent at that time.
A review of the subgroups reveals the lesions responsible for this difference: In the face, the total removal of lesions 3 months after one daylight PDT was 85.2% with Ameluz® and 84.2% with Metvix®. After 12 months, however, 25.0% of these lesions were visible again for lesions treated with Metvix® and only 20.1% for Ameluz® treated lesions. The difference was greater for lesions on the scalp, which are generally more difficult to treat than lesions in the face: After AK treatment with Ameluz®, a clinical clearance rate of 74.2% was observed 3 months after daylight PDT, of which 23.4% were recurrent within 12 months. With Metvix®, the clearing rate was 67.5%, and after 12 months 43.7% recurrences were observed. In patients with mild AKs only, 93.7% of all lesions were initially not clinically detectable after Ameluz® treatment, and in patients with at least one moderate AK, 77.5% of AKs could no longer be diagnosed three months after treatment. After 12 months, these patients were again diagnosed with 16.7% and 20.5% of the previously invisible

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AKs. With the comparator product Metvix®, 91.2% of the lesions in patients with only mild and 74.1% in patients with also moderate AKs were not clinically detectable 3 months after treatment, 17.5% and 34.3% of these AKs, however, were recurrent after 12 months. The weather conditions also play a role for Daylight PDT. At temperatures up to 20°C and above 20°C, the healing rates for Ameluz® after three months were 80.1% and 79.5%, the recurrence rates were 21.5% below 20°C and 18.6% above 20°C ambient temperature. This parameter displayed another strong difference observed with Metvix®, for which clearing rates of 78.4% and 74.6% and recurrence rates of 26.8% and 36.1% were observed.
Overall, the comparison of Ameluz® and Metvix®, which is marketed as an identical product for daylight PDT under the brand name Luxerm®, shows a clear trend towards improved efficacy and, in particular, lower recurrence rates for Ameluz®, which is in line with previous comparative phase III studies on AK and basal cell carcinoma.

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