Biofrontera
Experts in photodynamic therapy

Ad hoc release

Ad-hoc Release pursuant to Art. 17 MAR

Biofrontera Reports Positive Phase III Results with Ameluz® for photodynamic therapy of actinic keratoses on the extremities and trunk/neck

Leverkusen, Germany, 20.03.2019 – Biofrontera AG (NASDAQ: BFRA; Frankfurt Stock Exchange: B8F), an international biopharmaceutical company, today received positive preliminary results for the primary endpoint of its Phase III clinical trial evaluating 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 trunk and neck. The study met its primary regulatory endpoint, demonstrating that Ameluz® was superior ($p<0.0001$) to placebo based on its mean total lesion clearance rate of 86% compared to 33% for placebo. These results will be utilized for the filing of the label extension with the European Medicines Agency (EMA) and the US Food and Drug Administration (FDA), which Biofrontera plans to submit in 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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