Ad hoc release

Ad-hoc Release pursuant to Section 15 of the German Securities Trading Act (Wertpapierhandelsgesetz)

Biofrontera Reports Positive Phase III Results for Ameluz® in Combination with Daylight-PDT

Leverkusen, Germany, February 6, 2017 – Biofrontera AG (FSE: B8F), the specialist for the treatment of sun-induced skin cancer, today received positive preliminary results for the primary endpoint of its Phase III clinical trial evaluating the safety and efficacy of its topical drug BF-200 ALA (Ameluz®) in combination with daylight photodynamic therapy (PDT). The study met its primary regulatory endpoint, demonstrating that Ameluz® in combination with daylight PDT was non-inferior ($p<0.001$) to standard of care MAL (Metvix®) for the treatment of mild to moderate actinic keratosis (AK), a superficial early skin cancer. These results will be employed for the filing of the EU label extension, which Biofrontera plans to submit in the second quarter of 2017. Detailed results for secondary endpoints will become available in the coming weeks.

The study met its primary endpoint, resulting after a single daylight PDT in 79.8% total lesion clearance rate per patient's side in the areas treated with BF-200 ALA and daylight PDT, compared to 76.5% total lesion clearance in areas treated with MAL and daylight PDT. For comparison, the much larger study ALA-AK-CT002, which compared the two products and demonstrated superiority of BF-200 ALA over MAL, resulted in lesion complete clearance rates after the first PDT with narrow-spectrum lamps of 77.1% with BF-200 ALA and 73.0% with MAL, respectively (1).

The intra-individual, randomized, observer-blind, multi-center study was performed with 52 patients at 7 centers in Spain and Germany. Every patient had 3 to 9 mild to moderate AK lesions in each of two comparable treatment areas on the face and/or scalp. For an intra-patient comparison of the treatments, each patient received daylight-PDT with BF-200 ALA on one side, and MAL on the other side. The study will be followed by assessments of lesion recurrence 6 and 12 months after daylight PDT.

BF-200 ALA is a topical prescription drug approved in the U.S. and EU (2,3). Daylight PDT offers a rather painless alternative to PDT with a specialized lamp, as the topical medication is activated by exposure to natural or artificial daylight.

References:

1) https://www.ncbi.nlm.nih.gov/pubmed/21910711

2) http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Product_Information/human/002204/WC500120044.pdf

3) http://www.accessdata.fda.gov/drugsatfda_docs/label/2016/208081s000lbl.pdf

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