Ad hoc release

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

Biofrontera's Ameluz® achieves excellent results in clinical study for basal cell carcinoma

Leverkusen, Germany, January 28, 2016 – Biofrontera AG (FSE: B8F), the specialist for sun-induced skin cancer, has received preliminary phase III study results for the treatment of basal cell carcinoma using PDT, photodynamic therapy. The results confirm the company's positive expectations. The clinical study compared the efficacy and safety of Ameluz® to Metvix®, a drug approved for BCC in the European Union. Included in the study were non-aggressive, superficial or nodular BCCs with a thickness of up to 2 mm. With 93.4% removal of all BCCS Ameluz® achieved higher clearing rates than Metvix® with 91.8%. The calculation of the relationship between total clearance and tumor thickness will be reported when available.

A total of 278 patients were treated in the pivotal phase III study. The study was performed at 27 clinical centers in Britain and Germany with Principal investigators Prof. Dr. Colin Morton (Great Britain) and Prof. Dr. Markus Szeimies (Germany).

Based on the results of the phase III study Biofrontera will apply with the European Medicines Agency for approval of Ameluz® for treatment of BCC in the EU. The expanded approval only requires an extension of the existing approval, which is expected to be granted later this year.

BCCs are the most frequent infiltrating tumors in humans and represent 50-80% of all infiltrating non-melanoma skin cancers. Approximately 30% of Caucasians worldwide develop at least one BCC in their lifetime, with increasing incidence due to higher UV load. BCCs are most frequently removed by surgery, a procedure that often leads to scar formation. The use of photodynamic therapy (PDT) is a highly effective alternative which leads to excellent cosmetic results.

The BCC expanded approval for Ameluz® will provide Biofrontera the opportunity to increase market share through market penetration in clinical settings. With the anticipated indication expansion the company expects a substantial increase of Ameluz® sales in Europe.

Ad hoc Meldung

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