Biofrontera
Experts in photodynamic therapy

Ad hoc release

Ad-hoc Release pursuant to Art. 17 MAR

European Commission approves use of Ameluz® in combination with Daylight Photodynamic Therapy

Leverkusen, Germany, 05 March 2018 (14:55 CET) – Biofrontera AG (FSE: B8F), the specialist for the treatment of sun-induced skin cancer, today announced that the European Commission has approved the use of Biofrontera's topical prescription drug Ameluz® in combination with daylight Photodynamic Therapy (daylight PDT). The approval for daylight PDT is expected to greatly increase the market potential for Ameluz® in Europe, and to improve the drug's reimbursement status in Germany.
The approval by the European Commission followed a positive opinion by the European Medicines Agency (EMA; compare ad-hoc release of January 29) and is based on a phase III trial comparing Ameluz® side-by-side with its competitor Metvix®. While the difference in clearance rates was only minor between both products three months after treatment, statistically significant differences became apparent during the 1-year follow-up period. Three months after a single treatment with daylight PDT, 79.8% of the Ameluz® and 76.5% of the Metvix® patients were fully cleared. One year after the treatment, however, 19.9% of the lesions were recurrent after Ameluz® PDT and 31.6% after Metvix® PDT, respectively ($p<0.01$). Recurrence rates for more difficult to treat lesions such as moderately thick lesions (Olsen II) or lesions on the scalp were 20.5% and 23.4% for Ameluz®, and 34.3 and 43.7% for Metvix®, respectively ($p<0.01$). This superior efficacy 1 year after PDT is expected to facilitate market penetration of Ameluz®.

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