Biofrontera
Experts in photodynamic therapy

Ad hoc release

Ad-hoc Release pursuant to Art. 17 MAR

Biofrontera Receives Favorable CHMP Assessment for Ameluz® in Combination with Daylight Photodynamic Therapy

Leverkusen, Germany, 29 January 2018 (12:20 CET) – Biofrontera AG (FSE: B8F), the specialist for the treatment of sun-induced skin cancer, today announced that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has issued a positive opinion regarding Biofrontera's submission for label extension for the use of its topical prescription drug Ameluz® in combination with daylight Photodynamic Therapy (daylight-PDT). This mode of application eliminates the requirement of illuminating with a special red light in the dermatology office. An additional advantage of daylight-PDT is its good tolerability. Conventional PDT can be accompanied by pain during illumination while daylight-PDT is almost completely pain-free. Based on the positive opinion, Biofrontera anticipates formal approval by the European Commission in the coming weeks, significantly expanding the market opportunity for Ameluz® in Europe. Following final approval Ameluz® can be used without doctor's office procedures, allowing easier reimbursement of Ameluz® in the German but also in other European markets.

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