

News Release

PDT with Ameluz[®] is the most efficacious treatment option for actinic keratosis

Leverkusen, 2 July 2014 - A meta-analysis of all hitherto published clinical trials on drugs treating actinic keratosis was performed at the University of Groningen and at the Tolley Health Economics Consultancy Ltd in Buxton, United Kingdom. The resulting analysis demonstrated that Biofrontera's Ameluz[®] is, with overwhelming likelihood, the most efficacious drug¹. Until now, a direct clinical comparison of the efficacies was only available with competitor Metvix[®]. In this comparison, Ameluz[®] had already displayed a significantly higher rate of patients completely cleared of all keratotic lesions².

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The new scientific publication applied a mathematical approach to determine the relative efficacy of all available treatment options, including those outside photodynamic therapy (PDT). The publication by S. Vegter and K. Tolley has, based on data with nearly 5,500 patients in 25 clinical studies, demonstrated with high likelihood that Ameluz[®] displays the highest efficacy in the treatment of AK¹. The topical products, currently favoured in clinical praxis, were left far behind Ameluz[®] with respect to their efficacy.

Commenting, Prof. Hermann Lübbert, Biofrontera's CEO, said: "The publication confirms that with Ameluz[®] we have developed a product that should, not only in regulatory terms, but also in the clinical praxis, be the first-choice treatment option for actinic keratosis. In addition to the clinical efficacy confirmed in the new publication, the excellent cosmetic result should be taken into consideration. The long-lasting treatment success² renders Ameluz[®]-PDT extremely attractive not only clinically but also pharmaco-economically. In the interest of patients clinical decision makers should rethink the choice of treatment options. Modern dermatology will not get around Ameluz[®]."

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Sources:

¹ Vegter S, Tolley K (2014) A Network Meta-Analysis of the Relative Efficacy of Treatments for Actinic Keratosis of the Face or Scalp in Europe. PLoS ONE 9(6): e96829.doi:10.1371/journal.pone.0096829.

<http://www.plosone.org/article/info:doi/10.1371/journal.pone.0096829>

² Dirschka et al. (2012) Photodynamic therapy with BF-200 ALA for the treatment of actinic keratosis: results of a multicentre, randomized, observer-blind phase III study in comparison to Metvix[®] and placebo. *Br J Dermatol* 166:137-146.

³ Dirschka et al. (2013) Long-term (6 and 12 months) follow-up of two prospective, randomized, controlled phase III trials of photodynamic therapy with BF-200 ALA and methyl aminolaevulinate for the treatment of actinic keratosis. *Br J Dermatol* 168: 825–836.

Biofrontera AG

Biofrontera aims at attending and treating the skin, recognizing the aesthetic needs of a person's visual reflection.

Biofrontera AG is listed in the Prime Standard of the Frankfurt stock exchange under the symbol B8F and the ISIN number DE0006046113.

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