

News Release

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Actinic keratosis, most efficiently treated by Ameluz[®], recognized as occupational disease

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Leverkusen, Germany - Biofrontera AG (DSE : B8F) announces that actinic keratosis, the disease for which Biofrontera's Ameluz[®] is approved in the EU, was classified as an occupational disease in Germany. This was the result of the "expert medical advisory board occupational diseases" at the Federal Ministry of Labor and Social Affairs, Germany.

Actinic keratoses are superficial skin tumors, which may develop into malignant squamous cell carcinomas. The scientific rationale for the classification as an occupational disease was published in the 'Ministerialblatt' of the German federal government¹. The medical advisory board concluded that an occupational UV exposure of 40 % above normal levels at the site of tumor formation argues for a mostly work-related cause. The acceptance as an occupational disease is contingent upon providing evidence for sufficient work-related outdoor activity, in general occurring in the following occupational groups: agriculture, forestry, fishing and marine, construction and crafts (such as roofers, carpenters, building labor, bricklayers, steel fitter, welder on bridges), road workers, garbage collectors, window cleaners, sports instructors, lifeguards, preschool teachers, mountain guides, and the like. In Germany, about two million people are employed in these occupational groups¹. The statutory accident insurances are now required to create policies and forms for implementation.

As a consequence of the recognition of actinic keratosis as a work-related disease patients with multiple keratoses will now be reimbursed for the costs of treatment by the employer's mutual insurance association. Similar to private health insurances the medical services can then be paid for individually rather than by the flat fee per patient used in German public health insurances. Photodynamic therapy is a treatment option using a drug in combination with a red light illumination. Most public insurance companies remunerate the dermatologist's work in the procedure just by the flat fee. The recognition as an occupational disease is now providing

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access to this highly effective treatment option for patients with public health insurance.

Since the pivotal clinical studies for Ameluz[®] demonstrated the highest overall efficacy rates reported thus far, particularly when considering the long-term results², Ameluz[®] will most likely benefit most from the classification of actinic keratosis as an occupational disease.

Prof. Dr. Hermann Lübbert, CEO of Biofrontera AG, commented: "Actinic keratosis is frequently not taken seriously as precursor of a dangerous form of skin cancer. The recognition as an occupational disease illustrates the different appreciation by the medical expert's advisory board. Consequently, optimal efficacy rates should be the determining factor in selecting the appropriate therapy."

References:

¹ Gemeinsames Ministerialblatt, Herausgegeben vom Bundesministerium des Innern, 64. Jahrgang, Nr. 35, 12. August 2013, Page 669

² Dirschka et al., British Journal of Dermatology (2013) 168, pp825–836

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

Biofrontera AG is listed on the regulated market of the Frankfurt stock exchange under the symbol B8F and the ISIN number DE0006046113.

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