News Release

8 January 2013

Biofrontera receives positive EMA opinion on extended storage conditions for Ameluz®

For further information please contact:

Anke zur Muehlen
Director PR/IR

+ 49 214 87632 0
+ 49 214 87632 90
a.zurmuehlen@biofrontera.com
Biofrontera AG
Hemmelrather Weg 201
D- 51377 Leverkusen, Germany

Leverkusen, Germany – Biofrontera AG (DSE: B8F) today announced that the European Medicines Agency EMA has provided a positive opinion on several variations of the marketing authorisation of Ameluz® and informed the European Commission accordingly. The variations are based on extended stability data and related to the storage conditions of Ameluz®, Biofrontera's first prescription drug for the treatment of actinic keratosis. The unopened tube can now be stored for 3 years, while 2 years had been approved before. After the first opening the tube can be used repeatedly during 3 months. The warning 'do not freeze' will be deleted since, opposite to previous concerns, freezing and thawing does not harm the product quality.

The extended storage period of the unopened tube will reduce production costs by facilitating the planning of production and storage at the whole salers. A cycle of actinic keratosis treatment with Ameluz® includes one photodynamic therapy that is repeated after three month if residual lesions remain. Although Ameluz is generally used for larger skin areas where the entire tube is used up in one treatment, residual product may now be applied in the second treatment. Freezing the product may occur during transport in winter and in the Nordic countries, which is now not considered critical.

'The active ingredient aminolaevulinic acid is known for its instability in aqueous solutions. The new stability data represent an impressive confirmation of the advantages of the innovative nanoemulsion technology developed by Biofrontera. The three-month stability after opening allows doctors and patients to use the same tube in a repeat of the treatment on the same patient', commented Biofrontera's CEO, Prof. Hermann Luebbert.

Background

Ameluz® (developed as BF-200 ALA gel) was centrally approved in the entire European Economic Area for the treatment of actinic keratosis in December 2011. The product is applied in the relatively novel photodynamic therapy (PDT). PDT of

Biofrontera
Experts in dermatology

News Release

actinic keratosis lesions with Ameluz® leads to very high efficacy and excellent cosmetic results, without the side-effects and discomfort of a long-term treatment. The treatment can be repeated after three months if residual lesions remain. A direct clinical comparator study testing the clearance of all actinic keratoses of a patient proved the strong superiority of Ameluz® compared to its closest competitor[1,2].

Actinic keratosis is a superficial skin cancer that is still restricted to the upper skin layer (the epidermis). These tumours result from UV-light induced damage accumulating during the entire life time. Thus, they occur very frequently in sun-exposed skin regions. In about 10-15% of the affected people the actinic keratosis lesions develop into malignant, potentially fatal squamous cell carcinomas.

For further information please contact:

Anke zur Muehlen
Director PR/IR

+ 49 214 87632 0
+ 49 214 87632 90
a.zurmuehlen@biofrontera.com
Biofrontera AG
Hemmelrather Weg 201
D- 51377 Leverkusen, Germany

About Biofrontera AG

Biofrontera Pharma GmbH is a wholly-owned subsidiary of Biofrontera AG. The Biofrontera group aims at attending and treating the skin, recognizing the aesthetic needs of a person's visual reflection. Biofrontera is listed at the regulated market of the Frankfurt stock exchange under the symbol B8F and the ISIN number DE0006046113.

www.biofrontera.com

This press release contains forward-looking statements based on the currently held beliefs and assumptions of the management of Biofrontera AG, which are expressed in good faith and, in their opinion, reasonable. Forward-looking statements involve known and unknown risks, uncertainties and other factors, which may cause the assumptions expressed or implied in this press release to be faulty. Given these risks, uncertainties and other factors, recipients of this document are cautioned not to place undue reliance on the forward-looking statements. Biofrontera AG disclaims any obligation to update these forward-looking statements to reflect future events or developments.

References

1.) Ameluz® Summary of Product Characteristics; www.ema.europa.eu.
2.) Dirschka et al. (2012) Br. J. Dermatol. 166: 137-146.