

## News Release

### Allergan launches Ameluz® in Spain

Leverkusen, Germany, 21. October 2013 – Biofrontera AG (DSE : B8F) announces today that at the end of September Allergan, her representative in Spain, had started marketing and sales of Biofrontera's prescription drug Ameluz® in Spain with an educational event for Spanish dermatologists in Madrid. This was preceded by extensive negotiations with the Spanish authorities about reimbursement and price. Ameluz® is now fully reimbursed in the photodynamic treatment of actinic keratosis in Spain.

Actinic keratosis, a precursor of malignant skin cancer, requires medical treatment. In countries like Spain, where people are often exposed to direct sunlight over many years, actinic keratosis is widespread particularly among people at higher ages. Its high incidence renders actinic keratosis one of the five cancer types with the highest cost for the health care system<sup>1</sup>. In up to 10% of the patients untreated actinic keratosis develops into life-threatening squamous cell carcinoma<sup>2</sup>.

Ameluz® combines the active ingredient 5-aminolevulinic acid with a nanoemulsion that improves skin penetration. The medicine is applied in the context of photodynamic therapy (PDT) in combination with red light, and selectively destroys the tumor tissue<sup>3,4</sup>.

"Due to the high number of sun hours we have in the year, actinic keratosis is a very frequent disease in Spain," said Dr. Carlos Guillén of the Institute of Oncology in Valencia at Allergan's event. "Men are preferentially affected. The precancerous damage occurs especially in the face and on the scalp. With Ameluz® a very effective treatment becomes available, which often erases all tumor cells after a single application."

"We are excited about the market introduction of Ameluz® in Spain, since we are aware of the large number of people suffering from this skin disease, especially in rural areas or after frequent activities in the open. It is one of our top priorities in Spain to help the large number of people suffering from actinic keratosis who may benefit from this new and effective treatment," said Christoph Duenwald, Business Unit Director, Allergan Spain. "Our exclusive partnership with Biofrontera in marketing Ameluz®-PDT in Spain illustrates our experience in dermatology and our continuous commitment to the dermatologists," he concludes.

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### Background

*Ameluz® was approved by the European Commission as a first-line therapy for the treatment of mild and moderate actinic keratosis on the face and scalp in December 2011. Clinical studies have shown the highest cure rates of actinic keratosis ever reported in Phase III studies with prescription drugs. The product is a photosensitizing agent used in photodynamic therapy (PDT). Actinic keratosis is mostly seen in fair-skinned people on skin areas that have had long-term sun exposure. The condition affects about 10% of the entire Caucasian population world-wide. About 5-20% of patients with actinic keratosis lesions develop malignant and potentially fatal squamous cell carcinomas.*

### About Biofrontera

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](http://www.biofrontera.com)

### About Allergan

Allergan is a pharmaceutical company with approximately 11,200 employees and a presence in more than 100 countries. With over 60 years of experience, the company is specialized on the medical disciplines ophthalmology, neuroscience, urology and aesthetic medicine. [www.allergan.com](http://www.allergan.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.*

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### References:

- <sup>1</sup> Mudigonda T et al. (2010) The economic impact of non-melanoma skin cancer: a review. *J Natl Compr Canc Netw* 8: 888-96.
- <sup>2</sup> Glogau RG (2000) The risk of progression to invasive disease. *J Am Acad Dermatol* 42: 23-4.
- <sup>3</sup> Szeimies RM et al. (2010) Photodynamic therapy with BF-200 ALA for the treatment of actinic keratosis: results of a prospective, randomized, double-blind, placebo-controlled phase III study. *Br J Dermatol* 163: 386-94.
- <sup>4</sup> Dirschka T 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: 825-36.