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**Rapid progress in phase III studies for BF-200 ALA in the treatment of actinic keratosis**

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Leverkusen, Germany – Biofrontera AG (DSE: B8F) announces that by the end of March all patients for the first relevant phase III study for BF-200 ALA were recruited and treated. The study compares the efficacy of BF-200 ALA in patients with actinic keratosis to placebo. After receiving all relevant national and international approvals Biofrontera kicked off the second phase III study relevant for approval. This study is to compare BF-200 ALA with the established standard medication and will be performed in Germany, France, Austria and Switzerland.

The patient recruitment for the first study had only started at the end of 2007 and was completed earlier than expected. In accordance with the study protocol, 120 patients were treated, whereby two thirds received BF-200 ALA and one third placebo. The study results are expected in the fourth quarter of 2008.

In the second phase III study a total of 616 patients are to be treated, of which 264 patients will receive BF-200 ALA; 264 patients the comparator Metvix<sup>®</sup>, and the remaining 88 patients will be treated with placebo. To date eleven study centres in Germany and four in Austria have been selected to participate in the latter clinical trial. To enhance the recruitment process, the number of participating dermatological surgeries are to be increased over the next few weeks. The study is monitored by Accovion GmbH in Eschborn, Germany, with PD Dr. med. Thomas Dirschka taking up the position of principal investigator. The recruitment process is expected to be completed within six to nine months. Hence Biofrontera awaits the clinical results in 2009.

Biofrontera's product candidate BF-200 ALA combines the nanoemulsion BF-200, developed and patented by Biofrontera, with the active ingredient 5-aminolevulinic acid (ALA). The latter active ingredient is used in the photodynamic therapy of precancerous and cancerous skin lesions.

## News Release

“With the approval of the study, the starting signal for the largest phase III study in the field of photodynamic therapy has been given” announces Prof. Hermann Lübbert, CEO of Biofrontera AG. “The study shall prove the excellent product characteristics of BF-200 ALA compared to the standard medication”.

### Actinic Keratosis

Actinic keratosis primarily develops in skin regions exposed to the sun e.g. face, head and hands. Taking up the form of individual, small skin alterations, actinic keratosis is classified as an early skin cancer, which develops into malignant squamous cell carcinoma in approximately 10% of the cases.

Actinic keratosis is the third most common reason for visiting a dermatologist. In Europe approximately 5 million new cases of actinic keratosis are reported each year

### About Biofrontera AG

Biofrontera AG is specialized in the development of pharmaceutical products in the area of dermatology. The company is characterized by a broad, relatively close to the market product portfolio and a solid liquidity. Biofrontera is listed in the regulated market of the Düsseldorf stock exchange under the symbol B8F and the ISIN number DE0006046113.

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