Biofrontera
Experts in dermatology

News Release

## Data from pivotal Phase III studies with BF-200 ALA: First introduction to US dermatologists as a poster and two oral presentations at the 14th South Beach Symposium

Leverkusen, Germany, February 11, 2016 - Biofrontera AG (FSE: B8F), the specialist for sun-induced skin cancer, presents data from three pivotal Phase III trials for its lead drug candidate BF-200 ALA at the 14th Annual South Beach Symposium. The studies demonstrate very high efficacy, positive safety and excellent aesthetic outcomes that is activated using photodynamic therapy (PDT) for the topical treatment of actinic keratosis (AK), a superficial skin cancer caused by sun damage.

The results are being presented in a poster (Poster #118) on display February 11-14 and will be highlighted during two oral presentations on Friday, February 12 by two members of Biofrontera's Scientific Advisory Board at the 14th Annual South Beach Symposium, being held February 11-14, 2016 at the Fontainebleau Hotel in Miami Beach, Florida.

Two of the studies formed the basis for marketing authorization approval of BF-200 ALA as first-line treatment of mild to moderate actinic keratosis on the face and scalp by the European Medicines Agency in December 2011. The third study was performed to strengthen the New Drug Application submitted to the U.S. Food and Drug Administration in July 2015. Filing of the application was accepted in September, since when the FDA undertakes its substantive review. No review issue was reported by the FDA following their mid-term review meeting.

In the three Phase III trials conducted in centers in Germany, Switzerland and Austria, a total of 779 patients with 4 to 8 mild to moderate AK lesions were randomized, with all three studies using red light PDT with LED illumination sources at approximately 635 nanometers (nm).

- **A 122-patient Phase III study** demonstrated excellent efficacy of BF-200 ALA compared to placebo with a patient complete clearance rate of 87%, compared to placebo response of 13%.[1]

- **A 571-patient Phase III study** showed significantly improved patient clearance rates for BF-200 ALA (85%) compared to those of placebo (13%) and methylaminolevulinate (MAL) (68%), which is marketed as Metvix™ and was the current standard of care topical photosensitizing agent used in PDT. A 1-year follow-up showed slightly lower recurrence rates for BF-200 ALA compared to MAL, and PDT side effects were not enhanced using BF-200 ALA.[2]

- **An 86-patient Phase III study** used a field directed approach (the entire tube of BF-200 ALA was applied to a field of cancerized skin) and compared efficacy and cosmetic outcome of BF-200 ALA with placebo, finding that 91% percent of the patients

completely cleared after a maximum of two treatments with BF-200 ALA, compared to only 22% complete clearance with placebo. With BF-200 ALA treatment, clearance was sustained over one year of follow-up in 63.3% of the patients. Several cosmetic parameters were followed during follow-up and found to continuously improve, for the first time proving the strong skin rejuvenation of PDT in a controlled pivotal trial.[3]

In addition to the three phase III studies on AK, results of a Phase III study of BF-200 ALA for the treatment of non-aggressive basal cell carcinoma (BCC) showed high clearance rates of all superficial and nodular BCCs in more than 93.4% of the patients.

Prof. Dr. Hermann Lübbert, PhD, CEO of Biofrontera AG, commented, “These results from our three Phase III trials evaluating BF-200 ALA in actinic keratosis are substantial as they demonstrate the clinical viability of our novel combination therapy system. Our photosensitizer agent BF-200 ALA utilizes a unique delivery method through nanoemulsion technology which constitutes a stabilized and penetration-enhancing formulation for use in PDT, making it one of the most effective treatment modalities for the removal AK lesions and BCC tumors.”

Dr. Brian Berman, MD, PhD, Professor Emeritus, Dermatology and Cutaneous Surgery at the University of Miami Miller School of Medicine and SBS Session Director and presenter of the oral presentation *Futures Symposium: Innovations in Clinical and Aesthetic Dermatology*, added, “Skin cancer remains the most diagnosed cancer in the U.S., and can often be fatal, requiring better treatment options and improved outcomes for patients. Innovations in the clinic like BF-200 ALA could offer an effective and safe treatment option. Data from the large 570-patient comparator study in particular demonstrated that BF-200 ALA reaches a significantly superior patient complete clearance rate in AK-treatment as compared to Metvix® while the side-effect profile does not differ. Furthermore, the high therapeutic efficacy of BF-200 ALA becomes particularly evident when treating Olsen grade II lesions and lesions on the scalp.”

**References**

1. Szeimies et al., 2010.
2. Dirschka et al., 2012.
3. Reinhold et al, submitted.

**About South Beach Symposium**

The South Beach Symposium has an audience of more than 550 attendees, with approximately 95% physicians in core specialties including Dermatology, Plastic Surgery, Ophthalmology and Facial Plastic Surgery. The Symposium features cutting edge educational sessions with non-overlapping CME tracks: the Masters of Pediatric Dermatology Symposium, the South Beach Clinical Dermatology Symposium, the South Beach Aesthetics Symposium and the Practice Management Symposium.

**Ends**

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## About Biofrontera

**Biofrontera Group** (FSE/AIM: B8F, ISIN DE0006046113) is a biopharmaceutical company specialising in the development, sale and distribution of drugs and medical cosmetics for the care and treatment of skin diseases. Biofrontera's most important product is **Ameluz®**, a prescription drug which is approved in Europe for the treatment of mild and moderate actinic keratosis (superficial skin cancer) with photodynamic therapy (light therapy). Biofrontera is the first German pharmaceutical start-up company to obtain centralised approval for a drug it has developed itself. The company also plans for Ameluz® to be approved for basal cell carcinoma and is currently preparing for approval in other countries, especially in the largest pharmaceutical market in the world, the United States.

The company also markets the Belixos® dermatological range of cosmetics. Belixos® products, a cream, a gel and a scalp tonic, contain combinations of active substances extracted from plants, relieve itching and redness and are used for the regenerative care of chronic skin conditions such as atopic dermatitis or psoriasis. The Belixos® Protect, a daily skincare for sun-damaged skin, complements this dermo-cosmetic line. All products are available through Amazon.

The Biofrontera Group was established in 1997 by Prof. Dr Hermann Lübbert, the Chairman of the company's Management Board, and has its headquarters in Leverkusen, Germany.

For more information, visit **www.biofrontera.com**

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