Biofrontera
Experts in dermatology

Press Release

Biofrontera Reports Detailed Phase III Results for Ameluz® in Combination with Daylight-PDT

- **Data show daylight photodynamic therapy (PDT) with Ameluz® provided excellent results for the primary and all secondary study endpoints**
- **EMA filing for EU approval of daylight PDT for actinic keratosis (AK) expected in Q2 2017**

Leverkusen, Germany, March 12, 2017 – Biofrontera AG (FSE: B8F), the specialist for the treatment of sun-induced skin cancer, today announced detailed results from its Phase III clinical trial evaluating the safety and efficacy of its topical prescription drug Ameluz® in combination with daylight photodynamic therapy (PDT). The study met its primary endpoints, demonstrating that Ameluz® in combination with daylight PDT was non-inferior to standard of care Metvix® for the treatment of mild to moderate actinic keratosis (AK), a superficial skin cancer. Furthermore, Ameluz® compared favorably to Metvix® in all secondary endpoints. These results will serve as the basis for the filing for EU label extension, which Biofrontera intends to submit during the second quarter of 2017.

The study met its primary endpoint, exhibiting a total lesion clearance rate (percentage of completely cleared individual lesions per patient's side) of 78.7% for the areas treated with Ameluz®; demonstrating non-inferiority to Metvix®, where 75.0% of lesions were fully cleared after one daylight PDT ($p<0.0001$). Histological evaluation of lesion clearance resulted in a similar outcome, with 72.5% versus 66.7% of lesions fully cleared after treatment with Ameluz® and Metvix®, respectively.

All secondary endpoints compared favorably with Metvix® and showed equivalent or better clearance rates. 85% of lesions on the face were fully cleared after a single PDT with Ameluz®, and 72% of the more difficult to treat lesions were fully cleared on the scalp. For Metvix®, 84% and 65% of the lesions were fully cleared on face and scalp, respectively. The treatment of moderate AK lesions resulted in 76% fully cleared with Ameluz®, compared to 73% with Metvix®. Mild AK lesions had a clearance rate of 94% with Ameluz® and 91% with Metvix®. Lesions in patients with ≤5 AKs were fully cleared in 83% of cases with Ameluz® and 81% with Metvix®, while 77% versus 72% of lesions were fully cleared in patients with >5 AKs by Ameluz® and Metvix® treatment, respectively. The most notable differences between Ameluz® and Metvix® clearance rates were observed in patients younger than 65 years of age (83% vs. 74%) and for patients treated during cloudy weather (75% vs. 66%), respectively. Results of daylight PDT during sunny weather conditions improved lesion clearance rates to 85% with Ameluz® and 83% with Metvix®.

Complete clearance of all lesions was achieved by Ameluz® in 60% of patients with lesions on the face, compared to 50% for Metvix® treated patients. Patients with scalp lesions were fully cleared of all keratoses in 33% and 26% of cases using Ameluz® or Metvix® respectively.

There were no notable differences in side effects. Most relevant, pain during the illumination was rated by the patients on a scale of 0 (no pain) to 10 (very severe pain) as 1.4 for Ameluz® and 1.5 for Metvix®.

Prof. Dr. Hermann Lübbert, CEO of Biofrontera, commented, “Directly in line with our projected timeline for this Phase III trial, we are pleased to report positive results supporting an additional effective and consumer-friendly application of our technology. These findings will serve as the basis for the submission package to the EMA for approval in the EU, which we plan to file by the end of the second quarter of 2017. If approved, this label extension would allow Ameluz® to compete directly with self-applied topical drugs, and we look forward to the opportunity to provide an additional effective solution benefiting patients with superficial skin cancer, which if left untreated, could potentially develop into fatal skin disease.”

The intra-individual, randomized, observer-blinded, multi-center study took place at 7 sites in the EU, in Spain and Germany, and evaluated a total of 52 patients, each with 3 to 9 mild to moderate AK lesions in each of two comparable treatment areas on the face and/or scalp. For an intra-patient comparison of the treatments, each patient received daylight-PDT with Ameluz® on one side, and Metvix® on the other side of the face or scalp. The study will be followed by assessments of lesion recurrence 6 and 12 months after daylight PDT.

Ameluz® was granted marketing authorization by the European Medicines Agency (EMA) in December 2011 for the treatment of mild and moderate AK on the face and scalp and currently has established sales in 13 countries. The Company received marketing approval from the U.S. Food and Drug Administration (FDA) for its combination topical prescription drug Ameluz® and medical device BF-RhodoLED® in May 2016, for lesion and field-directed treatment of mild to moderate AK on the face and scalp. Further, Ameluz® also received approval in the EU for the treatment of superficial and nodular basal cell carcinomas in January 2017 as well as field cancerization in September 2016. Daylight PDT offers a painless alternative to PDT with a specialized lamp, as the topical medication is activated by exposure to natural or artificial daylight. Therefore, patients are able to self-apply the treatment to AK lesions, rather than visiting a physician’s office for application of the treatment.

-Ends-

Enquiries, please contact: Biofrontera AG	+49 (0) 214 87 63 2 0
Thomas Schaffer, Chief Financial Officer	press@biofrontera.com
IR Germany: Brainwell Asset Solutions	+49 (0) 152 08931514
Jürgen Benker	
IR UK: Seton Services	+44(0) 20 7729 0805
Toni Vallen	
IR and PR US: The Ruth Group	
IR: Lee Roth / Tram Bui	+1 646-536-7012 / 7035
PR: Kirsten Thomas	+1 508-280-6592

About Biofrontera

Biofrontera (FSE: B8F, ISIN DE0006046113) is a biopharmaceutical company specializing in the development, sale and distribution of drugs, medical devices and medical cosmetics for the care and treatment of skin diseases.

Press release

Biofrontera's lead product is Ameluz®, a prescription drug which was initially approved and marketed in Europe and is now also approved in the U.S. in combination with its medical lamp BF-RhodoLED® for photodynamic therapy (PDT) treatment (light therapy) of mild and moderate actinic keratosis, a precursor to squamous cell carcinoma. Since January 2017 Ameluz® is also approved in the EU for the treatment of superficial and nodular basal cell carcinomas. Biofrontera is the first German pharmaceutical start-up company to obtain centralized EU and now U.S. approval for a medical device/drug it has developed itself.

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 Belixos® products are available in Europe 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**

This communication expressly or implicitly contains certain forward-looking statements concerning the business activities of Biofrontera AG. These forward-looking statements reflect the opinion of Biofrontera at the time of this communication and involve certain known and unknown risks. The actual results achieved by Biofrontera may differ significantly from future results or performances which are published in its forward-looking statements. Biofrontera assumes no responsibility to update its forward-looking statements.