Biofrontera
Experts in dermatology

News Release

Biofrontera Completes Patient Recruitment of Phase III Trial of Ameluz® in Combination with Daylight-PDT

- **52 patients at 8 sites have been enrolled**
- **Study on track to be completed by end of 2016**
- **Filing for approval anticipated for Q1 2017**

Leverkusen, Germany, September 19, 2016 – Biofrontera AG (FSE: B8F), the specialist for the treatment of sun-induced skin cancer, today announced it has completed patient recruitment for its Phase III clinical trial evaluating the safety and efficacy of Ameluz® in combination with daylight photodynamic therapy (PDT) in comparison with Metvix® for the treatment of mild to moderate actinic keratosis (AK).

The head-to-head, randomized, observer-blinded, multi-center study in the European Union (EU) has enrolled 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, at eight sites in Spain and Germany. The last doctor's visit for each patient will be three months after treatment. With database lock anticipated for December, Biofrontera plans to complete the study by the end of 2016 and anticipates filing for approval in the first quarter of 2017.

"Our clinical sites have rapidly and thoroughly enrolled all patients in the Ameluz® Daylight-PDT trial in under three months, keeping the estimated timeline to completion in line with our expectations," commented Prof. Dr. Hermann Lübbert, CEO of Biofrontera. "The continued advancements for the Ameluz® program are extremely exciting as an approval for Ameluz® in combination with Daylight-PDT in the EU would represent a significant milestone for the Company. It would greatly increase Ameluz's® competitiveness and drive the Company's ability to capture increased market share from existing topical treatments, which currently represent the vast majority of all treatments performed in the EU. Daylight-PDT eases the amount of time and effort required by a dermatologist to administer the treatment, further making Ameluz® an attractive treatment option. We look forward to announcing data by end of year and filing for approval early in 2017, as we continue expanding indications of our unique PDT technology offering."

Each patient in the study receives Ameluz® with daylight-PDT on one side and Metvix® with daylight-PDT on the other side of the face or scalp. The assignment of sides is random. The study's primary endpoint is to determine the percentage total lesion clearance rate per patient's side. Secondary endpoints will include the evaluation of safety and secondary efficacy parameters.

-Ends-

Biofrontera
Experts in dermatology

News Release

Enquiries, please contact: Biofrontera AG
Anke zur Mühlen, IR
+49 (0) 214 87 63 2 0
press@biofrontera.com

IR Germany: Brainwell Asset Solutions
Jürgen Benker
+49 (0) 152 08931514

IR UK: Seton Services
Toni Vallen
+44(0) 20 7729 0805

IR and PR US: The Ruth Group
IR: Lee Roth / Tram Bui
+1 646-536-7012 / 7035
PR: Kirsten Thomas
+1 508-280-6592

Background:

Biofrontera Group (FSE: B8F, ISIN DE0006046113) **Biofrontera** 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. Biofrontera's most important product is Ameluz®, a prescription drug which was initially approved and marketed in Europe and is now also approved in the US for the treatment of mild and moderate actinic keratosis, a precursor to squamous cell carcinoma, with photodynamic therapy (light therapy). Biofrontera is the first German pharmaceutical start-up company to obtain centralized EU and now US 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, a scalp tonic and acute roll-on, 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**

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.