Biofrontera
Experts in dermatology

News Release

Biofrontera Files Label Extension for Ameluz® in EU to include Treatment with Daylight-PDT for Actinic Keratosis

Leverkusen, Germany, June 12, 2017 – Biofrontera AG (FSE: B8F), the specialist for the treatment of sun-induced skin cancer, today announced that it has filed a label extension for Ameluz® with the European Medicines Agency (EMA) on 31 May 2017, to include treatment with daylight photodynamic therapy (PDT) for actinic keratosis (AK), a precursor of squamous cell carcinoma, following positive results from its latest Phase III trial.

Ameluz® in combination with BF-RhodoLED® lamp is approved for the treatment of AK in both the European Union (EU) and United States. While this option requires a doctor to perform each treatment, Ameluz® with Daylight-PDT does not require illumination in the doctor's office, as patients can instead exposure the treatment areas to sunlight. Treatment with Daylight-PDT will allow hospitals throughout the EU health care system to treat more patients. In addition, the procedure will be reimbursed by the public health care system in Germany, as it will not require the PDT procedure at a doctor's office.

Prof. Dr. Hermann Lübbert, CEO of Biofrontera, commented, "As we continue to deliver a highly effective and convenient treatment option for skin cancers using Ameluz®, daylight PDT represents a natural progression from conventional PDT therapy for actinic keratosis. This almost painless alternative is particularly advantageous for the treatment of large fields with broadly distributed cancer precursor cells, for which Ameluz® is the only approved PDT drug. It will also greatly reduce the time required by dermatologists for treating the patient. We believe that approval for Ameluz® with Daylight-PDT will ultimately allow us to serve even more patients without an increased burden on dermatologists in the EU."

The filing with the EMA follows positive data from the Phase III trial of Ameluz® with Daylight-PDT for the treatment of AK. The study met its primary endpoints, demonstrating that it was non-inferior to Metvix®, the current standard of care. It also compared favorably to Metvix® in all secondary endpoints. Complete clearance of the lesions was achieved by a single daylight PDT with Ameluz® in 80% of all lesions, compared to 77% for Metvix®. Lesions on the scalp were fully cleared 72% and 65% of cases using Ameluz® or Metvix®, respectively.

Biofrontera anticipates a positive opinion from the EMA by the end of 2017 or early 2018.

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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. 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. 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, and its US presence in Wakefield, MA.

For more information, visit www.biofrontera.com