Biofrontera
Experts in photodynamic therapy

News release

Biofrontera Files Investigational New Drug Application

IND filed with U.S. FDA for Phase III Trial of Ameluz® to Treat Basal Cell Carcinoma

Leverkusen, Germany, December 19, 2017 – Biofrontera AG (ISIN: DE0006046113), the specialist for the treatment of sun-induced skin cancer, today announced that the Company has filed an investigational new drug (IND) application with the U.S. Food and Drug Administration (FDA) for its proposed phase III study protocol to evaluate Ameluz® photodynamic therapy (PDT) for the treatment of superficial basal cell carcinoma.

The IND filing is in accordance with the advice provided by FDA during a formal Type C meeting in July 2017, in which the requirements for the approval of Ameluz® for sBCC based on a single additional phase III trial to be conducted in the U.S. were discussed. The study will compare Ameluz® PDT to placebo PDT. The results exhibited in the European BCC trial demonstrating Ameluz's® high efficacy (approximately 95% of superficial BCCs were clinically cleared) and low recurrence rates (5.4% after 12 months) were taken into account for the design of the new trial.

"BCCs are the most common infiltrating tumors in humans, accounting for approximately 50-80% of all invasive skin cancers. Ameluz® offers a potential alternative to surgical removal, which can result in clearly visible scarring," commented Prof. Dr. Hermann Lübbert, CEO of Biofrontera. "With the submission of our IND application complete, we look forward to initiating the phase III trial to potentially expand the label of Ameluz® PDT to superficial BCC in the U.S., which would allow dermatologists and their patients to benefit from innovative and non-invasive treatment options."

Ameluz® is currently approved and available in the EU for the photodynamic therapy of superficial and nodular BCC. It is also approved in both the U.S. and EU for lesion-directed and field-directed PDT of actinic keratosis, a skin cancer precursor.

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About Biofrontera:

Biofrontera AG is a biopharmaceutical company specializing in the development, sale and distribution of dermatological drugs and medical cosmetics. The Leverkusen, Germany-based company, which has approximately 130 employees worldwide, develops and distributes innovative products for the care, protection and treatment of the skin. Biofrontera's combination lead product is topical prescription drug Ameluz® and medical device BF-RhodoLED® for the photodynamic therapy (PDT) treatment of superficial skin cancer and its precursors. Ameluz® has been marketed in the EU since 2012 and in the U.S. since 2016. The Company also markets the Belixos® dermocosmetics series in the EU, which offers specialized care for damaged or diseased skin.

Biofrontera is the first German, founder-led pharmaceutical company to obtain both EU and U.S. approval for a medical drug it has developed itself. The Biofrontera Group was established in 1997 by current CEO, Prof. Dr. Hermann Lübbert, and is listed on the Frankfurt Stock Exchange (Prime Standard).

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.

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