news release

Biofrontera Agrees with U.S. FDA on Ameluz® Development Plan to Treat Basal Cell Carcinoma

Leverkusen, Germany, 04 August 2017 – Biofrontera AG (ISIN: DE0006046113), the specialist for the treatment of sun-induced skin cancer, has received written feedback from the U.S. Food and Drug Administration (FDA) on the requirements for approval of Ameluz® for the treatment of basal cell carcinoma (BCC), to which the company has agreed following a formal meeting with the agency in July.

Under the agreed-upon plan, the approval of Ameluz® for superficial BCC could be based on a single additional phase III study to be conducted in the U.S., in which Ameluz® photodynamic therapy (PDT) is compared to placebo PDT. FDA expects Biofrontera to present a combined read-out of clinical and histological clearance. Clinical testing of patients with different ethnical backgrounds or children will not be required. With the high efficacy of Ameluz® (approx. 95% of superficial BCCs were clinically cleared) and low recurrence rates (5.4% after 12 months) exhibited in the European trial, the requested placebo-controlled trial can be conducted with relatively few patients, which minimizes time and cost. The safety and long-term follow-up data from the existing European study has also been accepted for review by FDA.

“U.S. dermatologists are seeking good alternatives to surgery to treat basal cell carcinoma, particularly for larger tumors, which are difficult to remove surgically. The approval of Ameluz® in the U.S. for superficial BCC would be a highly welcomed option,” said David M. Pariser, MD, the senior physician of Pariser Dermatology Specialists in Norfolk, Virginia and a practicing dermatologist of 40 years, who served as a medical consultant on Biofrontera’s behalf at the FDA meeting.

“FDA has proved flexible by accepting a single placebo-controlled pivotal trial in the US for the potential approval of Ameluz® for superficial BCC, which illustrates the agency’s commendable effort to help companies get new drugs approved with reasonable timelines and expense,” commented Prof. Hermann Lübbert, CEO of Biofrontera.

-End-

Biofrontera AG
Hemmelrather Weg 201 I D-51377 Leverkusen, Germany
Phone: +49 214 87632-0 I Telefax: +49 214 87632-90
info@biofrontera.com I www.biofrontera.com

Biofrontera
Experts in dermatology

news release

Enquiries, please contact:	+49 (0) 214 87 63 2 0
	press@biofrontera.com
Biofrontera AG	
Thomas Schaffer, Chief Financial Officer	
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: Tram Bui	+1 646-536-7035
PR: Kirsten Thomas	+1 508-280-6592

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 100 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.