Biofrontera
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News release

Biofrontera Files Label Extension for Ameluz® in EU to include Treatment of Actinic Keratosis on Extremities and Trunk/Neck

Leverkusen, Germany, September 17, 2019 – Biofrontera AG (NASDAQ: BFRA; Frankfurt Stock Exchange: B8F) (the "Company"), an international biopharmaceutical company, has filed a label extension for Ameluz® with the European Medicines Agency (EMA) on August 28, 2019 to include treatment of mild and moderate actinic keratosis (AK) of the extremities and trunk/neck with photodynamic therapy (PDT). The submission follows the positive treatment outcomes demonstrated for Ameluz® in the recent phase III trial.

"The label extension for the treatment of actinic keratosis of the trunk and extremities is a further step in our strategic efforts to expand the market for Ameluz®," says Prof. Dr. Hermann Lübbert, CEO of Biofrontera AG. "Our excellent results in the treatment of AK on these body regions, which are particularly difficult to treat, confirm the excellent outcome of PDT with Ameluz®. The EMA has confirmed the validity of our submission and will comment on the status of the submission process by mid-December, or request further documentation if necessary."

In the phase III trial, patients were treated with Ameluz® on one side of the body and a placebo gel on the other for control. The study met its primary endpoint with an average lesion healing rate per patient side of 86% for Ameluz® compared to 33% for placebo ($p<0.0001$). Additionally, significant superiority of Ameluz® was demonstrated for all secondary parameters investigated. Even if mild AKs were ignored and only moderate AKs were considered, mean lesion clearance rates per patient's side were 84% with Ameluz® compared to 27% with placebo ($p<0.0001$). In patients treated on the extremities, mean lesion clearance rates per patient's side were also 84% with Ameluz® compared to 27% with placebo. Mean lesion clearance rates in the area trunk/neck were even higher. Furthermore, the comparison parameter "patient complete clearance" also emphasized the superiority of Ameluz®: 67% of the patients' sides were completely cleared 12 weeks after the last PDT compared to 12% of the placebo-treated sides. All of the results were statistically highly significant. The treatment success was histologically confirmed in selected lesions of each patient. Thus, all secondary endpoints also confirm the high superiority of Ameluz® over the control group.

Biofrontera has also entered into discussions with the U.S. Food and Drug Administration (FDA) for approval in the U.S. and will report separately on this matter as soon as a schedule has been agreed upon with the FDA.

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For enquiries, please contact:

Biofrontera AG +49 (0) 214 87 63 2 0

Thomas Schaffer, Chief Financial Officer ir@biofrontera.com

IR UK: Seton Services

Toni Vallen +44 (0) 207 229 0805

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 and sale of dermatological drugs and medical cosmetics.

The Germany-based company, with almost 200 employees worldwide, develops and markets innovative products for the care, protection and treatment of the skin. The company's lead product is the combination of Ameluz®, a topical prescription drug, and medical device BF-RhodoLED® for the photodynamic therapy of certain superficial skin cancers and their precursors. Ameluz® has been marketed in the EU since 2012 and in the United States since May 2016. In addition, the company markets Xepi, a prescription medication for the treatment of impetigo in the United States. In the EU, the company also sells the dermocosmetics series Belixos®, which offers specialized care for damaged or diseased skin.

Biofrontera is the first German founder-led pharmaceutical company to receive a centralized European and a US approval for a drug developed in-house. The Biofrontera Group was founded in 1997 by the current CEO Prof. Dr. Hermann Lübbert and is listed on the Frankfurt Stock Exchange (Prime Standard) and on the US NASDAQ.www.biofrontera.com.