Biofrontera
Experts in dermatology

News Release

# Biofrontera Initiates U.S. Commercial Launch of Ameluz® for Actinic Keratosis

- **Commercial launch follows FDA approval in May 2016**
- **Rapidly onboarding experienced sales and marketing team with 4 regional sales managers and 13 representatives**
- **Well positioned to capture significant market share in PDT**
- **Launch VIP event at Fall Clinical Dermatology Conference**

Leverkusen, Germany, October 18, 2016 – Biofrontera AG (FSE: B8F), the specialist for the treatment of sun-induced skin cancer, today announced that it has initiated the U.S. commercial launch of its combination topical prescription drug Ameluz® and medical device BF-RhodoLED®, which has been approved by the U.S. Food and Drug Administration (FDA) for the treatment of mild to moderate actinic keratosis (AK) on the face and scalp.

Ameluz®, a topical prescription drug, is used in combination with the medical device BF-RhodoLED® for photodynamic therapy treatment (PDT). FDA approval of the combination treatment covers lesion-directed and field-directed treatment of AK. Typically, AK lesions occur on the face, scalp, lips, arms and hands, and when left untreated, AK lesions can develop into squamous cell carcinoma. Field-directed treatment is recommended by dermatological guidelines due to the observation that early AKs are particularly prone to progression to squamous cell carcinoma. In addition, after field-directed treatment with Ameluz®, patients benefit from the long-lasting skin rejuvenation effect demonstrated in Biofrontera's phase III trials.

The U.S. represents the largest photodynamic therapy market in the world, with approximately 58 million patients suffering from actinic keratosis. Photodynamic therapy in the U.S. is a well-established, accepted and reimbursed treatment option with a rapidly growing market share. Biofrontera is well positioned to enter the U.S. market, and is rapidly onboarding an experienced sales and marketing team, this year growing to 4 regional sales managers and 13 sales representatives who will drive early adoption with their strong prior experience in the PDT arena. The Company aims to expand its sales force to 5 regional sales managers and a total of 45 sales representatives by the end of 2017. The Company will initially target regions of the U.S. which have a high concentration of dermatology practices and build a strong foundation of support from key opinion leaders.

"The commercial launch of Ameluz® in the U.S. represents a major milestone for Biofrontera, and we are pleased with the initial feedback from our experienced sales force," commented Prof. Dr. Hermann Lübbert, CEO of Biofrontera. "We are well prepared to serve the rapidly growing PDT

market as indicated by the accelerated activity at our production facility for the accompanying BF-RhodoLED® lamps, many of which are in the process of being installed in dermatology offices across the U.S. Additionally we will host a VIP event at the Fall Clinical Dermatology Conference in Las Vegas later this week, to broadly announce the launch of Ameluz® to the US dermatology community."

In addition to the United States, Ameluz® is commercially available in 13 countries throughout the European Union, which recently expanded the label for Ameluz® to include field cancerization and the skin rejuvenation data.

The Fall Clinical Dermatology Conference is an annual meeting organized by the American Association of Dermatology (AAD). It is the second largest annual conference for US dermatologists and takes place in Las Vegas from October 20th to 23rd, 2016.

**-Ends-**

**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 7229 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.*