

# News Release

### Biofrontera Reports First Quarter 2016 Financial Results and Business Update

**Leverkusen, Germany, May 25, 2016** – Biofrontera AG (FSE: B8F), the specialist for the treatment of sun-induced skin cancer, today reported its financial results for the first quarter for the three month period ending March 31, 2016 and provided an update on recent operational and clinical developments.

### Q1 2016 Financial Highlights:

- Successfully completed additional capital raise
- Reported flat total revenue growth compared to Q1 2015
- International revenues increased 19% year over year
- Generated net income loss before taxes of € (0.4) million, which includes repayment of PDUFA fee of € 2.1 million by U. S. Food and Drug Administration ("FDA")
- Cash on balance sheet of € 8.0 million as of March 31, 2016

### Q1 2016 and Recent Operational & Clinical Highlights:

- Completed clinical trial for basal cell carcinoma ("BCC") in the European Union ("EU") with a complete response rate of 93.4%
- Received reimbursement status in Switzerland
- Mid cycle review in January by the FDA raised no major issues
- Granted U.S. FDA approval for Ameluz<sup>®</sup> in combination with BF-RhodoLED<sup>®</sup> for actinic keratosis ("AK") on May 10

Biofrontera reported total revenue of € 1,017 thousand in the first quarter of 2016 compared to € 1,030 thousand in the first quarter of 2015, which represents flat growth year over year. Revenues in Germany were € 633 thousand, compared to € 783 thousand in the previous year, which was mainly due to stock reduction at some wholesalers. International revenues reported were € 323 thousand compared to € 247 thousand in the first quarter of 2015, which is an increase of 19% year over year. Down payments were € 60 thousand in the quarter versus € 0 in the first quarter of 2015. The guidance for the full year remains unchanged.

Net income loss before taxes was  $\in$  (448) thousand compared to  $\in$  (2,363) thousand in the previous year. The net income loss includes the repayment of a PDUFA fee by the FDA in March 2013, which is classified under Other Income in the income statement.



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In February 2016, Biofrontera successfully completed a capital raise with institutional investors, which excluded the subscription rights of shareholders. Net proceeds from the capital raise were  $\in$  4.4 million. This represents a significant improvement in the liquidity of the Company. Cash and cash equivalents were  $\in$  8.0 million as of March 31, 2016.

#### Ameluz<sup>®</sup> U.S. FDA Approval

The U.S. FDA informed the Company in the first quarter of 2016 about the successful completion of its mid cycle review of Ameluz<sup>®</sup> without any major issues. On its designated PDUFA date of May 10, 2016 Biofrontera received U.S. FDA approval of Ameluz<sup>®</sup> in combination with the photodynamic therapy ("PDT") lamp BF-RhodoLED<sup>®</sup> for the treatment of mild to moderate actinic keratosis (AK). The approval includes labeling for both lesion and field directed treatment of AK. One of the most important strategic goals for Biofrontera for the remainder of the year is the preparation for the commercial launch of Ameluz<sup>®</sup> and BF-RhodoLED<sup>®</sup> in the United States planned for September 2016.

The approval of Ameluz<sup>®</sup> in the U.S. represents an outstanding achievement by Biofrontera which opens access to the world's largest pharmaceutical market with significant revenue potential.

#### **Clinical Trials**

Biofrontera is also strategically expanding the indication in Europe for Ameluz<sup>®</sup> for the treatment of basal cell carcinoma (BCC), one of the most frequent forms of non-melanoma skin cancer. The clinical Phase III trial of Ameluz<sup>®</sup> for BCC was successfully completed in the first quarter with outstanding results. Biofrontera plans to submit the application for label extension in Q2 2016, and expects approval by the end of 2016.

Preparations for a clinical Phase III study for daylight therapy were initiated in Q1. This study will be performed in clinical centers in Germany and Spain. Completion of the study is anticipated by the third quarter of 2016, with approval expected in the first half year of 2017.

#### International Commercialization

Biofrontera continues to progress in its efforts to expand the commercialization of Ameluz<sup>®</sup> and BF-RhodoLED<sup>®</sup>. The Swiss approval authority Swissmedic has granted approval in Switzerland, where reimbursement status has also been obtained. Biofrontera's partner Louis Widmer in Switzerland began commercialization of the products in April 2016.

The approval for Ameluz<sup>®</sup> in Israel was granted in April with reimbursement status established prior to the approval. Biofrontera's partner in Israel, Perrigo, is currently preparing the commercial launch of Ameluz<sup>®</sup>.

"2016 is rapidly becoming a critical year in Biofrontera's history with many of our initiatives coming to fruition," commented Prof. Dr. Hermann Lübbert, CEO of Biofrontera. "We are very



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pleased to report that on May 10<sup>th</sup> the FDA granted approval of our combination therapy Ameluz<sup>®</sup> and BF-RhodoLED<sup>®</sup> for the treatment of actinic keratosis. This represents a significant milestone achievement for the Company and we have begun to intensify our efforts to prepare for commercial entry into the world's largest healthcare market in September."

#### Ends

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#### **About Biofrontera**

**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<sup>®</sup>, 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<sup>®</sup> dermatological range of cosmetics. Belixos<sup>®</sup> 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. The Belixos<sup>®</sup> 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

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