

## **Biofrontera Reports Full Year 2016 Financial Results**

**Leverkusen, Germany, April 12, 2016** – Biofrontera AG (FSE: B8F), the specialist for the treatment of sun-induced skin cancer, today reported its financial results for the full year ended December 31, 2016 and provided an update on recent operational and clinical developments.

### **Fourth Quarter and Full Year 2016 Financial Highlights:**

- Sales increased 48% to €6.1 million for the full year 2016 compared to €4.1 million in 2015.
- Record fourth quarter revenue of over €3.2 million.
- Generated €1.1 million in revenues in the U.S. in the fourth quarter of 2016.
- Development projects with Maruho contributed €1.2 million to revenues in 2016.
- Operational result was €(11.8) million for the full year 2016 compared to €(10.2) million for 2015.
- Cash on balance sheet was €15.1 million as of December 31, 2016, strengthened by financings completed in 2016. An additional €5 million was raised in January 2017.

### **Operational and Clinical Development Highlights:**

- Received US marketing approval by the FDA for Ameluz<sup>®</sup> and BF-RhodoLED<sup>®</sup> in May 2016
- Received approvals by the European Commission of label extensions for Ameluz<sup>®</sup> to include the treatments of field cancerization and basal cell carcinoma.
- Reported positive Phase III results for Ameluz<sup>®</sup> in combination with daylight photodynamic therapy, with submission of label extension application expected during Q2 2017.
- Expanded sales and marketing infrastructure in the U.S.
- Appointed Randall Wilhoite as Chief Operating Officer of U.S. subsidiary.
- Signed co-development agreement with Maruho Co. Ltd. to develop formulations for four new pharmaceutical products.

Biofrontera reported total revenue of €6.1 million for the full year 2016, as compared to €4.1 million in 2015, which represents 48% growth year over year. Revenue from the U.S. was €1.1 million in the fourth quarter of 2016 after the commercial launch of Ameluz<sup>®</sup> and BF-RhodoLED<sup>®</sup> in October, in line with the Company's estimates. Revenues in Germany were €2.5 million for the full year 2016, as compared to €3.0 million in the previous year. The decrease was primarily

## News Release

a result of increased competition with Daylight PDT products in the market. Revenues in the rest of Europe were €1.2 million for the full year 2016 compared to €1.0 million in 2015, which represents an increase of 20% year over year.

Net income loss before taxes was €(10.6) million for the full year 2016, as compared to €(11.2) million for the same period in the previous year. Cash and cash equivalents were €15.1 million as of December 31, 2016.

Additionally, Biofrontera fully placed 49,990 subordinate convertible bonds of €100.00 each in a total nominal amount of €5.0 million in January 2017. This measure, in addition to the capital increases completed in 2016 in February (€4.4 million net proceeds), April (€4.9 million net proceeds) and November (€19.7 million net proceeds) significantly improved the Company's liquidity. In December, the company prematurely paid down €8.7 million in financial liabilities.

### U.S. Commercial Update

Biofrontera officially initiated U.S. commercial sales of Ameluz<sup>®</sup> and BF-RhodoLED<sup>®</sup> for actinic keratosis (AK) in October 2016, following U.S. FDA approval in May 2016. After a positive initial launch in targeted regions across the states that generated €1.1 million in revenues in the three months ended December 31, 2016, Biofrontera has expanded its sales efforts to include the entire U.S. as well as bolstered its sales force to 26 representatives which it expects to further expand throughout 2017. To complement its robust sales force and presence in the United States, the company launched a new U.S. corporate website for patients and physicians in order to provide comprehensive information about Ameluz<sup>®</sup>, including full prescribing information, clinical trial results, treatment with red light PDT, and ordering and reimbursement details. Since launch Biofrontera has presented its product to a wide dermatology audience at seven important congresses in the USA.

In order to manage and develop the strongly growing U.S. presence, the company recently appointed Randall Wilhoite as Chief Operating Officer of its U.S. subsidiary. Randall will oversee the acceleration of the Company's administrative and logistics efforts for Ameluz<sup>®</sup> in the U.S. He brings over 30 years of operational experience from the pharmaceutical and medical device industries, where he established a strong track record of driving the success of multi-million dollar operations.

### Regulatory Affairs Update

Biofrontera made significant regulatory progress in 2016 in both the EU and the U.S. for Ameluz<sup>®</sup>; formally receiving approval by the U.S. Food and Drug Administration (FDA) in May and continued label extensions in the EU throughout the year.

In September 2016, the European Commission (EC) issued marketing authorization for Ameluz<sup>®</sup> to include the treatment of field cancerization, which includes multiple actinic keratosis lesions on larger skin areas containing precancerous cells, allowing for a more appropriate treatment option. The treatment of continuous skin areas is recommended in dermatological guidelines, and allows patients to profit from the strong skin rejuvenation effect of PDT, which is also

## News Release

detailed in the EMA-approved product information. This approval came after a thorough examination by the EMA of all available efficacy and safety data for Ameluz<sup>®</sup> and further validates its value as a superior treatment option.

In January 2017, the European Commission extended the indication for Ameluz<sup>®</sup> to include basal cell carcinoma, following a positive opinion from the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA). This extension includes the treatment of superficial and/or nodular basal cell carcinoma which is deemed unsuitable for surgical options due to possible treatment-related morbidity or poor cosmetic outcome in adults. The additional approved indication significantly increases the market opportunity for Ameluz<sup>®</sup>, allowing for an increased presence in hospitals where dermatologists are primarily based in multiple European countries.

The company will continue to work towards additional approvals for Ameluz over the coming year. It intends to submit an application for label extension to the EMA for the use of Ameluz<sup>®</sup> with daylight PDT for actinic keratosis in the second quarter of 2017 with approval expected during the first half of 2018. The label extension to include Daylight PDT would allow patients to self-apply Ameluz<sup>®</sup> to AK lesions, reducing the time and number of visits required to a physician's office. The company also intends to apply for BCC approval in the US, and has applied for a meeting with the FDA, which is expected to be held in the second quarter of 2017.

### Clinical Developments

Biofrontera reported detailed results from its Phase III clinical trial of Ameluz<sup>®</sup> in March 2017, evaluating its safety and efficacy in combination with daylight photodynamic therapy (PDT) for the treatment of mild to moderate Actinic Keratosis. The study met its primary endpoint demonstrating that Ameluz<sup>®</sup> in combination with PDT was non-inferior to standard of care Metvix<sup>®</sup>, exhibiting a total lesion clearance rate of 78.7% compared to 75% respectively. Similarly all secondary endpoints for Ameluz<sup>®</sup> demonstrated equivalent or better clearance rates as compared to Metvix<sup>®</sup>. 85% of lesions on the face were fully cleared after a single PDT with Ameluz<sup>®</sup>, and 72% of the more difficult to treat lesions were fully cleared on the scalp. For Metvix<sup>®</sup>, 84% and 65% of the lesions were fully cleared on face and scalp, respectively. The most notable differences between Ameluz<sup>®</sup> and Metvix<sup>®</sup> clearance rates were observed in patients younger than 65 years of age (83% vs. 74%) and for patients treated during cloudy weather (75% vs. 66%), respectively.

In June 2016, Biofrontera announced a co-development agreement with Maruho Co. Ltd., a Japanese dermatology company, for the development of four new pharmaceutical products based on Biofrontera's proprietary nanoemulsion technology and known active ingredients. In 2016, the development of these projects generated €1.2 million in revenue.

### International Commercialization

Biofrontera continues to progress in its efforts to expand the commercialization of Ameluz<sup>®</sup> and BF-RhodoLED<sup>®</sup>. Ameluz is currently launched in 11 countries in Europe with Biofrontera making

## News Release

direct sales in Germany, Spain and the UK. The company has also continued to make great strides in Israel with its partner, Perrigo Israel, and in Switzerland through its partner, Louis Widmer S.A.

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### About Biofrontera

**Biofrontera** (FSE: B8F, ISIN DE0006046113) 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 lead product is Ameluz<sup>®</sup>, a prescription drug which was initially approved and marketed in Europe and later also approved in the U.S. in combination with its medical lamp BF-RhodoLED<sup>®</sup> for photodynamic therapy (PDT) treatment (light therapy) of mild and moderate actinic keratosis, a precursor to squamous cell carcinoma. Since January 2017 Ameluz<sup>®</sup> is also approved in the EU for the treatment of superficial and nodular basal cell carcinomas. Biofrontera is the first German pharmaceutical start-up company to obtain centralized EU and U.S. 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. Belixos<sup>®</sup> Protect, a daily skincare for sun-damaged skin, complements this dermo-cosmetic line. All Belixos<sup>®</sup> products are available in Europe 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, and its US presence in Wakefield, MA.

For more information, visit [www.biofrontera.com](http://www.biofrontera.com)

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