

Biofrontera Reports Financial Results and Business Update for Third Quarter and First Nine Months 2016

Leverkusen, Germany, November 30, 2016 – Biofrontera AG (FSE: B8F), the specialist for the treatment of sun-induced skin cancer, today reported its financial results for the third quarter and first nine month period of the year ending September 30, 2016 and provided an update on recent operational and clinical developments.

Q3 2016 and Nine Months 2016 Financial Highlights:

- Sales increased 9% to €2.881 million for the first nine months 2016 compared to €2.635 million in the same period 2015
- Sales outside Germany increased 151% to €1,365 thousand in the first nine months 2016 compared to €544 thousand in the nine month period ending September 2015
- Operational loss was €7.163 million in the nine month period for 2016 compared to €9.285 million in same period 2015
- Cash on balance sheet was €5.7 million as of September 30, 2016, and strengthened by subsequent financing

Recent Operational and Clinical Development Highlights:

- Launched commercial sale of Ameluz[®] and BF-RhodoLED[®] in the U.S. with launch event during the Fall Clinical Dermatology Conference in Las Vegas
- Further established sales and marketing operation in the U.S.
- Received approval by the European Commission of label extension for Ameluz[®] to include the treatment of field cancerization
- Completed patient recruitment of Phase III clinical trial for Ameluz® in combination with daylight photodynamic therapy (PDT)
- Announced positive 12-month follow-up results for Phase III trial evaluating Ameluz[®] for basal cell carcinoma and filed for label extension with EMA
- Received reimbursement for Ameluz[®] in Switzerland

Biofrontera reported total revenue of €2.881 million in the first nine months of 2016, as compared to €2.635 million in the first nine months of 2015, which represents 9% growth year over year. Revenues in Germany were €1.476 million for the first nine months of 2016, as compared to €2.091 million in the previous year. The strong decrease was the result of a special effect of an



Ameluz price increase in August 2015, which was preceded by massive stocking by the wholesalers. International revenues reported were €1.365 million in the first nine months of 2016 compared to €544 thousand in the first nine months of 2015, which represents an increase of 151% year over year. License payments from distributors were €40 thousand in the first nine months of 2016 versus €0 in the first nine months of 2015. The guidance for the full year remains unchanged.

Net income loss before taxes was € (7.164) million for the first nine months of 2016, as compared to € (9.286) million for the same period in the previous year. Cash and cash equivalents were €5.7 million as of September 30, 2016.

In November 2016, Biofrontera successfully placed an additional capital increase granting statutory subscription rights. The subscription price was €3.00 per new share, net proceeds from the capital raise were €14.8 million. In parallel, Biofrontera issued up to 49,990 convertible bonds of €100.00 each. Together, these measures significantly improved the Company's liquidity by €19.5 million.

U.S. Commercial Launch of Ameluz®

Biofrontera initiated its U.S. commercial launch of Ameluz® and BF-RhodoLED® for actinic keratosis at the Fall Clinical Dermatology Conference in Las Vegas, following U.S. FDA approval in May 2016. The U.S. represents the largest photodynamic therapy market in the world, with approximately 58 million patients suffering from AK, providing a significant revenue opportunity for Biofrontera. The Company is currently operating in targeted regions across the U.S. that have high concentrations of dermatology practices which will allow for the rapid adoption of Ameluz® and the development of strong support from key opinion leaders. Biofrontera's subsidiary in the U.S. is continuing to recruit experienced personnel in important functions, with the goal of developing a fully manned, highly effective sales organization by the end of 2017.

Regulatory Update

Biofrontera continues to work diligently to expand the indication opportunities for Ameluz®, and in September the Company received marketing authorization from the European Commission for the label extension of Ameluz® to include the treatment of field cancerization. Multiple actinic keratosis lesions or actinic keratosis on larger skin areas are the consequence of field cancerization, and the extended indication allows the most appropriate treatment for this very common situation.

Earlier this year, the company reported positive results from a clinical Phase III trial for the treatment of basal cell carcinoma (BCC), and filed for the label extension of Ameluz® for the treatment of non-aggressive BCC, including superficial and nodular BCC with the European Medicines Agency. The Company recently supplemented its application with the EMA with 12-month follow-up results from its Phase III trial in BCC, and expects to receive approval for the label extension of Ameluz® by the first quarter 2017.



After completion of the reporting period, the European Commission consented with an unlimited extension of the EU approval for Ameluz[®]. In the EU, approvals for new drugs are initially limited to five years, after which a thorough assessment of all then available efficacy and safety data is performed by the EMA before the approval gets an unlimited extension.

Clinical Developments

Biofrontera initiated its Phase III clinical trial of Ameluz[®] in June to evaluate its safety and efficacy in combination with daylight photodynamic therapy in comparison with Metvix[®] for the treatment of mild to moderate actinic keratosis. The multi-center study in the EU completed patient recruitment in September with a total of 52 patients across 8 sites, and is expected to be completed by the fourth quarter of 2016, with approval anticipated in 2017.

In addition to the daylight PDT trial, Biofrontera announced 12-month follow-up results of its Phase III trial evaluating Ameluz® for basal cell carcinoma. The analysis concluded that patients treated with Ameluz® PDT saw an overall lesion recurrence rate of 6.7% compared to 8.2% for those treated with comparator Metvix® at 12 months. Treatment with Ameluz® also resulted in an excellent cosmetic outcome at 12 months, with 68.3% of Ameluz® patients exhibiting improved aesthetic appearance compared to 65.5% of Metvix® treated patients.

International Commercialization

Biofrontera continues to progress in its efforts to expand the commercialization of Ameluz[®] and BF-RhodoLED[®]. The Swiss medical regulatory 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[®] in Israel was granted in April, Biofrontera's partner in Israel, Perrigo, is currently preparing the commercial launch of Ameluz[®].

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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[®], 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

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