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Biofrontera Reports Financial Results and Business Update for Second Quarter and First Half 2016

Leverkusen, Germany, August 31, 2016 – Biofrontera AG (FSE: B8F), the specialist for the treatment of sun-induced skin cancer, today reported its financial results for the second quarter and six month period ending June 30, 2016 and provided an update on recent operational and clinical developments.

Q2 2016 and H1 2016 Financial Highlights:

- Sales increased 9% to €1.709 million in H1 2016 compared to €1.568 million in H1 2015
- Sales outside Germany increased 66% to €635 thousand compared to €382 thousand in H1 2015
- Net income loss was €3.472 million in H1 2016 compared to €7.323 million in H1 2015
- Company successfully completed financing rounds in February and April 2016
- Cash on balance sheet was €10.2 million as of June 30, 2016

Recent Operational and Clinical Development Highlights:

- Received U.S. FDA approval for Ameluz® and BF-RhodoLED® for actinic keratosis (AK)
- Received positive assessment from the European Medicines Agency (EMA) for the label extension of Ameluz® to include the treatment of field cancerization
- Completed clinical trial for Ameluz® for basal cell carcinoma (BCC) in the European Union (EU) with a clinical clearance rate of 95% and filed for label extension with the EMA
- Swiss compulsory health insurance reimbursed Ameluz® for treatment of AK
- Initiated Phase III clinical trial for Ameluz® in combination with daylight photodynamic therapy (PDT)
- Signed co-development agreement with Maruho Germany to develop four new pharmaceutical products
- Appointed key operations, quality control, market access, and medical affairs team for the U.S.
- Appointed senior regional sales, medical and operational managers and representatives in the U.S.

Biofrontera
Experts in dermatology

News Release

- Appointed four new supervisory board members

Biofrontera reported total revenue of €1.709 million in the first half of 2016, as compared to €1.568 million in the first half of 2015, which represents 9% growth year over year. Revenues in Germany were €1.034 million in the first half of 2016, as compared to €1.186 million in the previous year. International revenues reported were €635 thousand in the first half of 2016 compared to €382 thousand in the first half of 2015, which represents an increase of 66% year over year. License payments from distributors were €40 thousand in the first half of 2016 versus €0 in the first half of 2015.The guidance for the full year remains unchanged.

Net income loss before taxes was € (3.472) million for the first half of 2016, as compared to € (7,323) million in the previous year.

In February and April 2016, Biofrontera successfully placed capital increases. Net proceeds from the capital raises were €9.3 million. This represents a significant improvement in the liquidity of the Company. Cash and cash equivalents were €10.2 million as of June 30, 2016.

U.S. Commercial Launch of Ameluz®

Following the recent U.S. FDA approval of Ameluz® and BF-RhodoLED® for actinic keratosis on May 10, 2016, Biofrontera has been diligently preparing for its commercialization in the U.S. The Company has developed a comprehensive sales and marketing strategy for a successful launch in September 2016. The U.S. represents the largest PDT market in the world, as well as a significant revenue opportunity for Biofrontera. The Company has decided to systematically conduct targeted geographic launches in areas with the highest potential to build momentum and early success. These select regions have a high concentration of dermatologists with large practices and influential private insurers offering PDT. This approach will allow the Company to identify the early adopters and key opinion leaders who will be critical to the success of Ameluz® in the U.S. Biofrontera's subsidiary in the U.S. is continuing to recruit experienced regional sales managers and representatives, who have already begun to ensure that early adopting practices will have the BF-RhodoLED device installed prior to the launch of Ameluz®. In addition to bolstering the sales force, Biofrontera has appointed key operational and medical advisory staff to its U.S. subsidiary in order to support the sales efforts.

Regulatory Update

Biofrontera continues to make progress in strategically expanding the available indications in Europe for Ameluz®. The Company recently received a positive assessment from the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) for the company's submission for the label extension of Ameluz® to include the treatment of field cancerization, which would significantly increase the addressable market for Ameluz®. Biofrontera anticipates that the European Commission will issue formal approval within the coming weeks.

Earlier this year, the company reported positive results for the treatment of basal cell carcinoma (BCC), which is classified as abnormal, uncontrolled growths in the skin's basal cells and is a common form of non-melanoma skin cancer. In July, the Company filed for the label extension of Ameluz® for the treatment of non-aggressive BCC, including superficial and nodular BCC. The European Medicines Agency has accepted the Company's application and begun its thorough review, a process that is expected to take several months.

Clinical Developments

Biofrontera launched its Phase III clinical trial of Ameluz® to evaluate its safety and efficacy in combination with daylight photodynamic therapy (PDT) in comparison with Metvix® for the treatment of mild to moderate actinic keratosis (AK). The multi-center study in the EU will include eight sites in Germany and Spain, and plans to enroll approximately 50 patients. The trial is expected to be completed by the fourth quarter of 2016, with approval expected in the first half of 2017.

In June, Biofrontera announced a co-development agreement with Maruho Germany, a Japanese dermatology company and a strategic Investor in Biofrontera AG, to co-develop four new pharmaceutical products. The products will be based on Biofrontera's proprietary nanoemulsion technology and known active ingredients. In the agreement, Maruho will finance the full cost of the clinical development and personnel from both companies. Under the agreement, Maruho will retain ownership of the rights for any pharmaceuticals developed from the agreement, with Biofrontera receiving a royalty free license to commercialize the products in Europe.

International Commercialization

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

Supervisory Board

During Biofrontera's Annual Shareholder Meeting held on May 31, 2016, four new supervisory board members were elected by the shareholders. Mark Reeth, John Borer III, Kevin Weber, and Hansjörg Plaggemars will replace Andreas Fritsch, Ulrike Kluge, Alfred Neimke, and Prof. Bernd Wetzel, PhD as members of the board. In addition to the new appointments, Jürgen Baumann and Dr. Ulrich Granzer were re-elected to the Board.

Biofrontera
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News Release

“As we prepare for the commercial launch of Ameluz® in the U.S. in September, we are making every effort to ensure that it will be a success,” said Prof. Hermann Lübbert, PhD, CEO of Biofrontera. “We have been actively recruiting an experienced team of regional managers and sales representatives and providing them with the support of key operations, market access, and medical affairs personnel that we believe will quickly drive the revenue growth trajectory of Biofrontera. We look forward to expanding the indication and reach of Ameluz®, as we remain focused on our regulatory and clinical development programs in both the EU and U.S. to include field cancerization treatment and basal cell carcinoma. We have many substantial opportunities ahead of us, along with strong clinical data, which will help to establish the Company as a leader in the treatment of skin cancers. The agreement that we signed with Maruho Germany further validates our pipeline expansion opportunities.”

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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 lead product is Ameluz®, a prescription drug which was initially approved and marketed in Europe and is now also approved in the U.S. in combination with its medical lamp BF-RhodoLED® for photodynamic therapy (PDT) treatment (light therapy) of mild and moderate actinic keratosis, a precursor to squamous cell carcinoma. Biofrontera is the first German pharmaceutical start-up company to obtain centralized EU and now U.S. 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 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® Protect, a daily skincare for sun-damaged skin, complements this dermo-cosmetic line. All Belixos® products are available in Europe through Amazon.

Biofrontera

Experts in dermatology

News Release

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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