Biofrontera

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News Release

Biofrontera Reports First Quarter 2017 Financial Results

Leverkusen, Germany, May 19, 2017 – Biofrontera AG (FSE: B8F), the specialist for the treatment of sun-induced skin cancer, today reported its financial results for the first quarter ended March 31, 2017 and provided an update on recent operational and clinical developments.

"We had a very successful start into the year 2017 with the U.S. market turning into our most important sales market in Q1. And while we continue to invest into marketing and sales in the U.S. for the treatment of AK, we look forward to expanding our reach into the hospitals and outpatient clinics in the EU with the recent approval of Ameluz® for BCC. With the support of the recent capital raises, we are working diligently towards our operational milestones, including preparations to meet with the U.S. FDA in the second quarter to discuss requirements for BCC approval, and our label extension application for daylight PDT in the EU. 'Success Stories' was the title of the annual report for the past year and we hope to maintain the momentum that we have built and look forward to sharing our continued progress with you in the near future," commented Prof. Dr. Hermann Lübbert, CEO of Biofrontera.

First Quarter 2017 Financial Highlights:

- Sales increased c. 160% to €2.6 million for first quarter 2017, compared to €1.0 million in the same period 2016.
- Generated €1.3 million in revenues in the U.S. in the first quarter of 2017.
- Research and development costs amounted to €1.1 million in the first quarter, an increase of 12%, year-over-year. These costs were mainly due to development partnerships.
- Development projects with Maruho generated sales revenue of €393 thousand in the first quarter of 2017.
- Net loss was €(3.5) million for the first quarter 2017, compared to €(448) thousand for the same period in 2016.
- Cash on balance sheet was €15.4 million as of March 31, 2017, strengthened by a €5 million financing completed in January 2017.

Recent Operational and Clinical Development Highlights:

- Grew sales and marketing infrastructure in the U.S.: expanded sales team to 26 staff and added a fifth region, the Midwest.
- Launched new U.S. corporate website with much more factual and medical information than in Europe.
- Appointed Randall Wilhoite as Chief Operating Officer of U.S. operations.
- Received approval from the European Commission for label extension of Ameluz® to include the treatment of basal cell carcinoma.
- Reported detailed Phase III results for Ameluz® in combination with daylight photodynamic therapy.
- Added a sixth product to our belixos® active cosmetic range.

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Biofrontera generated total sales revenue of €2,616 thousand in the first quarter of 2017, representing an increase of almost 160% year-on-year. Sales revenue in Germany amounted to €640 thousand, reflecting a slight rise of €7 thousand compared with the previous year. Foreign revenues performed particularly well in the first quarter, driven mainly by the U.S. as a new sales market compared with the previous year with sales revenue amounting to €1,304 thousand. In Europe, sales revenue was down by 14%, chiefly reflecting a lower level of deliveries to license partners.

The first quarter consolidated net result was posted at €(3,513) thousand. This is significantly below the previous year's €(448) thousand, predominantly due to higher sales and marketing expenses in the U.S. and the missing other income effect (PDUFA fee repayment) of the first quarter of 2016.

The liquidity position at the end of the first quarter of 2017 improved slightly compared with 31 December 2016 as the convertible bond issuance proceeds of €4,999 thousand more than offset the operating cash outflows. Cash and cash equivalents stood at €15,433 thousand as of 31 March 2017, an increase of €307 thousand compared with 31 December 2016.

U.S. Commercial Update

Biofrontera continues to make great strides in its commercial expansion of Ameluz® and BF-RhodoLED® for actinic keratosis (AK) in the United States. After a strong launch in the fourth quarter of 2016 with €1.1 million in revenue, Biofrontera saw sales rise to €1.3 million, representing 18% sequential growth. On top of the encouraging sales growth, the Company is working diligently to find a resolution to the initial difficulties of reimbursement, which currently covers Ameluz® under a Miscellaneous CPT code. It expects to receive coverage under a dedicated CPT code in January 2018.

The U.S. sales force currently stands at 26 representatives covering five regions, including the recent expansion to the Midwest. Randall Willhoite, the U.S. Chief Operating Officer, has ensured the efficient and effective operational growth in the U.S. subsidiary. In addition to the strong leadership, the Company launched a new U.S. corporate website to support the sales and marketing of Ameluz®, providing information for healthcare professionals and patients about Ameluz®, including prescribing information, trial results, treatment with red light PDT, and ordering and reimbursement information.

The Company also intends to apply for BCC approval in the U.S., and has applied for a meeting with the FDA, which is expected to be held in the second quarter of 2017.

EU Regulatory and Clinical Development Update

In January, the Company received approval from the European Commission for the indication expansion of Ameluz® to include basal cell carcinoma (BCC), which accounts for 50-80% of all skin cancer tumors and is primarily treated in hospitals in multiple European countries.

The detailed results from the Phase III daylight study, which demonstrated that Ameluz® in combination with daylight PDT is non-inferior to standard of care Metvix®, will serve as the basis of a label extension application to the EMA for the use of Ameluz® with daylight PDT for actinic keratosis (AK). The Company intends to submit this application in the second quarter of 2017.

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Once approval is issued, Ameluz® will be competing directly with products that patients can apply themselves, drawing them within the refund scope of statutory health funds in countries such as Germany, and thereby leading Biofrontera to expect better distribution of Ameluz® in Germany and other European countries.

The quarterly statement including financial statements is available at http://www.biofrontera.com/en/investors/financial-reports.

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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®, 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. Since January 2017 Ameluz® 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 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. Belixos® Protect, a daily skincare for sun-damaged skin, complements this dermo-cosmetic line. All Belixos® 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