Biofrontera
Experts in dermatology

News Release

Q3 Results well on track

Leverkusen, 20 Nov ember 2015 – Biofrontera (FSE/AIM:B8F), the biopharmaceutical company focusing on sun-induced skin cancer has published its unaudited consolidated results for the nine month period ended 30 September 2015, reporting an increase in revenues by 32% to EUR 2.635 million (2014 9M: EUR 1.922 million). The published quarterly report is available in full on the Company's website www.biofrontera.com.

Financial highlights

- Significant growth in sales revenue compared to the same period in the previous year
- Exceptionally strong revenue growth in Q3 in Germany (87% growth vs. prior year period)
- Consolidated loss before tax of EUR 9.3 million (2014: EUR 8.0 million), inclusive of the FDA submission fee of EUR 2.1 million
- Cash and cash equivalents of EUR 2.4 million as at 30 September 2015

Operational highlights

- Approval application for Ameluz® and BF-RhodoLED® accepted for detailed examination by the FDA in the USA; after preliminary examination, FDA has identified no specific review issues and holds out the prospect of an interim report in March 2016 and approval in May 2016; marketing preparations have begun
- Last patient concluded the clinical part of the phase III trial on the treatment of basal cell carcinoma in November; preliminary results of the trial expected around the end of the year
- Strengthening of the management team with the appointment of Christoph Dünwald as Chief Commercial Officer
- Addition of Belixos® Protect, a daily skincare product for sun-damaged skin, to the dermo-cosmetic line
- Long-term results of the field therapy of actinic keratosis with Ameluz® prove a continuous increase in the anti-ageing effect of PDT

Prof. Hermann Lübbert, Chief Executive Officer, commented: "We are well in line with our targets for revenue development and can confirm our annual growth target of 30%, as well as our revenue expectation for the full year. We have also met important milestones in the history of our company with the acceptance of the filing by FDA in the US as well as with completion of the clinical part of our Phase III study for basal cell carcinoma in Europe. We believe Biofrontera is well underway to become a much larger and much more prominent company in the short to medium term and we are very confident that we will also be able to successfully achieve our future goals".

The majority of revenues were again recorded in Germany with EUR 2.091 million, which represents an increase of 49%. Revenue growth in Q3 increased 87% compared to the same period in the prior year, whereby exceptionally high stocking at wholesalers was observed.

Product revenues in other European countries were EUR 544,000, which represents an increase of 4% of the same period ending Q3 2014.

The Company reported a net loss before tax of EUR 9.3 million (2014 9M loss: EUR 8.0 million) which includes development and regulatory costs of EUR 5.4 million (2014: EUR 3.1 million). The increase was primarily a result of the application fee (PDUFA fee) of EUR 2.1 million which was paid to the FDA during the period. Biofrontera meets the criteria for a waiver of that fee and has applied for reimbursement. This application is currently in process at the FDA.

Milestone Approaching - US filing for Ameluz®

One of Biofrontera's most important strategic goals is that of entering the US market with its combination prescription drug Ameluz® and PDT-lamp BF-RhodoLED®. Both products are used together in photodynamic therapy for the treatment of mild and moderate actinic keratosis. As announced during the period, the Company's phase III actinic keratosis field therapy study with the drug/light combination reported complete clearance in over 90% of treated patients, along with a strong skin rejuvenation effect.

Submission of the NDA (New Drug Application) to the FDA was effected on 10 July 2015. On 11 September FDA accepted the application for extensive review ("acceptance to file"). This was followed by a "74-day-letter" submitted by FDA to Biofrontera on 2 October, according to which the FDA did not find any major review issues after a first review, announced a comprehensive intermediate report for 30 March 2016 and the final approval date (PDUFA date) for 10 May 2016. Biofrontera has further submitted a "120-day safety update", which was due in this process and has answered all questions submitted by FDA in the 74-day letter.

Marketing authorization will provide Biofrontera access to the largest pharmaceutical market in the world with the associated significant and transformational revenue potential for the Company.

European Approval Process for Ameluz® for the treatment of BCC

Biofrontera has also made good progress in its second project of strategic importance, the label extension of the European approval of Ameluz® for the treatment of basal cell carcinoma, one of the most frequently occurring forms of skin cancer. Patient recruitment for this study was completed in May. The last patient had its final clinical visit in mid-November. The clinical part of the study is now completed and preliminary study results should become available at the end of 2015. The extended approval is expected to be achieved by mid-2016. This approval will, in management's view, provide further revenue opportunities to the Company far greater than with the existing label.

Ends

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Background:

Biofrontera Group (FSE/AIM: B8F, ISIN DE0006046113) is a biopharmaceutical company specialising in the development, sale and distribution of drugs and medical cosmetics for the care and treatment of skin diseases. Biofrontera's most important product is **Ameluz®**, a prescription drug which is approved in Europe for the treatment of mild and moderate actinic keratosis (superficial skin cancer) with photodynamic therapy (light therapy). Biofrontera is the first German pharmaceutical start-up company to obtain centralised approval for a drug it has developed itself. The company also plans for Ameluz® to be approved for basal cell carcinoma and is currently preparing for approval in other countries, especially in the largest pharmaceutical market in the world, the United States.

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 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.

www.biofrontera.com

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