

Biofrontera Reports Full Year 2015 Financial Results

Leverkusen, Germany, April 15, 2016 - Biofrontera AG (FSE: B8F), the specialist for sun-induced skin cancer, today reported its full year 2015 financial results for the year ended 31 December 2015.

- New Drug Application (NDA) for BF-200 ALA in U.S. remains on track with 10 May 2016 PDUFA date
- Launched Ameluz[®] for Actinic Keratosis in Belgium
- Successfully transitioned Ameluz[®] in Spain to direct sales force
- Completed Phase III trial for Ameluz[®] for Basal Cell Carcinoma in Europe and reported positive results in January 2016
- Established a U.S. subsidiary with Monica Tamborini as U.S. CEO
- Appointed Christoph Duenwald as Chief Commercial Officer
- Strengthened shareholder base with a new anchor investor

Key financial data within expectations

Biofrontera reported total revenues of €4.1 million for the full year, which represents a 34% increase year-over-year and was well within expectations. Revenues in Germany increased by 27% and in other European countries by 61%, when compared to 2014. Gross margin improved to 70%, compared to 64% in 2014. Research and development expenses were €6.2 million in 2015, compared to €4.5 million in 2014, and includes a PDUFA fee of €2.1 million for the NDA for Ameluz[®] that was paid in May 2015 and has been reimbursed by the U.S. Food and Drug Administration (FDA) in March 2016. The 2015 net loss before tax (including the PDUFA fee) was €11.3 million, compared to a loss of €10.7 million in 2014. The Company had €4 million cash on the balance sheet as of 31 December 2015.

Operational progress

Since the July NDA submission to the FDA for BF-200 ALA for the treatment of mild to moderate actinic keratosis (AK) on the face and scalp in the U.S., the Company has made substantial progress in the approval process. In the FDA's 74-day letter that was received in September, there were no major review issues identified and the PDUFA date was set for 10 May 2016. Since the closing of 2015, Biofrontera has received a positive FDA mid-cycle review and subsequently the proposed labelling for BF-200 ALA in March 2016. The Company is working with the FDA to finalize the labelling that will appropriately reflect the drug's efficacy and safety indications. All outstanding questions regarding the quality management system as well as the manufacturing process of the accompanying photodynamic therapy lamp have been addressed. The BF-RhodoLED[®] lamp activates the topically applied BF-200 ALA and will be approved in conjunction with the medicinal product. Biofrontera's medical device manufacturing facility is scheduled for inspection by the FDA in May, which will represent the final site visit.



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In anticipation of a U.S. approval of BF-200 ALA, the Company established Biofrontera, Inc., its U.S. subsidiary, with an office in Boston, Massachusetts. Monica L. Tamborini was appointed the U.S. CEO and has been building the company's infrastructure in preparation for the commercial launch of BF-200 ALA stateside. Ms. Tamborini has more than 20 years of experience in executive leadership positions within the healthcare sector and more specifically the pharmaceutical industry at both private and public companies. She brings a wealth of knowledge and expertise in operations and finance as well as quality management systems and FDA compliance regulations.

Biofrontera also appointed Christoph Duenwald as Chief Commercial Officer and a member of its Management Board. With 24 years of healthcare sales and marketing experience worldwide, including management positions at Bayer Healthcare and Allergan, Mr. Duenwald is leading the global sales and marketing effort for Ameluz[®] and will be instrumental to establishing the sales force in the US.

Europe remains a growth opportunity for the Company as Ameluz[®] expands its reach and garners favorable reimbursement. Biofrontera has successfully transitioned the marketing and sales of Ameluz[®] and the BF-RhodoLED[®] in Spain from Allergan to the Company's direct salesforce in an effort to realize the full margin potential. Ameluz[®] was launched in Belgium with full reimbursement by the Belgian healthcare system during the first quarter of 2015.. During the fourth quarter, Biofrontera's partner Louis Widmer received approval for Ameluz[®] in Switzerland with a planned launch to occur in Q2 of 2016.

Clinically, Biofrontera completed its Phase III clinical trial evaluating BF-200 ALA for the treatment of Basal Cell Carcinoma (BCC) in 2015 and recently reported the full results. The results from the trial demonstrated that 93.4% of patients that were treated with BF-200 ALA were cleared of all BCC's, compared to only 91.8% for those treated with Metvix[®]. In addition to the high clearance rate of BCC's, BF-200 ALA also demonstrated excellent cosmetic results where 60% of patients treated showed a good or very good improvement in skin appearance as evaluated by study physicians, compared to 48.6% when treated with Metvix[®]. These results clearly exhibit the high efficacy of PDT with BF-200 ALA to destroy BCC tumor tissue without the formation of scar tissue. The label extension of BF-200 ALA for BCC in Europe is expected to be approved by Q4 2016.

Over the course of 2015, Biofrontera was able to strategically strengthen its shareholder base through two fund raises. The first raise in April issued 1,377,272 new shares with net proceeds of approximately €3.1 million. The second raise in October issued 1,916,588 new shares with investors and provided net proceeds to the Company of €3.5 million. The proceeds from these placements have enabled the Company to finance its ongoing business operations into 2016 and to initiate the establishment of a sales and marketing infrastructure for BF-200 ALA in the U.S.

"We concluded the year having built a strong foundation that will support the tremendous opportunities that are still ahead of us," commented Hermann Luebbert, CEO of Biofrontera AG. "Our expansion in Europe continues to flourish as Ameluz[®] increases its presence in additional countries alongside our pursuit of a BCC indication for BF-200 ALA. As we advance

News Release

Biofrontera's operations in the U.S., our interactions with the FDA thus far gives us confidence that we remain on track for the planned U.S. launch of BF-200 ALA in September. The Company has a solid financial standing as we continue to execute on our strategic growth initiatives and drive shareholder value."

Ends

Enquiries, please contact: Biofrontera AG Thomas Schaffer, Chief Financial Officer	+49 (0) 214 87 63 2 0 press@biofrontera.com www.biofrontera.com
IR Germany: Brainwell Asset Solutions Jürgen Benker	+49 (0) 152 08931514
IR UK: Seton Services Toni Vallen	+44(0) 20 7729 0805
IR and PR US: The Ruth Group IR: Lee Roth / Tram Bui PR: Kirsten Thomas	+1 646-536-7012 / 7035 +1 508-280-6592

About Biofrontera

Biofrontera Group (FSE/AIM: B8F, ISIN DE0006046113) is a biopharmaceutical company specializing 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 BF-200 ALA, a prescription drug approved in Europe under the name of Ameluz[®] 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 centralized 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 of BF-200 ALA 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.

For more information, visit www.biofrontera.com



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