

# **Biofrontera Reports Full Year 2019 Financial Results**

**Leverkusen, Germany, April 20, 2020** – Biofrontera AG (NASDAQ: BFRA; Frankfurt Stock Exchange: B8F) (the "Company"), an international biopharmaceutical company, today reported its financial results for the full year ended December 31, 2019 and provided an update on recent operational and clinical developments.

# **Full Year 2019 Financial Highlights:**

- Revenue increased 48% to EUR 31.3 million for the full year 2019 compared to EUR 21.1 million for the full year 2018;
- Net loss before taxes was EUR (4.8) million for the full year 2019 compared to EUR (19.3) million in the previous year; and
- Cash and cash equivalents were EUR 11.1 million as of December 31, 2019 compared to EUR 19.5 million as of December 31, 2018.

# 2019 Operational and Clinical Development Highlights:

- Expanded research program with Maruho to further develop the branded generics program;
- Positive results of phase III study to treat actinic keratosis on the extremities, trunk/neck with Ameluz®:
- Acquisition of Cutanea Life Sciences, Inc. and integration into Biofrontera's wholly owned US-subsidiary Biofrontera Inc.;
- Obtaining unrestricted coverage with major private payer groups and launch of Xepi<sup>™</sup> for the treatment of impetigo in the U.S.; and
- Discontinuation of Aktipak® due to manufacturing issues.

# **Recent Operational and Clinical Development Highlights:**

- Approval from the European Commission for the label expansion of Ameluz® for the treatment of actinic keratosis (AK) on the extremities and trunk/neck;
- Initiation of pharmacokinetic (PK) study to evaluate the safety of photodynamic therapy (PDT) with three tubes of Ameluz<sup>®</sup>;
- Exclusive license agreement with Maruho for the development and commercialization of

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Ameluz® for all indications in East Asia and Oceania with an immediate upfront payment of EUR 6 million; and

Re-organization of Biofrontera's US-business and appointment of Christopher Pearson as Chief Commercial Officer and Erica Monaco as Chief Financial Officer of Biofrontera Inc.

"We have significantly advanced Biofrontera in 2019. Through the acquisition and integration of Cutanea Life Sciences, Inc. we were able to expand our market access in the USA. The improved reimbursement for treatment with Ameluz® in the USA and the growing acceptance of daylight PDT in Europe have led to an annual revenue growth of 48%. We recorded our highest guarterly sales in the fourth quarter, mainly driven by the strong demand for Ameluz® in the USA", commented Prof. Dr. Hermann Lübbert, CEO of Biofrontera AG. "In 2020 we will continue to intensify our educational work with dermatologists, so that even more patients will be offered our highly effective treatment option for actinic keratoses and, in the EU, also for basal cell carcinomas. With Xepi™ we have a second highly innovative drug in our US portfolio. The fact that around 50% of the US population already receive unrestricted reimbursement for the treatment with Xepi™ from their insurance companies shows how much the payors appreciate our new drug". Hermann Lübbert further explains: "The COVID-19 pandemic, however, has been affecting sales worldwide since March 2020. The reason for this is the decreasing number of medical treatments, especially treatments that are carried out in doctors' offices. Clinical studies are also affected by this. We have therefore implemented a number of cost-cutting measures that came into effect last month. As the situation is still very volatile, planning and predictability for revenue development remain very limited."

# Key financial figures for the 2019 financial year:

In EUR thousands	12M 2019	12M 2018	Change
(Except where noted)			
Total revenue	31,265	21,107	48%
Research and development costs	(4,636)	(4,427)	5%
General administrative costs	(16,275)	(12,963)	26%
Sales costs	(28,856)	(17,744)	63%
Net loss before taxes	(4,777)	(19,269)	303%
Net loss after taxes	(7,358)	(8,878)	21%

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### Full Year 2020 Guidance

As it is currently impossible to foresee how long and how strongly the pandemic will affect the economy, no reliable estimate or more precise quantification of the specific implications for sales and earnings can be made for the 2020 financial year. For this reason, Biofrontera's ability to forecast is significantly impaired at this time. In its initial budget for the 2020 financial year, the Group had assumed a 25% increase in revenue compared to the previous year, and operating costs at approximately the same level as in the previous year. However, the effects of the coronavirus pandemic may lead to a significant deviation from previous projections and to a noticeable decline in sales compared to previous plans and possibly even compared to the previous fiscal year. The anticipated reduced revenue will also have a negative impact on the profitability of the Group and the liquidity of Biofrontera AG as well as the Group in the 2020 financial year, as the lack of revenue may not be fully offset by cost reduction measures. At the same time, the cost reduction measures already initiated and published on March 20, 2020 will continue. These measures include in particular the introduction of short-time work in Germany and comparable measures in Spain and the UK, the reduction of the workforce in the USA by almost 20% and mandatory unpaid leave for all employees in the USA. Steps to secure liquidity and strengthen cash flow are given high priority.

# **U.S. Commercial Update**

The market opportunity in the United States continues to represent the major growth driver for Biofrontera, accounting for 75% of total sales in 2019. For the full year 2019, Biofrontera achieved revenue in the United States amounting to approximately EUR 23.3 million, representing revenue growth of approximately 57% compared to the full year 2018. This growth was driven by the continued expansion of our sales and distribution infrastructure as well as improved reimbursement of PDT, which was increased in 2019. Product sales of Xepi™ and Aktipak® contributed approximately EUR 0.8 million to total revenue since the acquisition of Cutanea Life Sciences, Inc.

In March 2019, Biofrontera acquired Cutanea Life Sciences, Inc., which expanded its product portfolio in the U.S. with the FDA-approved drug Xepi<sup>™</sup>, the first topical antibiotic to be approved since a decade. Xepi<sup>™</sup> is specifically also approved by the FDA for the treatment of infections with antibiotic-resistant bacterial strains such as MRSA. There are approximately 10 million prescriptions

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for topical antibiotics annually in the U.S., representing a significant growth opportunity for Xepi<sup>™</sup> as Biofrontera optimizes Xepi<sup>™</sup> reimbursement along with its marketing strategy.

# **EU Commercial Update**

Sales revenue in Germany for the full year 2019 grew significantly to approximately EUR 4.6 million, representing a 40% increase compared to the same period in 2018. The growth is primarily due to the increased adoption of daylight PDT. In the rest of Europe, sales revenue decreased approximately 5% year over year to EUR 2.6 million.

In Germany, which remains the largest European market for Ameluz<sup>®</sup>, Biofrontera's market share increased to 57% of PDT treatments compared to 52% in 2018. Ameluz<sup>®</sup> is thereby continuously established as the leader in the PDT market compared to competitive products. As daylight PDT – unlike conventional PDT - is reimbursed by the German public health care system, it allows Ameluz<sup>®</sup> to directly compete also with self-applied topical creams, which represent the majority of the actinic keratosis market in Europe.

In Spain, sales grew approximately 10%, more than compensating a major price decrease enforced by the Spanish government. In the United Kingdom, Biofrontera continues to focus on training hospital administrations to add Ameluz® as an approved drug in the respective hospital pharmacies. To date, the Company has seen success as some major hospitals now rate Ameluz® as the first choice PDT drug for the treatment of actinic keratosis and basal cell carcinoma. These successes are beginning to translate into steep sales growth; however, the UK still remains a minor portion of the Company's revenue. Shipments to license partners in other European countries declined significantly.

### **Clinical Update**

In March 2019, Biofrontera announced positive results from its Phase III trial evaluating the safety and efficacy of conventional PDT with Ameluz® and BF-RhodoLED® for the treatment of actinic keratosis on the extremities, trunk and neck. The study met its primary endpoint, demonstrating mean lesion clearance rates per patient's side of 86% for Ameluz® compared to 33% for placebo. In January 2020, Biofrontera reported 12-month follow-up results from the study with overall lesion

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recurrence rates after one year of 14.1% after Ameluz® treatment, compared to 27.4% after placebo treatment. Based on the results of the trial, the European Commission approved the label expansion of Ameluz® for the treatment of actinic keratosis on extremities and trunk/neck in March 2020. At the same time, the European Commission approved listing an additional superiority claim over European PDT competitors in the product information with Ameluz®, showing lower recurrence rates after daylight PDT with Ameluz® than after daylight PDT with the competitor.

In the U.S. Biofrontera is working on various initiatives to expand the indication of Ameluz® and for continued development of sustained growth over the coming years. Biofrontera continues to enroll patients in its U.S. phase III study with Ameluz® for the treatment of superficial basal cell carcinoma (BCC). Due to slow recruitment, the Company expects to announce results from the study not before 2021. The approval of Ameluz® for superficial BCC would significantly expand the market opportunity for Ameluz® as it would be the only PDT-drug available in the United States for the treatment of this indication. Additionally, Biofrontera has initiated a pharmacokinetics (PK) study, as requested by the U.S. Food and Drug Administration (FDA), to examine the safety and efficacy of three tubes of Ameluz®. The study is expected to be completed in the second half of 2020. In relation to using Ameluz® on larger body areas, Biofrontera is also developing a next generation "BF-RhodoLED® XL" lamp and currently expects to submit an application for approval to the FDA in the second half of 2020.

Biofrontera is also progressing with its research cooperation agreement with Maruho for the development of branded generics based on the Company's nanoemulsion technology. In addition, Biofrontera and Maruho have signed an exclusive license agreement to commercialize Ameluz® in East Asia and Oceania. Under the terms of the license and supply agreement, Maruho will obtain exclusive development and commercialization rights including the right to sublicense Ameluz® in East Asia and Oceania. Biofrontera will supply Ameluz® to Maruho at cost plus 25%. Maruho will make an upfront payment to Biofrontera AG in the amount of EUR 6 million plus additional future payments subject to achievement of certain regulatory and sales milestones. Maruho will also make royalty payments at an initial rate of 6% of net sales in the countries of its territory, which will increase depending on sales volume and will be reduced should generic products become available in the respective countries.

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### **Conference Call**

Conference calls for shareholders and interested investors will be held on April 21, 2020 at the following times:

In German, April 21, 2020 at 10:00 am CEST (4:00 am EST)

Dial-in number Germany: +49 69201744220

Conference code: 26923241#

In English, April 21, 2020 at 2:00 pm CEST (8:00 am EST)

Dial-in number USA: +1 8774230830 Dial-in number UK: +44 2030092470

Conference code: 92360370#

Please dial in 10 minutes ahead of time to ensure a timely start of the conference call.

Biofrontera's annual report 2019 is available at <a href="https://www.biofrontera.com/en/investors/financial-reports.html">https://www.biofrontera.com/en/investors/financial-reports.html</a>.

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# **About Biofrontera:**

Biofrontera AG is a biopharmaceutical company specializing in the development and sale of dermatological drugs and medical cosmetics.

#### **Biofrontera AG**

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Supervisory board: Dr. Ulrich Granzer (Chairman) I Jürgen Baumann (Vice-Chairman) Executive board: Prof. Dr. rer. nat. Hermann Lübbert (CEO)

Thomas Schaffer (CFO)

Commercial register: Handelsregister Köln | Register number: HR B 49717 (AG) VAT-identification number according to § 27 a UStG VAT act: DE 812374102



The Germany-based company, with almost 200 employees worldwide, develops and markets innovative products for the care, protection and treatment of the skin. The company's lead product is the combination of Ameluz®, a topical prescription drug, and medical device BF-RhodoLED® for the photodynamic therapy of certain superficial skin cancers and their precursors. Ameluz® has been marketed in the EU since 2012 and in the United States since May 2016. In addition, the company markets the prescription medication Xepi™ for the treatment of impetigo in the United States. In the EU, the company also sells the dermocosmetics series Belixos®, which offers specialized care for damaged or diseased skin.

Biofrontera is the first German founder-led pharmaceutical company to receive a centralized European and a US approval for a drug developed in-house. The Biofrontera Group was founded in 1997 by the current CEO Prof. Dr. Hermann Lübbert and is listed on the Frankfurt Stock Exchange (Prime Standard) and on the US NASDAQ.www.biofrontera.com.

### **Forward Looking Statements:**

Certain statements in this press release are forward-looking within the meaning of the Private Securities Litigation Reform Act of 1995 regarding the public offering and the intended use of proceeds from the offering. These statements may be identified by the use of forward-looking words such as "anticipate," "believe," "forecast," "estimate" and "intend," among others. Such forward-looking statements are based on the currently held beliefs and assumptions of the management of Biofrontera AG, which are expressed in good faith and, in their opinion, reasonable. Forward-looking statements involve known and unknown risks, uncertainties and other factors, which may cause the actual results, financial condition, performance, or achievements of the Company, or industry results, to differ materially from the results, financial condition, performance or achievements expressed or implied by such forward-looking statements. These risks, uncertainties and other factors are set forth in the Registration Statement on Form F-1 filed with the SEC, including in the section "Risk Factors," and in future reports filed with the SEC. Given these risks, uncertainties and other factors, prospective investors are cautioned not to place undue reliance on these forward-looking statements. The Company does not undertake an obligation to update or revise any forward-looking statement.

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