

## **Biofrontera shows robust growth during first six months of 2019**

**Leverkusen, Germany, August 27, 2019** – Biofrontera AG (NASDAQ: BFRA; Frankfurt Stock Exchange: B8F) (the “Company”), an international biopharmaceutical company, today reported its results for the first six months ended June 30, 2019. At the same time, Biofrontera provided an update on recent business developments.

### **H1 2019 Financial Highlights**

- Total revenue increased 55% to EUR 13.9 million compared to EUR 9.0 million in the first half of 2018.
- Due to the one-time positive effect of the goodwill resulting from the purchase price allocation of Cutanea Life Sciences, Inc. (Cutanea) Biofrontera reported a positive net result of EUR 8.6 million for the reporting period.
- Cash and cash equivalents amounted to EUR 21.6 million as of June 30, 2019, compared to EUR 19.5 million as of December 31, 2018. This figure includes cash and cash equivalents of Cutanea in the amount of EUR 5.8 million.

### **H1 2019 Operational Highlights**

- Expansion of the product portfolio with Xepi® in the US, as a result of the successful integration of Cutanea, a specialty pharmaceutical company focused on dermatology;
- Marketing of Aktipak® discontinued due to quality problems in the production at Cutanea’s contract manufacturer, which could not be solved in the short term, along with a comparatively lower market potential;
- Expansion of the research cooperation with Maruho Co., Ltd. (Maruho) for the further development of branded generics as well as letter of intent for the indication expansion of Ameluz® for acne and for the marketing of Ameluz® in parts of East-Asia and Oceania;
- Positive Phase III results on the safety and efficacy of Ameluz® in combination with Biofrontera’s BF-RhodoLED® lamp for the treatment of actinic keratosis on the extremities, trunk and neck.

#### **Biofrontera AG**

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**Commercial register:** Handelsregister Köln | **Register number:** HR B 49717 (AG)  
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“Overall, Biofrontera continues to perform remarkably well. Our revenue has increased significantly since 2016. And we will continue our dynamic revenue growth in 2019. In the first half of this year, we achieved key milestones in driving forward the global positioning and further development of Biofrontera as a leading specialist in dermatology. In the reporting period, we increased total revenue by 55%. Growth was driven in particular by the US, but also by the German market, where revenue grew by 82% year-over-year. In the US, revenue growth was 59%, such that in this market we are now in an excellent position due to our expanded commercial portfolio with Ameluz® and Xepi®. We expect overall revenue growth during the remainder of 2019 to be at a similar level as in the first half of the year with around 50%. Adjusted for the Cutanea acquisition, we continue to expect to reach operating break-even in the fourth quarter,” said Prof. Dr. Hermann Lübbert.

### Key financial figures for the first six months of 2019

In EUR thousands	6M 2019	6M 2018	Change
Revenue	13,904	8,969	4,935
Research and development costs	-2,322	-2,188	-134
General administrative costs	-7,768	-4,079	-3,689
Sales and marketing costs	-14,195	-8,311	-5,884
Other expenses and income	23,236	638	22,598
Net profit / loss	9,027	-7,685	16,712

### US commercial update

In the first half of 2019, Biofrontera’s revenue amounted to EUR 10.2 million in the US, which corresponds to a revenue growth of 59% year-over-year. This growth results mainly from the expansion of our sales infrastructure and from improvements in the reimbursement of PDT for US-dermatologists.

In January 2019, Biofrontera received approval from the U.S. Food and Drug Administration (FDA) to increase the production batch size for Ameluz®. The five-fold increase in batch size ensures a secure supply of Ameluz® enabling Biofrontera to sustainably meet the growing demand in the US and to improve gross margins.

With the successfully completed integration of Cutanea, acquired in March 2019, Biofrontera has expanded its product portfolio with the FDA-approved prescription drug Xepi® for the treatment of impetigo. In addition to the commercialization of Ameluz®, Biofrontera is now also focusing on Xepi® in the US. It is the first new topical antibiotic that has entered the American market in almost 10 years and for which no antibiotic resistance is known.

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## EU commercial update

Revenue in Germany improved to EUR 2.2 million, representing an 82% increase compared to the same period last year. In the rest of Europe, revenue rose to EUR 1.4 million, 12% higher than in the first half of 2018. The positive development in the EU is a consequence of the European approval of daylight PDT last year.

## Clinical update

In March 2019, Biofrontera announced positive results from its phase III study evaluating the safety and efficacy of conventional PDT with Ameluz® and the BF-RhodoLED® lamp for the treatment of actinic keratoses on the extremities, trunk and neck. The study showed that Ameluz®, with an average complete healing rate of 86% of AK lesions, is significantly superior to the placebo rate of 33%. These results, along with equally positive secondary endpoints, will form the basis to file an extension to the license with the European Medicines Agency (EMA) in the third quarter of 2019.

In addition, Biofrontera signed an agreement to continue the research collaboration with Maruho for the development of branded generics based on Biofrontera's nanoemulsion. As conclusion of an earlier project phase one of four jointly examined active ingredients was selected. The current phase of the project aims at preparing this active ingredient formulated in Biofrontera's nanoemulsion for clinical trials. The costs associated with this project phase of up to EUR 1.1 million will be paid solely by Maruho. Furthermore, the company has signed a letter of intent with Maruho about the financing of the indication expansion of Ameluz® for the treatment of moderate to severe acne. Related to this, Biofrontera and Maruho are negotiating a license for Maruho to market Ameluz® in parts of East-Asia and Oceania.

## Full year 2019 guidance

Biofrontera is currently expecting its annual revenue to be in the range of EUR 32 and 35 million. This expectation is slightly below the previous guidance, which targeted EUR 35 to 40 million. The adjusted guidance is primarily attributable to the continued dynamic but slightly weaker growth in the US. Sales of Cutanea products are not yet included. The management board also forecasted a result from operating activities of EUR -7 to -9 million for 2019. Taking into account the charges to Maruho reported under other income, Biofrontera continues to expect to reach the operating break-even during the fourth quarter of 2019. Following the discontinuation of Aktipak® marketing, Biofrontera expects total sales from its new products of around EUR 1 to 1.5 million in 2019.

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## Conference call

Conference calls for shareholders and interested investors will be held on August 27, 2019 at the

following times:

In German, at 10:00 am CET (4:00 am ET)  
Dial-in number Germany: +49 69201744220  
Conference code: 74039909#

In English, at 2:00 pm CET (8:00 am ET)  
Dial-in number USA: +1 8774230830  
Dial-in number UK: +44 2030092470  
Conference code: 89026773#

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

The Company's half-year report is available at  
<https://www.biofrontera.com/en/investors/financial-reports.html>.

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### For enquiries, please contact:

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### About Biofrontera:

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

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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<sup>®</sup>, a topical prescription drug, and medical device BF-RhodoLED<sup>®</sup> for the photodynamic therapy of certain superficial skin cancers and their precursors. Ameluz<sup>®</sup> has been marketed in the EU since 2012 and in the United States since May 2016. In

addition, the company markets Xepi<sup>®</sup>, a prescription medication for the treatment of impetigo in the United States. In the EU, the company also sells the dermocosmetics series Belixos<sup>®</sup>, 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](http://www.biofrontera.com).

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