Biofrontera
Experts in dermatology

Press release

Biofrontera publishes report on the third quarter of 2014

- **Significant progress in business operations: excellent results in the phase 3 clinical study on the broad area therapy of actinic keratosis and completion of the safety studies required by the FDA**
- **Patient recruitment for phase 3 study on basal cell carcinoma is in progress in Germany and the United Kingdom**
- **Growth in sales of 31% in Germany compared to the nine-month period of the previous year**
- **Other international sales remain slow ahead of the planned basal cell carcinoma trial**

Leverkusen, 13 November 2014 - Today, Biofrontera AG (FSE/AIM: B8F), the biopharmaceutical company focusing on skin cancer, presents the company results for the first nine months of 2014. The quarterly report now published on the company's website (at http://biofrontera.com/en/) goes into detail in particular on the clinical development activities surrounding Biofrontera's skin cancer drug, Ameluz®, and the preparations for the approval process in the US. In addition, the report covers national and international sales activities.

Development of the key financial figures in the first nine months of 2014

In the third quarter of the 2014 financial year, Biofrontera achieved a significant increase in revenue of 61% compared to the same period of the previous year. In Germany, where Biofrontera manages sales activities itself, sales grew by 54% compared to the same quarter of the previous year. The first nine months of the year resulted in revenue of EUR 1,992 thousand. While this was 7% higher overall than in the period for the previous year, sales in Germany increased significantly by 31% to EUR 1,399 thousand, which exceeded the revenue growth target for Germany. In contrast to this, the development in revenue outside Germany was still slow; in the first nine months, revenue from sales to foreign licensing partners fell from EUR 798 thousand in the first nine months of the previous year to EUR 523 thousand. Although revenue increased sales in the individual countries, the majority of these sales were

fulfilled from existing inventory previously purchased by Biofrontera's local distribution partners. At this stage, it remains challenging to position Ameluz® in hospitals while the medicine is only approved for the treatment of actinic keratosis but not for the treatment of basal cell carcinoma. Consequently, we are expecting sales to increase as approval is extended for the treatment of basal cell carcinoma and the phase 3 clinical study required for this is under way.

Our gross margin has improved to 56% compared to 31% in the same period of the previous year. This was due both to systematic cost management and to a considerable reduction in expenditures incurred in 2013 for the qualification of new production methods and manufacturers carried out upon request by the EMA, which have not yet been completed but were reduced considerably in 2014.

Research and development costs increased from EUR 1,950 thousand in the previous year to EUR 3,146 thousand in the first nine months of 2014. The increase is due to clinical activities in connection with extending the range of indications for basal cell carcinoma and the work undertaken towards the approval of Ameluz® in the US. As a result of savings, however, R&D costs remain below the projected amount. As planned, sales and administration costs increased from EUR 3,773 thousand to EUR 5,588 thousand compared with the same period of the previous year as a result of the approval process in the US and the setting up of an internal company infrastructure to meet the requirements of pharmaceutical companies.

The loss before tax was EUR 7,955 thousand; in the previous year it was EUR 6,022 thousand. As at 30 September 2014 cash and cash equivalents amounted to EUR 9,962 thousand.

On 30 September 2014, Biofrontera employed 41 employees, compared to 39 employees on 30 September 2013.

Study results, preparation of the approval of Ameluz® in the US

Three clinical trials have been conducted in preparation for the submission of the approval dossier to the FDA (US Food and Drug Administration). As expected, the two safety studies required by the FDA did not reveal any critical aspects in respect of drug safety. In a third, recently completed phase 3 study, in which the combination of Ameluz® was tested with Biofrontera's PDT lamp BF-RhodoLED®, 91% of the patients treated with Ameluz® and 94% of the individual actinic keratoses were completely cured at the end of the study. In this study, photodynamic therapy (PDT) was tested on

larger areas (fields) of skin for the first time in a phase 3 trial, although this therapy is actually recommended in the dermatological guidelines for field therapy. In field therapy, the significant effect of skin rejuvenation which occurs with PDT proves to be particularly beneficial.

The submission of the approval dossier in the US is scheduled for March 2015, after a combined analysis of all clinical results has been performed. The approval is expected to be issued around one year later.

The pre-NDA (new drug application) meeting, at which significant issues relating to the approval dossier were discussed again, took place shortly after the reporting date of this report, on 08 October 2014. Due to the few remaining outstanding questions following the FDA's examination of the documents submitted, this meeting was held as a conference call on the recommendation of the FDA. At this meeting, any remaining outstanding questions were also clarified.

Extension of indications to basal cell carcinoma

A recently published meta-analysis of all clinical trials already carried out for the treatment of actinic keratosis clearly showed that Ameluz® is by far the most effective form of treatment for mild and moderate actinic keratosis on the face and scalp. Despite this, the lack of approval for the indication of basal cell carcinoma (BCC), for which there are several competing drugs, has proven to be a challenge in the marketing of Ameluz®.

Therefore, Biofrontera has begun the implementation of a phase 3 trial in order to have Ameluz® European approval extended to include the treatment of BCC. BCCs are the most common invasive tumors to affect humans and account for approximately 80% of all invasive skin cancers in Caucasians. About 30% of all Caucasians develop at least one BCC in their lifetime, and cases are increasing rapidly worldwide due to increased exposure to UV light. Surgical removal is the most frequent treatment currently used in Germany but this can lead to clearly visible scarring, whereas treatment with photodynamic therapy (PDT), which is an alternative particularly in the treatment of thin, nonaggressive BCCs, is not only a highly effective treatment method, but also produces excellent cosmetic results.

The recruitment of the 360 planned patients began in Germany in early February and in the UK in May 2014. Because patient recruitment has been slower than expected, Biofrontera has included 8 further centers in Germany in the trial, which has increased

the number of study centers involved to a total of 27. It is expected that the recruitment process will be completed at the end of this year or the beginning of next year, which will mean that the expansion of indications can probably take place in early 2016. The expansion of the European approval to include BCC will be of particular importance for sales development in European countries outside Germany.

The management board of Biofrontera AG will outline the main developments in the period under review in a telephone conference.
The telephone conference for shareholders and potential investors begins in German at 9:00 AM, and in English at 10:30 AM.

Telephone conference in German:
Access number: +49-(0)69 271340800
Confirmation number: 73218216#

Telephone conference in English:
Access number: +49-(0)69 271340801
Access UK: +44 20 33645807
Confirmation number: 51595435#

Please dial in 5 minutes before the start of the telephone conference to enable the conference to start on time.

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Background:

The **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® contains a combination of active substances extracted from plants, relieves itching and redness and is used for the regenerative treatment of chronic skin conditions such as atopic dermatitis or psoriasis. At the moment, Belixos® is available as a cream and scalp tonic.

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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