Press release

Biofrontera explains corporate strategy and clinical development program in telephone conference

For further information:

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Leverkusen, 12 March 2013 - Biofrontera AG announces that in a telephone conference on Friday, 15 March 2013, it will illustrate its strategy for the national and international development of the company. The conference for shareholders and interested investors will start in German language at 9:30 a.m., in English at 11:00 a.m..

Telephone conference
March 15, 2013, 9:30 a.m. (German), 11:00 a.m. (English)
Dial-in number: +49 (0)69 271 340 800
Room number: 17675723#
Please dial into the conference 10 minutes earlier to allow a start in time.

Background:
Compared to similar companies, Biofrontera has been choosing a rather low-risk profile. With this corporate strategy it has, as first German Biotech ever, managed to obtain a centralized European approval for a prescription drug that was entirely developed in-house. The product, called Ameluz®, has now been marketed since one year by Biofrontera in Germany. Distribution deals for other European countries were formed with regional representatives, some of whom already launched Ameluz® in the second half of 2012. In parallel, in the past 12 months Biofrontera's market cap increased by about EUR 34.05 mln[1]. If this number is reduced by the March 2012 capital increase (press release of 23 March 2012) minus the final redemption of the convertible bond 2005/2012 (press release of 3 May 2012) and the payment to ASAT AG (press release of 16 June 2011), the adjusted increase in value amounted to EUR 27.87 mln.. This substantial accretion reflects the increasing trust of investors into the future revenues with the subscription drug Ameluz®.
The company anticipates further value enhancements through the approval of further indications for Ameluz® as well as the marketing authorization for other regions, particularly the USA as largest Pharma market of the world. The indication expansion and the approval in the USA are believed by

Biofrontera to be associated with manageable cost and low risk. The resulting value appreciation should exceed the cost many fold.
To implement these goals, four clinical trials with Ameluz® are currently being prepared, partly to fulfill the requests expressed in a hearing by the US Food and Drug Association, FDA (compare press release of 23 July 2012):

1) Ameluz® will be tested in the treatment of basal cell carcinoma (BCC) against the comparator Metvix®. BCCs are the most abundant infiltrating tumours in humans and account for 80% of non-melanoma skin cancers[2]. About 30% of all Caucasians worldwide develop at least one BCC during their life-time, and the global incidence grows rapidly due to increasing UV-exposure[3, 4]. Surgical removal may lead to disfiguring scars, while photodynamic therapy (PDT) represents an alternative particularly for thin BCCs, resulting in excellent cosmetic outcomes. Biofrontera intends to compare Ameluz® with comparator Metvix® which is approved for BCC. Ameluz has already proven superiority to Metvix® with respect to the total clearance of all lesions of actinic keratosis patients[5,6].

2) A study for actinic keratosis, in which patients are treated on entire fields, such as forehead, bald scalp etc., and illuminated with Biofrontera's CE-marked PDT lamp BF-RhodoLED®. This study is intended to add data about Biofrontera's own lamp to the existing phase III studies, in which a variety of different PDT-lamps had been compared. The application of Ameluz® to entire fields may provide additional safety information and allow a more thorough analysis of the long-term efficacy and cosmetic outcome.

3) A trial to test the sensitizing potential of Ameluz®, i.e. to measure potential allergic reactions to the product. This study has been requested by the FDA even though the phase III trials did not reveal any indication for sensitization and aminolevulinic acid (ALA), the active ingredient of Ameluz®, naturally occurs in every cell of the body.

4) A maximal-use pharmacokinetics study. The FDA has requested a trial in which an entire tube of Ameluz® is applied to a maximally damaged skin area, to observe the potential uptake of ALA into and the elimination from the blood. Since ALA naturally occurs in the blood,

and small temporary increases in its concentrations do not impose a safety risk, the outcome of this trial does not appear to be critical.

"This development program is currently initiated with all four trials in parallel. Through this we anticipate an escalation of the value of Ameluz®, reflected presumably by the price of Biofrontera shares. The cost/risk relationship in studies with approved drugs is greatly advantageous compared to that of development products. Together we expect costs for the studies in the range of EUR 5 to 6 mln. which should greatly be outbalanced by the anticipated value escalation. The sensitization and pharmacokinetics trials should be completed by the end of this year, the clinical part of the other two studies by the middle of next year", commented Prof. Hermann Lübbert, chief executive officer of Biofrontera AG.

References:

1) Xetra final price EUR 3.15 on March 8, 2012, and EUR 4.40 on March 8, 2013
2) Leiter & Garbe, Adv Exp Med Biol. 2008;624:89-103
3) Walling et al., Cancer Metastasis Rev. 2004;23(3-4):389-402
4) Wolberink et al., J Eur Acad Dermatol Venereol. 2012 [Epub ahead of print]
5) Ameluz® SmPC
6) Dirschka et al., Br J Dermatol. 2012;166(1):137-46

About Biofrontera AG

Biofrontera aims at attending and treating the skin, recognizing the aesthetic needs of a person's visual reflection.
Biofrontera is listed in the regulated market of the Frankfurt stock exchange under the symbol B8F and the ISIN DE0006046113.
www.biofrontera.com