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Detailed phase III results confirm superiority of BF-200 ALA over Metvix[®]

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Leverkusen, Germany - Biofrontera AG (DSE: B8F) announced that it has received detailed results of the phase III comparative study with BF-200 ALA and Metvix[®] for the treatment of actinic keratosis.

A total of 27 study centers in Germany, Austria and Switzerland collected 570 Patient with between 4 and 8 independent actinic keratosis lesions. The patients were treated by photodynamic therapy, combining one of the test compounds or a placebo with a brief red light illumination. With different types of red light sources BF-200 ALA on average erased all lesions of 78% of the patients, whereas the registered comparator Metvix[®] only reached a complete healing rate of 64%, and the placebo group of 17%.

The results obtained with different light sources showed that with LED lamps emitting a narrow light spectrum, which were in a first phase III study already recognized as the most efficient red light sources, BF-200 ALA completely eliminated all lesions in 85 % of the patients, whereas with Metvix[®] only 68% and in the placebo group 13% of the patients were completely healed. The superiority of BF-200 ALA was most impressively demonstrated with the more persistent lesions on the scalp. Averaging all light sources, BF-200 ALA displayed the complete removal of all actinic keratoses in this area in 70% of the patients, whereas only 40% of the patients were healed with Metvix[®].

The study impressively confirms that the combination of the active ingredient 5-aminolevulinic acid with Biofrontera's proprietary nanoemulsion BF-200 not only facilitates the application and handling of the compound but also displays significantly higher efficacy than Metvix[®]. This advantage becomes most relevant in the treatment of deeper lesions. The low placebo rates illustrate the quality of the data, which document the superiority of BF-200 ALA with high statistical significance.

News Release

The determination of the adverse effects showed no substantial differences between the treatment with BF-200 ALA or Metvix[®]. In the pain perception during the illumination, BF-200 ALA showed a slight advantage, with 25 % of the patients reporting severe pain, while 29 % of the patients treated with Metvix[®] complained about severe pain.

The detailed results impressively confirm the outcome of the previous phase III trial with BF-200 ALA, in which the treatment combining BF-200 ALA with an LED light source completely erased all lesions in 96% of the patients. The combined results of both studies document an efficacy in the treatment of actinic keratosis that has never before been achieved with any other treatment. The current trial completes the clinical development of BF-200 ALA, after which Biofrontera will prepare the application for marketing authorization. The filing is anticipated in the late summer this year. Due to BF-200 ALA's high technical innovation the European agency EMEA has already acknowledged the eligibility of the product for the centralized registration process, such that Biofrontera anticipates the approval for the entire European Union in a single registration process.

About Biofrontera AG

Biofrontera AG is specialized in the development of pharmaceutical products in the area of dermatology. The company is characterized by a broad, relatively close to the market product portfolio. Biofrontera is listed in the regulated market of the Düsseldorf stock exchange under the symbol B8F and the ISIN number DE0006046113.

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