

Press Release

Due to a legal complaint by Galderma SA the following press release was modified such that any interpretation of the differences between the two products was removed.

For detailed information on the reported study, please visit the following link:

http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002204/smops/Positive/human_smop_001076.jsp&mid=WC0b01ac058001d127

Biofrontera Announces 12-Month Follow-Up Results of Phase III Trial Evaluating Ameluz[®] for Basal Cell Carcinoma

Leverkusen, Germany, October 20, 2016 – Biofrontera AG (FSE: B8F), the specialist for the treatment of sun-induced skin cancer, today announced 12-month follow-up results from its Phase III clinical trial evaluating its combination topical prescription drug Ameluz[®] and medical device BF-RhodoLED[®] for the treatment of basal cell carcinoma (BCC).

The 12-month follow-up results from the multi-national study in the European Union reported that patients treated with Ameluz[®] PDT saw an overall lesion recurrence rate of 6.7% and 8.2% for those treated with the comparator treatment, methyl aminolevulinate (MAL) PDT, marketed as Metvix[®]. For the treatment of Superficial BCC, patients treated with Ameluz[®] saw a recurrence rate of 5.4%, compared to 7.9% for those treated with Metvix[®]. In Nodular BCC, Ameluz[®] had a recurrence rate of 9.1% versus 10.0% recurrence for Metvix[®]. Recurrence rates of BCC's on the head were 7.7% and 18.2% for Ameluz[®] and Metvix[®], respectively. In BCC's of the trunk, Ameluz[®] and Metvix[®] had recurrence rates of 6.7% and 7.6%, respectively.

In 60.0% of patients treated with Ameluz[®], after 3 months skin aesthetic appearance was notably improved and rated by study physicians as good or very good, compared to 48.6% of patients treated with Metvix[®]. After 1-year follow-up the improvement of skin aesthetic appearance was rated as good or very good for 68.3% of Ameluz[®] and 65.5% of Metvix[®] treated patients, respectively.

“These very positive follow-up results demonstrate the long term clinical efficacy of Ameluz[®] in reducing the risk of recurring BCC alongside sustained improvements of skin appearance,” stated Prof. Hermann Lübbert, CEO of Biofrontera AG. “Ameluz[®] remains an excellent photodynamic therapy treatment option for Actinic Keratosis and BCC, and these results will aid our ongoing EU application for the label extension to include basal cell carcinoma with expected approval by Q1 2017. The expansion of Ameluz[®] to BCC would significantly expand our market and revenue opportunity in the EU.”

The Phase III study included 281 patients with 1 to 3 non-aggressive BCCs, including both superficial and nodular BCC with a tumour thickness of up to 2mm. The analysis confirmed that 93.4% of patients treated with Ameluz[®] were cleared of all BCCs, compared to 91.8% of patients treated with Metvix[®]. Counting the clearance of individual BCCs this corresponded to total lesion clearance rates of 94.6% after Ameluz[®] vs. 92.9% after Metvix[®] PDT, respectively.

Press release

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About Biofrontera

Biofrontera Group (FSE: B8F, ISIN DE0006046113) **Biofrontera** is a biopharmaceutical company specializing in the development, sale and distribution of drugs, medical devices and medical cosmetics for the care and treatment of skin diseases. Biofrontera's most important product is Ameluz[®], a prescription drug which was initially approved and marketed in Europe and is now also approved in the US for the treatment of mild and moderate actinic keratosis, a precursor to squamous cell carcinoma, with photodynamic therapy (light therapy). Biofrontera is the first German pharmaceutical start-up company to obtain centralized EU and now US approval for a medical device/drug it has developed itself. The company also markets the Belixos[®] dermatological range of cosmetics. Belixos[®] products, a cream, a gel, a scalp tonic and acute roll-on, contain combinations of active substances extracted from plants, relieve itching and redness and are used for the regenerative care of chronic skin conditions such as atopic dermatitis or psoriasis. The Belixos[®] Protect, a daily skincare for sun-damaged skin, complements this dermo-cosmetic line. All products are available through Amazon. 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.

For more information, visit www.biofrontera.com

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