Biofrontera
Experts in dermatology

News Release

Biofrontera reports final patient visit in phase III trial for basal cell carcinoma

Leverkusen, 19 November 2015 – Biofrontera (FSE/AIM:B8F), the biopharmaceutical company focusing on sun-induced skin cancer, announces that the last patient in the ongoing phase III trial for basal cell carcinoma ("BCC") has had its final clinical visit, concluding the clinical phase of the study. Biofrontera expects preliminary results of the main clinical endpoints before the end of the year and the final report by the end of Q1 2016.

BCC is the most common infiltrating tumour in humans. Approximately 1-2% of the western population is treated for BCCs every year. BCCs can grow variably aggressive with metastasizing (spreading) tumours as the most extreme form, the latter of which represents less than 1% of all BCCs. More abundant are the non-aggressive forms, which include superficial and nodular BCCs. Biofrontera's study focusses on thin, non-aggressive BCCs, which may represent about one-third of all BCCs. The study compares the efficacy and safety of Ameluz® with those of Metvix, a drug approved in the EU for the treatment of superficial and nodular BCCs against which Ameluz® is already showing superior results for other indications. The primary clinical endpoint is for Ameluz® to deliver total clearance of all patient's BCCs.

The clinical study will be followed by a five year follow-up period, during which recurrence of treated BCCs as well as new BCCs and other skin tumours will be recorded.

Prof. Dr. Hermann Luebbert, CEO of Biofrontera commented: "The data from this phase III study will allow us to obtain approval for BCC treatment with Ameluz® in Europe, which technically is a variation of the existing centralized approval. The agency's decision on such a variation takes three months from the application plus the time required to answer questions of the agency. We anticipate the approval in the summer of 2016 and subsequently envision a significantly larger market potential for Ameluz®."

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Enquiries, please contact:

Biofrontera AG	+49 (0) 214 87 63 2 0
Thomas Schaffer, Chief Financial Officer	press@biofrontera.com
	www.biofrontera.com
IR Germany: Brainwell Asset Solutions	+49 (0) 152 08931514
Jürgen Benker	
Nomad and Broker: Shore Capital	+44(0) 20 7408 4090

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Bidhi Bhoma / Toby Gibbs	
IR UK: Seton Services	+44(0) 20 7603 6797
Toni Vallen	
Financial PR: Gable Communications	+44(0) 20 7193 7463
John Bick / Justine James	+44 (0)7872 061007

Background:

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® products, a cream, a gel and a scalp tonic, 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.

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