Biofrontera
Experts in photodynamic therapy

news release

CMS issues new reimbursement codes for Ameluz® and for Photodynamic Therapy

- **Product-specific J-Code to improve reimbursement coding for prescribing physicians**
- **New CPT® Codes establish favorable reimbursement for Photodynamic Therapy**

Leverkusen, Germany, November 10, 2017 Biofrontera AG (ISIN: DE0006046113), the specialist for the treatment of sun-induced skin cancer, today announced that the U.S. Centers for Medicare & Medicaid Services (CMS) have assigned a unique, product-specific billing code, or J-Code (J7345), for Biofrontera's lead product Ameluz® for the photodynamic therapy (PDT) of actinic keratosis, a skin cancer precursor. The J-code, which will become effective on January 2, 2018, provides reimbursement coding clarity for physicians prescribing Ameluz® in the United States. Ameluz® is classified by CMS as buy-and-bill drug, such that reimbursement through CMS requires prior purchase of the drug by the doctor's office. This forces the office to initially accept the cost, and missing security in reimbursement poses a major problem on the distribution of such a drug. Issuing a specific J-code is therefore elementary for the future commercial success of the drug.

In addition to the assignment of the permanent J-code, CMS announced the revision of current procedural terminology (CPT) codes relating to PDT, of which codes 96567, 96573 and 96574 will be relevant for the treatment of actinic keratoses with PDT. New code 96574 provides the highest remuneration for PDT application since it includes a provision for a debridement procedure of premalignant hyperkeratotic lesion(s). Ameluz® is the only PDT drug available in the U.S. that includes debridement in the label.

"We are pleased with these decisions from CMS, which we believe will drive greater access and adoption of Ameluz® in the U.S. The permanent J-code significantly simplifies the reimbursement process for dermatologists in the U.S., lowering the barrier to entry," commented Prof. Dr. Hermann Lübbert, CEO of Biofrontera. "Additionally, as a result of the revised CPT codes, we expect dermatologists will be more easily reimbursed by payers in the U.S., providing further support for our customers and allowing more patients to benefit from our treatment."

Ameluz® received U.S. FDA approval in May 2016 as a combination topical prescription drug with BF-RhodoLED® lamp for PDT treatment of mild to moderate actinic keratosis (AK) on the face and scalp. During the first year of commercialization in the U.S., Ameluz® achieved $5 million in revenue in the U.S., representing what Biofrontera believes the fastest market uptake of a PDT drug to date.

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About Biofrontera:

Biofrontera AG is a biopharmaceutical company specializing in the development, sale and distribution of dermatological drugs and medical cosmetics. The Leverkusen, Germany-based company, which has approximately 130 employees worldwide, develops and distributes innovative products for the care, protection and treatment of the skin. Biofrontera's combination lead product is topical prescription drug Ameluz® and medical device BF-RhodoLED® for the photodynamic therapy (PDT) treatment of superficial skin cancer and its precursors. Ameluz® has been marketed in the EU since 2012 and in the U.S. since 2016. The Company also markets the Belixos® dermocosmetics series in the EU, which offers specialized care for damaged or diseased skin.

Biofrontera is the first German, founder-led pharmaceutical company to obtain both EU and U.S. approval for a medical drug it has developed itself. The Biofrontera Group was established in 1997 by current CEO, Prof. Dr. Hermann Lübbert, and is listed on the Frankfurt Stock Exchange (Prime Standard).

www.biofrontera.com

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