# Ad hoc release

Ad-hoc Release pursuant to Section 15 of the German Securities Trading Act (Wertpapierhandelsgesetz)

## Biofrontera AG – FDA accepts filing of Ameluz® and BF-RhodoLED® application

Leverkusen, Germany, 11 September 2015 – Biofrontera AG (FSE/AIM:B8F), the biopharmaceutical company focusing on sun-induced skin cancer, has today been informed that the Food and Drug Administration (FDA), the responsible US government agency, has accepted filing of the New Drug Application (NDA) of Biofrontera's anti-skin cancer drug Ameluz® combined with the PDT lamp BF-RhodoLED®. This constitutes the first key step in the approval process of Ameluz® and BF-RhodoLED® in the USA. Successfully passing this stage is a major milestone in the approval process and one of the most important steps in the history of the company. With the positive decision, an FDA Review team is assigned to evaluate the research Biofrontera has performed on the drug's safety and effectiveness as well as the control measures in place to warrant the quality of the products. Within 5-6 months, the FDA will now prepare the mid-term review that will identify any outstanding issues and therefore provide a good indication for the timely approvability of the products.

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