



Biofrontera AG receives FDA-approval of the BF-RhodoLED® XL lamp

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Leverkusen, Germany, Oct. 22, 2021 (GLOBE NEWSWIRE) -- Biofrontera AG (NASDAQ: BFRA; Frankfurt Stock Exchange: B8F) (the "Company"), an international biopharmaceutical company, today announced the approval of the new red-light source for photodynamic therapy (PDT), the BF-RhodoLED® XL, by the U.S. Food and Drug Administration (FDA). In accordance with FDA requirements, the approval was granted as a combination approval with our prescription drug Ameluz®, same as the approval with the predecessor model BF-RhodoLED®.

The new, larger BF-RhodoLED® XL was approved in combination with Ameluz® for the treatment of mild and moderate actinic keratoses on the face and scalp, which corresponds to the current approval of Ameluz®. The new PDT lamp enables the illumination of larger areas, enabling the simultaneous treatment of several actinic keratoses distant from each other.

Ahead of the approval by the FDA, the new lamp was protected by several patent applications, which, due to the specifics of the FDA's combination approval, will also contribute to the protection of the prescription drug Ameluz® in the US-market once the patents are granted.

The treatment parameters of the new BF-RhodoLED® XL, such as light dose, illumination time and wavelength of light are identical to the predecessor model BF-RhodoLED®. In order to meet the FDA's strict requirements for the manufacture of a class III medical device, production of the new lamp has, similar to the older model, been established at the Company's headquarters in Leverkusen. At present, there are no plans to market the new BF-RhodoLED® XL in Europe. The BF-RhodoLED® model will continue to be offered in all our markets.

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Forward-Looking Statements: Certain statements in this press release are forward-looking within the meaning of the Private Securities Litigation Reform Act of 1995 regarding the public offering and the intended use of proceeds from the offering.

These statements may be identified by the use of forward-looking words such as "anticipate," "believe," "forecast," "estimate" and "intend," among others. Such forward-looking statements are based on the currently held beliefs and assumptions of the management of Biofrontera AG, which are expressed in good faith and, in their opinion, reasonable. Forward-looking statements involve known and unknown risks, uncertainties and other factors, which may cause the actual results, financial condition, performance, or achievements of the Company, or industry results, to differ materially from the results, financial condition, performance or achievements expressed or

implied by such forward-looking statements. These risks, uncertainties and other factors are set forth in the annual report on Form 20-F filed with the SEC, including Item 3.D. "Key Information - Risk Factors," and in future reports filed with the SEC. Given these risks, uncertainties and other factors, prospective investors are cautioned not to place undue reliance on these forward-looking statements. The Company does not undertake an obligation to update or revise any forward-looking statement.

Tags

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FDA-approval

BF-RhodoLED®

XL lamp

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Biofrontera AG

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