

FOR IMMEDIATE RELEASE

Sun Pharma Announces FDA Approval of Next Generation BLU-U® Blue Light Photodynamic Therapy Illuminator for Actinic Keratosis

The BLU-U Model 4170E offers a compact, easy-to-use option with the same BLU-U safety and efficacy healthcare professionals have trusted for years.

Mumbai, India, Princeton, NJ and Billerica, MA, May 16, 2025: Sun Pharmaceutical Industries Limited (Reuters: SUN.BO, Bloomberg: SUNP IN, NSE: SUNPHARMA, BSE: 524715) (together with its subsidiaries and/or associates referred as “Sun Pharma”) today announced that the U.S. Food and Drug Administration (FDA) has granted premarket approval application (PMA) approval of the next generation of BLU-U® Blue Light Photodynamic Therapy (PDT) Illuminator which features light emitting diode light (LED) panels as a replacement for the previous model’s fluorescent tubes. The new model (LED BLU-U) in combination with LEVULAN® KERASTICK® (aminolevulinic acid HCl) Topical Solution, 20%, is indicated for the treatment of minimally to moderately thick actinic keratoses (AK) of the face, scalp, or upper extremities.

The new LED BLU-U is approved for the same indications as the previous model but takes up less space in a dermatologist’s office, and has a more flexible five-panel shape, improved LED arrangement, lighter weight, and other updated functions that may increase patient comfort and ease of use.

“We are pleased to receive the FDA’s approval of LED BLU-U and look forward to seeing the positive impact this next generation device will have for those living with actinic keratosis,” said Abhay Gandhi, Sun Pharma North America CEO. “As a company committed to innovation, we are confident that this new LED BLU-U model will provide improved efficiency and reliability while maintaining the safety and efficacy that healthcare professionals and people with AKs have come to trust from Sun Pharma.”

The approval of LED BLU-U was granted under FDA’s Real-Time Review Program, reflecting the robustness of the submission and Sun Pharma’s continued collaboration with the Agency.

The LED BLU-U will be available for delivery in the near future. For details regarding availability, ordering, or implementation, please direct inquiries to your Sun Pharma Specialty Dermatology representative. For more information, healthcare professionals are encouraged to visit www.levulanhcp.com.

About Actinic Keratosis (AK)

AK is a chronic condition that can lead to skin cancer. AKs are rough, dry, and scaly patches on the skin resulting from extended sun exposure. These spots can vary in size from a tiny pinhead to a quarter and are commonly found on sun-exposed areas such as the face, scalp, arms and hands.

About LEVULAN KERASTICK + BLU-U

LEVULAN KERASTICK + BLU-U blue light is the only FDA-approved photodynamic therapy (PDT) that effectively targets and clears actinic keratosis (AK) on the face, scalp, arms and hands. LEVULAN KERASTICK (a topical 20% ALA [aminolevulinic acid] solution) + BLU-U blue light photodynamic therapy (PDT) has earned the trust of dermatologists for more than 20 years, offering a proven safe and effective treatment that can eliminate actinic keratoses (AKs) in one or two in-office visits.

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About Sun Pharmaceutical Industries Limited. (CIN - L24230GJ1993PLC019050)

Sun Pharma is the world's leading specialty generics company with a presence in specialty, generics and consumer healthcare products. It is the largest pharmaceutical company in India and is a leading generic company in the U.S. as well as global emerging markets. Sun Pharma's high-growth global specialty portfolio spans innovative products in dermatology, ophthalmology, and onco-dermatology and accounts for over 18% of company sales. The company's vertically integrated operations deliver high-quality medicines, trusted by physicians and consumers in over 100 countries. Its manufacturing facilities are spread across six continents. Sun Pharma is proud of its multicultural workforce drawn from over 50 nations. For further information, please visit www.sunpharma.com and follow us on [LinkedIn](#) & [X](#) (Formerly Twitter).

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