

Sun Pharma announces availability of UNLOXCYT™ for advanced cutaneous squamous cell carcinoma in US

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Available for the treatment of adults in the US with metastatic cutaneous squamous cell carcinoma



Mumbai-based Sun Pharmaceutical Industries has announced that UNLOXCYT™ (cosibelimab-ipdl) is now available in the US for healthcare professionals to prescribe for adults with metastatic cutaneous squamous cell carcinoma (mCSCC) or locally advanced CSCC (laCSCC) who are not candidates for curative surgery or curative radiation.

"Patients with unresectable or metastatic CSCC now have a new and important treatment option to manage their disease. UNLOXCYT is a novel anti-PD-L1 antibody that is capable of antibody-dependent cellular cytotoxicity and associated with clinically meaningful efficacy, as shown by a disease control rate of 71%," said Ann W. Silk, MD, MS, medical oncologist at Dana-Farber Cancer Institute and Assistant Professor of Medicine at Harvard Medical School. "Because these patients tend to be older and have multiple comorbidities, it's extremely valuable to have a therapy that offers durable disease control and proven tolerability."

"UNLOXCYT is an evolution in checkpoint inhibition, combining durable efficacy with a proven tolerability profile for a group of aCSCC patients who traditionally would struggle to strike that therapeutic balance," said Richard Ascroft, CEO of Sun Pharma North America.

The US Food and Drug Administration (FDA) recently approved an updated label for UNLOXCYT to reflect long-term follow-up data from the pivotal CK-301-101 clinical trial. This study showed improvements in objective response rates (including more patients who achieved a complete response [CR]) and duration of response. The safety data did not change from the original UNLOXCYT label.

UNLOXCYT is available through a limited distribution network of authorised specialty distributors and one contracted specialty pharmacy.

Cutaneous squamous cell carcinoma is among the most common skin cancers worldwide. While early stages are treatable,

an estimated 40,000 US patients each year progress to advanced disease, resulting in nearly 15,000 deaths.