# Sun Pharma gets FDA nod for Unloxcyt label expansion

Label expansion has been granted based on the results of long-term follow-up data from the CK-301-101 trial where the therapy demonstrated rapid response and, 14 per cent of mCSCC patients and 32 per cent of laCSCC patients reported progression-free survival.


Mumbai: Indian pharma major Sun Pharmaceuticals announced that US Food and Drug Administration (FDA) has approved an updated label for its onco-derma therapy Unloxcyt label (cosibelimab-ipdl).

The approval Unloxcyt indication to adults with metastatic CSCC (mCSCC) or locally advanced CSCC (laCSCC) who are not candidates for curative surgery or curative radiation

Label expansion has been granted based on the results of long-term follow-up data from the CK-301-101 trial, involving 109 patients (31 with laCSCC; 78 with mCSCC).

Under the clinical program Unloxcyt demonstrated rapid response and, 14 per cent of mCSCC patients and 32 per cent of laCSCC patients reported progression-free survival.

At the time of the follow-up analysis, the median duration of response had not been reached in either group and median time to response was 1.9 months and 3.6 months, respectively.

"The longer-term results confirm that Unloxcyt represents an advancement in the available treatment options for people living with aCSCC and we support, these pivotal data highlight that more patients responded and maintained their responses to UNLOXCYT for longer than observed in the primary analysis" said Richard Ascroft, CEO, Sun Pharma North America.

Sun Pharma had onboarded Unloxcyt under its acquisition of Checkpoint Therapeutics in March this year.

**News Source:**

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