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Sun Pharma's NDA for OTX-101 accepted by USFDA

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Sun Pharmaceutical Industries announced that the US FDA has accepted a new drug application (NDA) filed by its US based wholly owned subsidiary for OTX-101 (cyclosporine A, ophthalmic solution) 0.09%

It is a novel nanomicellar formulation of cyclosporine A 0.09% in a clear, preservative-free aqueous solution.

OTX-101 is now under review for approval by the US FDA and can be an important developmental milestone for Sun Pharma's dry eye candidate.

Previously, in a completed phase 2b/3 clinical trial in 455 patients, OTX-101 demonstrated a rapid onset of action and was well tolerated by the study population. Based on published data, the efficacy and safety endpoints in these trials compared favorably to other formulations of cyclosporine A with the advantage of faster onset.

Dilip Shanghvi, managing director, Sun Pharma, said: "Dry eye disease is a complex, chronic condition that affects patient quality of life, often significantly. OTX-101, a novel formulation of cyclosporine, will allow us to participate in the rapidly growing underserved and dynamic dry eye market. When approved, it will be a milestone for millions of dry eye patients across the globe that are yet to find relief for their condition."

Commenting on the development Abhay Gandhi, CEO - North America Business, Sun Pharma, said, "We are excited about the acceptance of this filing by the US FDA. In January 2017, we had announced positive topline results of confirmatory phase-3 clinical trial for OTX-101, demonstrating both efficacy and faster onset of action in a trial environment."

“The 12 week trial saw 744 dry eye patients being treated either with OTX-101, or its vehicle. Compared to the vehicle, OTX-101 showed statistically significant improvement in the primary end point in the trial. The demonstration of efficacy of OTX-101 was earlier than other drugs approved for dry eye in the same class1. We hope to bring OTX-101 to patients in the United States as soon as possible, and look forward to working closely with the US FDA over the coming months”, he added.