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ASIA EDITION

FDA approves Sun Pharma's ILUMYA for treating plaque psoriasis

22 March 2018 | News

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Singapore – Sun Pharmaceutical Industries Ltd., announced that the U.S. Food and Drug Administration (FDA) has approved ILUMYA (tildrakizumab-asmn) for the treatment of adults with moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy. ILUMYA selectively binds to the p19 subunit of IL-23 and inhibits its interaction with the IL-23 receptor leading to inhibition of the release of pro-inflammatory cytokines and chemokines. ILUMYA is administered at a dose of 100 mg by subcutaneous injection every 12 weeks, after the completion of initial doses at weeks 0 and 4. ILUMYA is contraindicated in patients with a previous serious hypersensitivity reaction to tildrakizumab or to any of the excipients.

"With the approval of ILUMYA and our long-standing commitment in dermatology, we are focused on making a difference for people living with moderate-to-severe plaque psoriasis," said Abhay Gandhi, President and Chief Executive Officer, North America, Sun Pharma. "We are committed to working with all relevant stakeholders to make ILUMYA available to appropriate people with plaque psoriasis."

The FDA approval of ILUMYA for the treatment of adults with moderate-to-severe plaque psoriasis was supported by data from the pivotal Phase-3 reSURFACE clinical development program. In the two multicenter, randomized, double-blind, placebo-controlled trials (reSURFACE 1 and reSURFACE 2), 926 adult patients were treated with ILUMYA (N=616) or placebo (N=310).