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Sun Pharma announces US FDA filing acceptance of BLA for Tildrakizumab

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Sun Pharmaceutical Industries announced the U.S. Food and Drug Administration (FDA) acceptance of the Biologics License Application (BLA) for tildrakizumab. The FDA filing acceptance follows the acceptance of the regulatory filing of tildrakizumab by the European Medicines Agency (EMA) in March 2017. Tildrakizumab is an investigational IL-23p19 inhibitor being evaluated for the treatment of moderate-to-severe plaque psoriasis. The BLA filing for tildrakizumab was submitted by Merck & Co., Inc., Kenilworth, NJ, USA.

According to Abhay Gandhi, CEO - North America Business, Sun Pharma, “At Sun Dermatology, we are committed to making a difference in the lives of patients and healthcare providers. The acceptance of the regulatory filing by the U.S. FDA marks a significant milestone as we seek to advance for tildrakizumab as a potential new treatment option for people who continue to struggle everyday with the chronic nature of psoriasis.”

The BLA filing for tildrakizumab with the U.S. FDA is based on two pivotal Phase III trials (reSURFACE 1 and 2) which included over 1,800 patients across more than 200 clinical trial sites, including some patients who have been treated with tildrakizumab for up to three and a half years. Data from these trials were most recently presented at the 2017 American Academy of Dermatology (AAD) Annual Meeting in March and previously presented at the 25th European Academy of Dermatology and Venereology Congress. Future presentations and publications of the reSURFACE Phase-3 pivotal trials will include more scientific insights on the data to week 52 and beyond. The clinical trials are designed to evaluate safety and efficacy for up to five years, and to date, some clinical trial participants have been treated with tildrakizumab for up to three and half years.