

Initial REMS Approval: 09/25/2009
Most Recent Modification: 09/2013

BLA 125261 STELARA[®] (ustekinumab)
Human interleukin 12 and 23 antagonist

RISK EVALUATION AND MITIGATION STRATEGY (REMS)

I. GOALS

To evaluate and mitigate the potential risks of serious infections and malignancy, and reversible posterior leukoencephalopathy syndrome (RPLS) associated with STELARA[®] by:

- alerting and warning healthcare providers about the risks

II. REMS ELEMENTS

A. COMMUNICATION PLAN

Janssen Biotech, Inc. will implement a communication plan to the following healthcare providers:

- Dermatologists, rheumatologists, and dermatology healthcare providers (HCPs) who are likely to prescribe and/or inject STELARA[®]
- Oncologists who may treat malignancies potentially associated with the use of immunosuppressants for chronic inflammatory and autoimmune disease and will need to ascertain cases of malignancy after a long latency period
- Rheumatologists who may treat adult patients with active psoriatic arthritis
- Infectious disease specialists and gastroenterologists who may be consulted about infections and will need to understand the potential for infectious complications of IL-12/IL-23 blockade
- Neurologists who may treat RPLS

The communication plan will provide for the dissemination of risk information about serious infection, malignancy, and RPLS.

Elements of the communication plan:

1. A Dear Healthcare Professional letter (see Attachment A) was distributed to dermatologists, oncologists, rheumatologists, infectious disease specialists, gastroenterologists, and neurologists within 60 days of STELARA[®] initial approval; and a Dear Healthcare Professional letter (see Attachment B) will be distributed to rheumatologists within 60 days of STELARA[®] Psoriatic Arthritis approval.
2. A Dear Pharmacist letter (see Attachment C) was distributed to pharmacists within 60 days of STELARA[®] initial approval.
3. Dissemination of information about serious infection, malignancy, and RPLS to health care providers through certain dermatology, oncology, rheumatology, infectious diseases, and gastroenterology professional societies' journals:
 - a. For display as a panel/poster and distribution as printed material at all dermatology and oncology scientific meetings where the company has a sponsored booth
 - b. For quarterly presentation as a printed information piece in the *Journal of the American Academy of Dermatology* and the *Archives of Dermatology* for 3 years from initial approval
 - c. For quarterly presentation as a printed information piece in the *Journal of Clinical Oncology* and *Blood* for 5 years from initial approval
 - d. For twice yearly presentation as a printed information piece in *Arthritis and Rheumatism*, the *Journal of Infectious Disease*, the *American Journal of Gastroenterology*, and *Gastroenterology* for 3 years from initial approval

The REMS Journal Information Piece is appended to this document (see Attachments D, E, F, G, and H).
4. Janssen Biotech, Inc. will ensure that all materials listed in or appended to the STELARA[®] REMS program will be available through the STELARA[®] REMS program website www.Stelararems.com . This information will remain on the website for a period of 5 years from initial approval.

B. TIMETABLE FOR SUBMISSION OF ASSESSMENTS

Janssen Biotech, Inc. will submit REMS assessments to FDA 18 months, 3 years, and 7 years from the initial date of the approval (September 25, 2009) of the REMS. To facilitate inclusion of as much information as possible while allowing reasonable time to prepare the submission, the reporting interval covered by each assessment should conclude no earlier than 60 days before the submission date for that assessment. Janssen Biotech, Inc. will submit each assessment so that it will be received by the FDA on or before the due date.