

Attachment A Dear Healthcare Professional Letter



Dear Healthcare Professional:

The purpose of this letter is to inform you of important safety information for STELARA[®] (ustekinumab), a human monoclonal antibody which has been approved by the Food and Drug Administration (FDA) for the treatment of adult patients (18 years or older) with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy and, alone or in combination with methotrexate, for the treatment of adult patients with active psoriatic arthritis. STELARA[®] targets interleukin-12 (IL-12) and interleukin-23 (IL-23).

FDA has determined that a Risk Evaluation and Mitigation Strategy (REMS) is necessary for STELARA[®] to ensure that the benefits of the drug outweigh the potential risks of serious infections and malignancy, and reversible posterior leukoencephalopathy syndrome (RPLS).

IMPORTANT SAFETY INFORMATION FOR POTENTIAL RISKS OF SERIOUS INFECTIONS AND MALIGNANCIES, AND RPLS

The following information is important for healthcare professionals and patients treated with STELARA[®]:

Infections

- STELARA[®] may increase the risk of infections and reactivation of latent infections. Serious bacterial, fungal, and viral infections, some requiring hospitalization, were observed in patients receiving STELARA[®]. STELARA[®] should not be given to patients with a clinically important active infection and should not be administered until the infection resolves or is adequately treated. Instruct patients to seek medical advice if signs or symptoms suggestive of an infection occur. Exercise caution when considering use of STELARA[®] in patients with a chronic infection or a history of recurrent infection.

Theoretical Risk for Vulnerability to Particular Infections

- Individuals genetically deficient in IL-12/IL-23 are particularly vulnerable to disseminated infections from mycobacteria, salmonella, and *Bacillus*

Calmette-Guerin (BCG) vaccinations. Serious infections and fatal outcomes have been reported in such patients.

- It is not known whether patients with pharmacologic blockade of IL-12/IL-23 from treatment with STELARA[®] will be susceptible to these types of infections. Appropriate diagnostic testing should be considered as dictated by clinical circumstances.

Pre-Treatment Evaluation of Tuberculosis (TB)

- Evaluate patients for TB infection prior to initiating treatment with STELARA[®]. Do not administer STELARA[®] to patients with active TB. Initiate treatment of latent TB before administering STELARA[®].
- Consider anti-tuberculosis therapy prior to initiation of STELARA[®] in patients with a past history of latent or active tuberculosis in whom an adequate course of treatment cannot be confirmed.
- Patients receiving STELARA[®] should be monitored closely for signs and symptoms of active TB during and after treatment.

Malignancies

- STELARA[®] (ustekinumab) is an immunosuppressant and may increase the risk of malignancy. Malignancies were reported among subjects who received STELARA[®] in clinical studies.
- The safety of STELARA[®] has not been evaluated in patients who have a history of malignancy or who have a known malignancy.

Reversible Posterior Leukoencephalopathy Syndrome (RPLS)

- One case of RPLS has been reported in a STELARA[®]-treated subject.
- RPLS is a neurological disorder, which is not caused by demyelination or a known infectious agent. RPLS can present with headache, seizures, confusion and visual disturbances. It has been associated with preeclampsia, eclampsia, acute hypertension, cytotoxic agents and immunosuppressive therapy.
- If RPLS is suspected, discontinue STELARA[®] and administer appropriate treatment.

Reporting Patient Adverse Events

It is important that you report all serious adverse events that occur in patients using STELARA[®]. If you have a patient who develops a serious infection or RPLS while being treated with STELARA[®], or if you have a patient with cancer at any time after receiving STELARA[®] therapy, it is important that you report the case even if you do not think there is a causal relationship.

The information that you can provide may inform therapy and monitoring decisions for psoriasis patients.

Reporting is easy and maintains patient confidentiality. Your patient's name or contact information is not needed. *HIPAA does not apply* to this adverse event reporting.

You can report your cases to the STELARA[®] manufacturer or directly to FDA.

- Janssen Biotech, Inc. at 1-800-526-7736
- MedWatch (FDA safety information and adverse event reporting program) at 1-800-332-1088 or online at www.fda.gov/medwatch/report.htm

VOLUNTARY REGISTRY INFORMATION

PSOLAR (PSOoriasis Longitudinal Assessment and Registry) is a Janssen Biotech, Inc. -sponsored voluntary psoriasis registry that will be available to enroll patients treated with STELARA[®]. Please call 1-888 PSOLAR-5 or go to www.clinicaltrials.gov for more information.

Please see the enclosed:

- STELARA[®] package insert, and
- Medication Guide

Please Note: This letter does not include a comprehensive description of the serious and significant risks associated with the use of STELARA[®]. Please read the accompanying Full Prescribing Information and Medication Guide for a complete description of the serious and significant risk that may be associated with the use of STELARA[®]. You are advised to discuss the risks that may be associated with STELARA[®] therapy with patients and their caregivers. We have enclosed a copy of the STELARA[®] Medication Guide, which is required to be provided to patients with every filled prescription. This Medication Guide contains information that can be used to facilitate discussions about the potential risks of therapy.

Sincerely,

Peter Callegari, MD
Vice President, Medical Affairs

Enclosures