STELARA® (ustekinumab) is a human monoclonal antibody that is indicated for the following:

- treatment of adult patients (18 years or older) with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy
- treatment of adult patients with active psoriatic arthritis (alone or in combination with methotrexate).

STELARA® targets interleukin-12 (IL-12) and interleukin-23 (IL-23). Based on data from rodent models and humans genetically deficient for components of IL-12 and IL-23 pathways, there is a theoretical concern that blockade of IL-12 and IL-23 may increase the risk for serious infections, including mycobacterial and recurrent salmonella infections. In addition, data from rodent models suggest there is a theoretical concern that blockade of IL-12 and IL-23 may increase the risk for malignancies.

One case of Reversible Posterior Leukoencephalopathy Syndrome (RPLS) has been reported in a STELARA®-treated patient in clinical trials. RPLS is a neurological disorder which is not caused by demyelination or a known infectious agent, and can present with headache, seizures, confusion and visual disturbances.

If you have a patient that 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, as a rheumatologist that may co-manage patients receiving STELARA® therapy, 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