An observational study of approximately 12,000 patients with plaque psoriasis:
- Part of a postmarketing commitment to fulfill regulatory requirements for Janssen biologics with indications in plaque psoriasis.

- **Population targets:**
  - 4,000 patients exposed to STELARA®.
  - 8,000 patients exposed to other biologic or non-biologic therapies.

- **Inclusion criteria:**
  - Adults aged 18 years and older.
  - Patients with psoriasis who are candidates for or who are currently receiving conventional systemic agents or biologic therapy.

- **Enrollment** began in June 2007.
  - Last patient enrolled in June 2013.
  - Over 12,000 patients enrolled.
  - Each patient evaluated for 8 years.
  - Anticipated study completion date: May 2021.

- **Data collection:**
  - Patient information collected at the enrollment visit and about every 6 months thereafter.
  - At enrollment, information on demographics, medical history and family medical history, status of psoriasis, and past and current psoriasis treatments is collected.
  - At follow-up visits, information on clinical disease status, current medications, and adverse events is collected.

- **References:**
STELARA® (ustekinumab) is indicated for the treatment of adult patients with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy.

IMPORTANT SAFETY INFORMATION

Infections
STELARA® may increase the risk of infections and reactivation of latent infections. Serious bacterial, fungal, and viral infections, some requiring hospitalization, were reported. In patients with psoriasis, serious infections included diverticulitis, cellulitis, pneumonia, appendicitis, cholangitis, sepsis, angioedema, and meningitis. In patients with psoriatic arthritis, serious infections included cellulitis, pneumonia, appendicitis, cholangitis, sepsis, and tuberculosis. Treatment with STELARA® should be initiated in patients with a clearly defined infection unless a superior alternative is adequately tested. Consider the risks and benefits of treatment prior to initiating use of STELARA® in patients with a chronic infection or history of recurrent infection.

Instruct patients to seek medical advice if signs or symptoms suggestive of an infection occur while in treatment with STELARA® and consider discontinuing STELARA® for serious or clinically significant infections until the infection resolves or is adequately treated.

Therapeutic Risk for Vulnerable to Particular Infections
Infections generally inadvertent in ≤1.0%, 1.1% to ≥10%, ≥10% to ≤1%, ≥1%, ≥1% to ≤1%, ≥1%, and ≥1%. Infections were self-limiting or severe in nature in some. STELARA® is an immunosuppressant and may increase the risk of infection. Malignancies were reported among patients who received STELARA® in clinical trials. The safety of STELARA® has not been established in patients who have a history of malignancy or who have had a malignancy.

There have been reports of the rapid appearance of multiple cutaneous squamous cell carcinomas in patients receiving STELARA® who had a risk factors for developing new malignancy cancer (SMC). All patients receiving STELARA® especially those with a history of one or a history of psoriasis or a history of psoriasis who are candidates for or who are currently receiving systemic therapy or biologic agents.

Study enrollment overview
– Patients with psoriasis who are candidates for or who are currently receiving conventional systemic therapy or biologic agents.
– Adults aged 18 years and older.

Study design and outcomes
– Randomized, double-blind, placebo-controlled, multicenter study.
– Two dosage levels are 90 mg or 45 mg every 8 weeks. The starting dose was 90 mg every 8 weeks.
– The study duration was 8 years.

The most common adverse reactions (≥3% and higher than that with placebo) in psoriasis clinical trials for STELARA® 45 mg, STELARA® 90 mg, or placebo were: nasopharyngitis (9%, 7%, 8%), upper respiratory tract infection (5%, 4%, 5%), headache (5%, 5%, 3%), and fatigue (5%, 3%, 2%) respectively. In psoriatic arthritis studies, a higher incidence of arthralgia and nausea was observed in patients treated with STELARA® both). In Crohn’s disease induction studies, common adverse reactions (3% or more of patients treated with STELARA® were: nasopharyngitis (13%, 11% vs 8%), injection site erythema (5% vs 0%), vulvovaginal candidiasis/mycotic infection (5% vs 1%), bronchitis (5% vs 3%), pruritus (4% vs 2%), upper respiratory tract infection (4% vs 2%) and sinusitis (3% vs 2%).

Most Common Adverse Reactions

Reversible Posterior Leukoencephalopathy Syndrome (RPLS)
RPLS was observed in clinical trials of psoriasis and psoriatic arthritis. No cases of RPLS were observed in clinical trials of Crohn’s disease. If RPLS is suspected, administer appropriate treatment and discontinue STELARA®. RPLS is a neurological disorder, which is not caused by an infection or demyelination. RPLS can present with headache, seizures, confusion, and visual disturbances. RPLS has been associated with an immunosuppressant therapy.

Concomitant Therapies

The safety of STELARA® in combination with other immunosuppressive agents or phototherapy was not evaluated in clinical trials of psoriasis. Ultrapotent-potential calcineurin inhibitors, biologic agents, and topical corticosteroids were used frequently, with no apparent increased risk of infection. Frequency of severe infections was similar among all treat groups in the psoriasis studies. Common adverse reactions of non-live vaccines were more frequent in STELARA® patients, as shedding and subsequent transmission to STELARA® patients may occur. Live-activated vaccines were not administered in a course of STELARA® may not achieve an immunogenic response to prevent infections.

Individuals genetically deficient in IL-12/IL-23 are particularly vulnerable to disseminated infections from mycobacteria, especially in association with immunotherapy. Therefore, caution should be exercised in patients receiving or who have received allergen immunotherapy, particularly for anaphylaxis.

Hypersensitivity Reactions

STELARA® in patients with psoriasis who are clinically significant hyperhidrosis to卫 determined or consistent. Hypersensitivity reactions, including anaphylaxis, and anaphylactic shock, have been reported with STELARA®. If an anaphylactic or other clinically significant hypersensitivity reaction occurs, institute appropriate therapy and discontinue STELARA®.

Providing the Medication Guide to your patients and encouraging discussion.

If you have any questions, please call 1-888-287-2333.