STELARA® (ustekinumab) Data on Initial Nonresponders From Phase 3 Clinical Trial Program in Crohn's Disease

Clinical Trial Background:

Based on data from the STELARA® Phase 3 clinical program in adults with moderately to severely active Crohn's disease, some patients who received an intravenous infusion dose of STELARA® (approximately 6 mg/kg) did not demonstrate a clinical response at 8 weeks post induction dose. These patients were not included in the primary efficacy analyses but were eligible to receive a 90-mg subcutaneous injection of STELARA® upon entry into the maintenance trial (8 weeks post induction dose). Of these initial nonresponders, 47% (102/219) demonstrated a clinical response 8 weeks later (16 weeks post induction) as described in the STELARA® Prescribing Information.[1]

These results may support a potential benefit to patients who do not demonstrate a clinical response at 8 weeks post induction through subcutaneous maintenance therapy with STELARA® 90 mg every 8 weeks post induction.

Please see the STELARA® Prescribing Information for additional information.

References:

1. STELARA® (ustekinumab) [Prescribing Information]. Horsham, PA: Janssen Biotech, Inc.

