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A Study to Evaluate the Efficacy and Safety of Ustekinumab in the Treatment of Anti-TNF(Alpha) Refractory Participants With Active Radiographic Axial Spondyloarthritis

Sponsor: Janssen Research & Development, LLC **ClinicalTrials.gov Identifier:**NCT02438787
Protocol # CNTO1275AKS3002

Official Title	A Phase 3, Multicenter, Randomized, Double-blind, Placebo-controlled Study Evaluating the Efficacy and Safety of Ustekinumab in the Treatment of Anti-TNF(Alpha) Refractory Subjects With Active Radiographic Axial Spondyloarthritis
Brief Summary	The purpose of this study is to assess the efficacy of ustekinumab, in adult anti-TNF(alpha) refractory participants with active radiographic axial spondyloarthritis (AxSpA), as measured by the reduction in signs and symptoms of radiographic AxSpA.
Detailed Description	This is a Phase 3, multicenter (when more than one hospital or medical school team work on a medical research study), randomized (study medication assigned to participants by chance), double-blind (neither the researchers nor the participants know what treatment the participant is receiving), placebo-controlled (an inactive substance; a pretend treatment [with no drug in it] that is compared in a clinical trial with a drug to test if the drug has a real effect) study. The study consists of 3 phases; Screening (up to 8 weeks), Treatment phase: placebo-controlled (Week 0 to 24) and active treatment (Week 24 to Week 52), and Safety Follow-up (up to 12 weeks). Participants will be randomly assigned to 1 of 3 treatment groups: placebo, ustekinumab 45 mg and ustekinumab 90 mg. The total duration of study will be up to 64 weeks. Participants will be primarily assessed for Assessment of SpondyloArthritis International Society (ASAS) 40 response at Week 24. Participants' safety will be monitored throughout the trial.
Condition	Axial Spondyloarthritis
Intervention	• Drug: Placebo - Placebo subcutaneous (SC) injection at Weeks 0, 4, and 16 in Group 1. • Drug: Ustekinumab 45 mg - Ustekinumab 45 mg SC injection at Weeks 24 and 28 followed by every 12 weeks (q12w) dosing, with the last administration of study agent at Week 52 in Group 1. Participants will start with ustekinumab 45 mg SC injection at Weeks 0 and 4, followed by q12w dosing, with the last administration of study agent at Week 52 in Group 2. • Drug: Ustekinumab 90 mg - Ustekinumab 90 mg SC injection at Weeks 24 and 28 followed by q12w dosing, with the last administration of study agent at Week 52 in Group 1. Participants will start with ustekinumab 90 mg SC injection at Weeks 0 and 4, followed by q12w dosing, with the last administration of study agent at Week 52 in Group 3. • Drug: Golimumab 50 mg - Participants who meet EE criteria (less than [<] 10 percent [%] improvement from baseline in both total back pain and morning stiffness measures at both Week 12 and Week 16) will be administered open-

	label golimumab 50 mg SC administrations at Week 16 and every 4 weeks (q4w) thereafter through Week 52 in Group 1, 2 and 3.

Gender	**Both**
Ages	**18 Years and older**
Eligibility Criteria	**Inclusion Criteria:** Participants must have a diagnosis of definite ankylosing spondylitis (AS), as defined by the modified 1984 New York criteria. The radiographic criterion must be confirmed by a central xray reader and at least 1 clinical criterion must be met Participants must have symptoms of active disease at screening and at baseline, as evidenced by both a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score of greater than or equal to (>=4) and a visual analog scale (VAS) score for total back pain of >=4, each on a scale of 0 to 10 Participants with elevated high sensitivity C-reactive protein (hsCRP) level of >=0.300 milligram per deciliter (mg/dL) at screening Refractory by either lack of benefit or documented intolerance to 1 and no more than 1 anti-TNF(alpha) agent Inadequate response to at least 2 nonsteroidal anti-inflammatory drugs (NSAIDs) over a 4-week period in total with maximal doses of NSAID(s), or is unable to receive a full 4 weeks of maximal NSAID therapy because of intolerance, toxicity, or contraindications to NSAIDs. Participants with complete ankylosis of the spine are permitted to be included in the study, but will be limited to approximately 10 percent (%) of the study population **Exclusion Criteria:** Participants who have other inflammatory diseases that might confound the evaluations of benefit from the ustekinumab therapy, including but not limited to, rheumatoid arthritis, systemic lupus erythematosus, or Lyme disease Participants who have received infliximab or infliximab biosimilar, within 12 weeks of the first study agent administration; have received adalimumab, adalimumab biosimilar, or certolizumab pegol within 6 weeks of the first study agent administration; have received etanercept or etanercept biosimilar within 6 weeks of the first study agent administration Participants who have ever received golimumab Participants who are pregnant, nursing, or planning a pregnancy or fathering a child while enrolled in the study or within 5 months after receiving the last administration of study agent Participants who have received any systemic immunosuppressives or disease-modifying antirheumatic drugs (DMARDs) other than methotrexate (MTX), sulfasalazine (SSZ), or hydroxychloroquine (HCQ) within 4 weeks prior to first administration of study agent. Medications in these categories include, but are not limited to leflunomide, chloroquine, azathioprine, cyclosporine, mycophenolate mofetil, gold, and penicillamine