Appendix B.

Inclusion Criteria

Patients had to meet all of the following criteria to be enrolled in this study:

1. Patient was male or female aged 18 to 75 years old, inclusive.
2. Patient had a diagnosis of AS according to the 1984 modified New York classification criteria [van der Lindenet al 1984] for at least 3 months prior to Screening.
3. Patients had active disease as defined by a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score of ≥4 (range 0 to 10) at Screening in spite of following conventional treatment for AS for at least 3 months prior to Screening.
4. Patients had a visual analogue scale (VAS) score for spinal pain of ≥4 (range 0 to 10).
5. Both male and female patients and their partners of childbearing potential who had agreed to use 2 medically accepted methods of contraception (eg, barrier contraceptives [male condom, female condom, or diaphragm with a spermicidal gel], hormonal contraceptives [implants, injectables, combination oral contraceptives, transdermal patches, or contraceptive rings], and intrauterine devices) during the course of the study and for 6 months following discontinuation of study treatments (excluding women who were not of childbearing potential and men who had been sterilized).
6. Male or female patients and their partners who had been surgically sterilized for less than 6 months prior to study entry had agreed to use 2 medically accepted methods of contraception as per inclusion criterion 5.
7. Menopausal females had to have experienced their last period more than 12 months prior to study entry to be classified as not of childbearing potential.
8. Patients had adequate renal and hepatic function at Screening as defined by the following clinical chemistry results:
    - Serum creatinine <1.7 × upper limit of normal (ULN) or an estimated creatinine clearance level >75 mL/min
    - Serum alanine aminotransferase (ALT) <2 × ULN
    - Serum aspartate aminotransferase (AST) <2 × ULN
9. Patients had the following hematology laboratory test results at Screening:
    - Hemoglobin ≥8.0 g/dL
    - White blood cell count ≥3.5 × 10^3/μL (SI [Système International d'Unités] units: ≥3.5 × 10^9 /L)
    - Neutrophil count ≥1.5 × 10^3/μL (SI units: ≥1.5 × 10^9/L)
    - Platelet count ≥100 × 10^3/μL (SI units: ≥100 × 10^9/L)

10. Patients were permitted to receive both oral glucocorticoids equivalent to ≤10 mg daily prednisolone and nonsteroidal anti-inflammatory drugs, if they had received a stable dose for at least 4 weeks prior to Screening. In addition, patients were permitted to receive low-potency topical, otic, and ophthalmic glucocorticoid preparations provided the preparations were administered per the instructions on the product label.
11. Patients had the ability to comprehend the full nature and purpose of the study, including possible risks and side effects, to cooperate with the investigator, to understand verbal and written instructions, and to comply with the requirements of the entire study.
12. Patient (or legal guardian, if applicable) was informed of the full nature and purpose of the study, including possible risks and side effects, and given ample time and opportunity to read and understand this information, signed and dated the written informed consent before inclusion in the study.

Exclusion Criteria

Patients meeting any of the following criteria were excluded from the study:

1. Patients had previously been administered a biological agent for the treatment of AS.
2. Patients had total ankylosis of the spine, as defined by syndesmophytes present on the lateral views of spinal radiographs (cervical, thoracic, and lumbar) at all intervertebral levels from T6 to S1 within 3 months before Screening.
3. Patients had allergies to any of the excipients of infliximab or to any other murine and human proteins, and patients with a hypersensitivity to immunoglobulin product.
4. Patients had a current or past history of chronic infection with hepatitis B, hepatitis C, or infection with human immunodeficiency virus (HIV)-1 or -2 or had a positive result to the screening test for those infections.
5. Patients had a current diagnosis of TB or other severe or chronic infection (such as sepsis, abscess or opportunistic infections, or invasive fungal infection such as histoplasmosis) or a past diagnosis without sufficient documentation of complete resolution following treatment.
6. Patients had recent exposure to persons with active TB, or had a positive result to the screening test for latent TB defined as a positive result of interferon-γ release assay with negative examination of chest x-ray, and had not received at least the first 30 days of country-specific TB therapy and did not intend to complete the entire course of that therapy. Patients with an abnormal chest x-ray were discussed with the medical monitor before randomization.

7. Patients had an infection requiring oral antibiotics in the 2 weeks before Screening, parenteral injection of antibiotics in the 4 weeks before Screening, or other serious infection in the 6 months before Screening, or who had a history of recurrent herpes zoster or other chronic or recurrent infection.
8. Patients had a current or past history of drug or alcohol abuse.
9. Patients had a medical condition including one or more of the following:
    - Classified as obese
    - Bone marrow hypoplasia
    - Diabetes mellitus, unless on a stable dosing regimen for at least 4 weeks prior to Screening
    - Hypertension at Screening
    - Any other inflammatory or rheumatic diseases, including but not limited to psoriatic arthritis, RA, spondyloarthritis, systemic lupus erythematosus, Lyme disease, or fibromyalgia, that could confound the evaluation of the effect of study treatment
    - History of any malignancy within the previous 5 years except completely excised and cured squamous carcinoma of the uterine cervix, cutaneous basal cell carcinoma, or cutaneous squamous cell carcinoma
    - History of lymphoma or lymphoproliferative disease
    - History of congestive heart failure (New York Heart Association class III/IV) or unstable angina
    - History of organ transplantation
    - History of severe hypersensitivity
    - Severe physical incapacitation (unable to perform routine self-care, has RA American College of Rheumatology functional status class 4 [Arnett et al 1988], or who could not benefit from medication)
    - Any clinically significant respiratory disease, including but not limited to chronic obstructive pulmonary disease, asthma, bronchiectasis, or pleural effusion.
    - Previous diagnosis or symptoms suggestive of demyelinating disorders, including multiple sclerosis and Guillain-Barré syndrome
    - Any conditions significantly affecting the nervous system (ie, neuropathic conditions or nervous system damage) if it might interfere with the investigator's assessment on disease activity scores
    - Any other serious acute or chronic medical or psychiatric condition that might increase the risk associated with study participation or investigational product administration and that might interfere with the interpretation of study results
10. Patients taking any of the following concomitant medications:

- Corticosteroids, except oral glucocorticoids, of maximum equivalent daily dose of 10 mg of prednisolone within 4 weeks prior to Screening. (Patients were permitted to receive low-potency topical, otic, and ophthalmic glucocorticoid preparations provided the preparations were administered per the instructions on the product label.)
- Disease-modifying antirheumatic drugs (DMARDs), including hydroxychloroquine, chloroquine, sulfasalazine, or methotrexate, within 4 weeks prior to Screening. Patients who discontinued leflunomide and had successful chelation with 8 g of cholestyramine (3 times daily) for 11 days had to wait 4 weeks prior to Screening. Patients who discontinued leflunomide and did not have cholestyramine washout had to wait 12 weeks after last dose of leflunomide before Screening
- Alkylating agents within 12 months prior to Screening
- Live or live-attenuated vaccine within 8 weeks of Screening
- Any biological agents for the treatment of AS

11. Patients had participated in a study with an investigational drug within 6 months of Screening or who were currently receiving treatment with any other investigational drug or device.
12. Female patients who were currently pregnant or breastfeeding, or were planning to become pregnant or breastfeed within 6 months of the last dose of CT-P13 or Remicade reference product.
13. Patients had received a live or live-attenuated vaccination within 8 weeks of Screening or were scheduled to receive a live or live-attenuated vaccination. Killed vaccines were acceptable during the study.
14. Patients who, in the opinion of their general practitioner or the investigator, should not participate in the study.