ForPatients
by Roche

Autoimmune DisorderGiant Cell Arteritis

An Extension Study to Evaluate Long-Term Safety of Subcutaneous (SC) Tocilizumab in Participants With Giant Cell Arteritis (GCA)

Trial Status	Trial Runs In	Trial Identifier
Completed	1 Country	NCT03202368 2016-002716-41 ML39425

The information is taken directly from public registry websites such as ClinicalTrials.gov, EuClinicalTrials.eu, ISRCTN.com, etc., and has not been edited.

Official Title:

An Extension Study to Evaluate Long Term Safety of Subcutaneous Tocilizumab in Patients With Giant Cell Arteritis Who Have Completed WA28119 Core Study in France, and Subsequently Having Flare or Persisting Disease Activity.

Trial Summary:

This is a multicenter, interventional, open-label, long-term extension study of Study WA28119 (NCT01791153) to evaluate the long-term safety of SC tocilizumab in participants with GCA who subsequently have flare or persisting disease activity. A maximum of 11 participants from six centers in France that participated in the WA28119 study will be enrolled. The entire study duration is anticipated to be approximately 160 weeks.

Hoffmann-La Roche	Phase 3
Sponsor	Phase

NCT03202368 2016-002716-41 ML39425
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	# 50 Years	No

Inclusion Criteria:

- Participants who completed the 156-week WA28119 core study in France

- Participants who experienced at any time during the WA28119 core study a clinical improvement based on the Investigator's judgment and may continue to benefit from SC tocilizumab in this study
- Participants whom the investigator wants to treat with SC tocilizumab due to persistent active GCA at the time of completion of the 156-week WA28119 core study and/or new flare occurring within 3 years after completion of the 156-week WA28119 core study

Exclusion Criteria:

- Participants who have prematurely withdrawn from the WA28119 core study for any reason
- Participants who had major surgery within 8 weeks prior to screening or planned major surgery within the next 12 months
- Major ischemic event, unrelated to GCA, within 12 weeks of inclusion
- Transplanted organs (except corneal transplant performed more than 3 months prior to inclusion)
- History of severe allergic or anaphylactic reactions to human, humanized, or murine monoclonal antibodies or to prednisone
- Evidence of serious uncontrolled concomitant cardiovascular, nervous system, pulmonary (including obstructive pulmonary disease), renal, hepatic, endocrine (including uncontrolled diabetes mellitus), psychiatric, osteoporosis/osteomalacia, glaucoma, corneal ulcers/injuries, or gastrointestinal (GI) disease
- Current liver disease, as determined by the investigator (positive hepatitis B surface antigen or hepatitis C antibody)
- History of diverticulitis, diverticulosis requiring antibiotic treatment, or chronic ulcerative lower GI disease such as Crohn's disease, ulcerative colitis, or other symptomatic lower GI conditions that might predispose a participant to perforations
- Known active current or history of recurrent bacterial, viral, fungal, mycobacterial, or other infections (including but not limited to tuberculosis [TB] and atypical mycobacterial disease, hepatitis B and C, and herpes zoster, but excluding fungal infections of the nail beds)
- Any major episode of infection requiring hospitalization or treatment with intravenous (IV) antibiotics within 4 weeks of inclusion or oral antibiotics within 2 weeks of inclusion
- Active TB requiring treatment within the previous 3 years
- Primary or secondary immunodeficiency (history of or currently active)
- Evidence of malignant disease or malignancies diagnosed since last WA28119 study visit (except basal and squamous cell carcinoma of the skin or carcinoma in situ of the cervix uteri that have been excised and cured)
- Female participants of childbearing potential and female participants who are breastfeeding
- Male participants of reproductive potential who are not willing to use an effective method of contraception, such as condom, sterilization, or true abstinence throughout study and for a minimum of 6 months after study drug therapy
- History of alcohol, drug, or chemical abuse within 1 year prior to inclusion
- Body weight of more than (>) 150 kilograms
- Treatment with any investigational agent within 12 weeks (or five half-lives of the investigational drug, whichever is longer) of inclusion (except tocilizumab)
- Previous treatment with cell-depleting therapies including investigational agents, including but not limited to Campath (alemtuzumab), anti-cluster of differentiation (CD) 4, anti-CD5, anti-CD3, anti-CD19, and anti-CD20
- Treatment with IV gamma globulin or plasmapheresis within 6 months of inclusion
- Previous treatment with alkylating agents such as chlorambucil or with total lymphoid irradiation
- Immunization with a live/attenuated vaccine within less than or equal to (#) 4 weeks prior to inclusion
- Treatment with hydroxychloroquine, cyclosporine A, azathioprine, or mycophenolate mofetil within 4 weeks of inclusion
- Treatment with etanercept within 2 weeks; infliximab, certolizumab, golimumab, abatacept, or adalimumab within 8 weeks; or anakinra within 1 week of inclusion

- Previous treatment with tofacitinib
- Treatment with cyclophosphamide within 6 months of inclusion
- Participants requiring systemic corticosteroids for other conditions other than GCA, which, in the opinion of the Investigator, would interfere with the assessments of the protocol
- Receipt of more than (>) 100 mg daily intravenous methylprednisolone within 6 weeks of inclusion