ForPatients
by Roche

Non Hodgkin Lymphoma (NHL)

A Study Evaluating the Safety, Efficacy, and Pharmacokinetics of Mosunetuzumab Monotherapy in Participants With Select B-Cell Malignancies

Trial Status	Trial Runs In	Trial Identifier
Active, not recruiting	1 Country	NCT05207670 ML43389

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 Open-Label, Multicenter, Phase II Trial Evaluating the Safety, Efficacy, and Pharmacokinetics of Subcutaneous Mosunetuzumab Monotherapy in Patients With Select B-Cell Malignancies

Trial Summary:

This study will evaluate the efficacy, safety, and pharmacokinetics of mosunetuzumab subcutaneous (SC) formulation in participants with selected B-cell malignancies (types of non-Hodgkin's lymphoma [NHL]).

Genentech, Inc.
Sponsor

Phase 2
Phase

NCT05207670 ML43389
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	#18 Years	No

Inclusion Criteria:

- At least one bi-dimensionally measurable nodal lesion, defined as >1.5 cm in its longest dimension, or one bi-dimensionally measurable lesion, defined as >1.0 cm in its longest diameter by computed tomography (CT) scan, positivie emission tomography - computed tomography (PET- CT), or magnetic resonance imaging (MRI)
- Eastern Cooperative Oncology Group (ECOG) Performance Status of 0, 1, or 2
- Adequate hematologic function

- No active infection
- Negative HIV test at screening, with the following exception: Individuals with a positive HIV test at screening are eligible provided they are stable on antiretroviral therapy for at least 4 weeks, have a CD4 count # 200/µL, have an undetectable viral load, and have not had a history of opportunistic infection attributable to AIDS within the last 12 months
- For women of childbearing potential (except those in Cohort B): agreement to remain abstinent (refrain from heterosexual intercourse) or use contraceptive measures, and agreement to refrain from donating eggs, as defined by the protocol
- For men: agreement to remain abstinent (refrain from heterosexual intercourse) or use a condom, and agreement to refrain from donating sperm, as defined by the protocol

Inclusion Criteria Specific to Cohorts A1 and A2

- Previously untreated FL with indication to start systemic therapy
- Adequate renal function

Inclusion Criteria Specific to Cohort B

- Aged # 80 years at the time of signing informed consent form (ICF), or aged 65-79 years and considered ineligible for chemoimmunotherapy (R-CHOP) with at least one of the following: Impairment in # 2 Activities of Daily Living (ADL); impairment in # 2 Instrumental Activities of Daily Living (IADL); or Cumulative Illness Rating Scale-Geriatric (CIRS-G) score of # 1 comorbidity with a severity of 3-4 or a score of 2 in # 8 comorbidities
- Histologically confirmed DLBCL according to WHO 2016 classification expected to express the CD20 antigen (Swerdlow et al. 2016)
- Previously untreated DLBCL with indication to start systemic therapy and are not eligible for curative therapy
- High-grade B-cell lymphomas, not otherwise specified (HGBL NOS) and HGBL with MYC and B-cell lymphoma (BCL)-2 and/or BCL-6 rearrangements
- Adequate end-organ function

Inclusion Criteria Specific to Cohort C

- Histologically conformed MZL (splenic, nodal, and extra-nodal)
- Previously untreated MZL with indication to start systemic therapy
- Helicobacter pylori-positive disease that has remained stable, progressed, or relapsed following antibiotic therapy and requires therapy, as assessed by the investigator (for cases of gastric/MALT MZL)
- Adequate renal function

Inclusion Criteria Specific to Cohort D

- Histologically confirmed MCL
- Relapsed after or failed to respond to at least one prior treatment regimen containing a Bruton's tyrosine kinase (BTK) inhibitor
- Adequate renal function
- Adverse events from prior anti-cancer therapy resolved to Grade </= 1

Inclusion Criteria Specific to Cohort E

- Histologically confirmed RT or tFL
- Relapsed after or failed to respond to at least one prior systemic treatment regimen for RT or tFL
- Adequate renal function

- Absolute lymphocyte count </= 5000 uL
- Adverse events from prior anti-cancer therapy resolved to Grade </= 1

Exclusion Criteria:

- Current or past history of central nervous system (CNS) lymphoma or leptomeningeal infiltration
- Prior treatment with mosunetuzumab
- History of severe allergic or anaphylactic reactions to humanized or murine monoclonal antibodies or known sensitivity or allergy to murine products
- History of confirmed progressive multifocal leukoencephalopathy (PML)
- Known active SARS-CoV-2 infection
- Known or suspected chronic active Epstein-Barr virus (CAEBV) infection
- Patients with history of macrophage activation syndrome (MAS)/hemophagocytic lymphohistiocytosis (HLH)
- Positive test results for chronic hepatitis B infection (HBV), acute or chronic hepatitis C virus (HCV) infection, or known or suspected HIV infection
- Administration of a live, attenuated vaccine within 4 weeks before first mosunetuzumab administration or anticipation that such a live, attenuated vaccine will be required during the study
- Prior solid organ transplantation
- Prior allogenic stem cell transplant
- Treatment with CAR-T therapy within 30 days prior to C1D1
- History of autoimmune disease, including, but not limited to myasthenia gravis, myositis, autoimmune hepatitis, systemic lupus erythematosus, rheumatoid arthritis, inflammatory bowel disease, vascular thrombosis associated with anti-phospholipid syndrome, Wegener granulomatosis, Sjögren syndrome, Guillain-Barré syndrome, multiple sclerosis, vasculitis, or glomerulonephritis
- Received systemic immunosuppressive medications (including, but not limited to, cyclophosphamide, azathioprine, methotrexate, thalidomide, and anti-tumor necrosis factor agents) with the exception of corticosteroid treatment </= 10 mg/day prednisone or equivalent within 2 weeks prior to the first dose of mosunetuzumab
- Current or past history of CNS disease, such as stroke, epilepsy, CNS vasculitis, or neurodegenerative disease
- History of other malignancy that could affect compliance with the protocol or interpretation of results
- Evidence of significant, uncontrolled concomitant diseases that could affect compliance with the protocol or interpretation of results or that could increase risk to the patient
- Known active bacterial, viral, fungal, mycobacterial, parasitic, or other infection (excluding fungal infections of nail beds) at study enrollment or any major episode of infection requiring treatment with intravenous antibiotics or hospitalization (relating to the completion of the course of antibiotics) within 4 weeks before C1D1
- Clinically significant history of liver disease, including viral or other hepatitis, or cirrhosis
- Recent major surgery within 4 weeks before the start of C1D1, other than superficial lymph node biopsies for diagnosis
- Prior treatment with radiotherapy within 2 weeks prior to C1D1
- Adverse events from prior anti-cancer therapy not resolved to Grade </= 1 (with the exception of alopecia, anorexia, nausea, vomiting, and fatigue)
- Significant cardiovascular disease (such as New York Heart Association Class III or IV cardiac disease, congestive heart failure, myocardial infarction within the previous 6 months, unstable arrhythmias, or unstable angina) or significant pulmonary disease (including obstructive pulmonary disease and history of bronchospasm)
- History of severe allergic or anaphylactic reaction to humanized, chimeric or murine monoclonal antibodies (MAbs)
- Contraindication to tocilizumab

- Prior anti-lymphoma treatment with monoclonal antibodies, radioimmunoconjugates, or antibody-drug conjugates within 4 weeks before first mosunetuzumab administration

Exclusion Criteria Specific to Cohorts D and E

- Prior anti-lymphoma treatment with any monoclonal antibody (e.g., anti-CD20), radioimmunoconjugate, or antibody-drug conjugate therapy within 4 weeks before first mosunetuzumab administration