Efficacy and Safety of Remibrutinib Compared to Teriflunomide in Participants With Relapsing Multiple Sclerosis (RMS)

Last Update: Jun 04, 2025
A Randomized, Double-blind, Double-dummy, Parallel-group Study, Comparing the Efficacy and Safety of Remibrutinib Versus Teriflunomide in Participants With Relapsing Multiple Sclerosis, Followed by Extended Treatment With Open-label Remibrutinib
ClinicalTrials.gov Identifier:
NCT05147220
Novartis Reference Number:CLOU064C12301
See if you Pre-qualify
All compounds are either investigational or being studied for (a) new use(s). Efficacy and safety have not been established. There is no guarantee that they will become commercially available for the use(s) under investigation.

Study Description

To compare the efficacy and safety of remibrutinib versus teriflunomide in patients with relapsing multiple sclerosis (RMS) The study CLOU064C12301 consists of an initial Core Part (CP) (maximum duration per participant of up to 30 months), followed by an Extension Part (EP, of up to 5 years duration) for eligible participants.

The Core Part is a randomized, double-blind, double-dummy, active comparator-controlled, fixed-dose, parallel-group, multi-center study in approximately 800 participants with relapsing multiple sclerosis (RMS).

The Extension Part is an open-label, single-arm, fixed-dose design in which eligible participants are treated with remibrutinib for up to 5 years.

A second study of identical design (CLOU064C12302) will be conducted simultaneously. Both studies will be conducted globally and data from the two studies will be pooled for some of the endpoints.

Condition
Relapsing Multiple Sclerosis
Phase
Phase3
Overall Status
Recruiting
Number of Participants
800
Start Date
Dec 16, 2021
Completion Date
Oct 30, 2030

Gender
All
Age(s)
18 Years - 55 Years (Adult)

Interventions

Drug

Remibrutinib

tablet taken orally
Drug

Teriflunomide

capsule taken orally

Eligibility Criteria

Inclusion Criteria:

* 18 to 55 years of age
* Diagnosis of RMS according to the 2017 McDonald diagnostic criteria
* At least: 1 documented relapse within the previous year. OR 2 documented relapses within the previous 2 years, OR 1 active Gadolinium (Gd)-enhancing lesion in the 12 months.
* EDSS score of 0 to 5.5 (inclusive)
* Neurologically stable within 1 month

Exclusion Criteria:

* Diagnosis of primary progressive multiple sclerosis (PPMS)
* Disease duration of more than 10 years in participants with EDSS score of 2 or less at screening
* History of clinically significant CNS disease other than MS
* Ongoing substance abuse (drug or alcohol)
* History of malignancy of any organ system (other than complete resection of localized basal cell carcinoma of the skin or in situ cervical cancer),
* Participants with history of confirmed Progressive Multifocal Leukoencephalopathy (PML) or Neurological symptoms consistent with PML
* suicidal ideation or behavior
* Evidence of clinically significant cardiovascular, neurological, psychiatric, pulmonary , renal, hepatic, endocrine, metabolic, hematological disorders or gastrointestinal disease that can interfere with interpretation of the study results or protocol adherence
* Participants who have had a splenectomy
* Active clinically significant systemic bacterial, viral, parasitic or fungal infections
* Positive results for syphilis or tuberculosis testing
* Uncontrolled disease states, such as asthma, or inflammatory bowel disease, where flares are commonly treated with oral or parenteral corticosteroids
* Active, chronic disease of the immune system (including stable disease treated with immune therapy (e.g.

Leflunomide, Methotrexate)) other than MS (e.g. rheumatoid arthritis, systemic lupus erythematosus, etc.) with the exception of well-controlled diabetes or thyroid disorder.
* Participants with a known immunodeficiency syndrome (AIDS, hereditary immune deficiency, drug induced immune deficiency), or tested positive for HIV antibody
* History or current treatment for hepatic disease including but not limited to acute or chronic hepatitis, cirrhosis (including all Child-Pugh classes) or hepatic failure or any chronic liver or biliary disease.
* History of severe renal disease or creatinine level
* Participants at risk of developing or having reactivation of hepatitis
* Hematology parameters at screening:

* Hemoglobin: \< 10 g/dl (\<100g/L)
* Platelets: \< 100000/mm3 (\<100 x 109/L)
* Absolute lymphocyte count \< 800/mm3 (\<0.8 x 109/L)
* White blood cells: \<3 000/mm3 (\<3.0 x 109/L)
* Neutrophils: \< 1 500/mm3 (\<1.5 x 109/L)
* B-cell count \< 50% lower limit of normal (LLN) or total IgG \& total IgM \< LLN (only required for participants who had a history of receiving B-cell therapies, such as rituximab, ocrelizumab or ofatumumab, prior to screening)
* History or current diagnosis of significant ECG abnormalities
* Resting QTcF ≥450 msec (male) or ≥460 msec (female) at pre-treatment as per central ECG reading at screening visit
* Use of other investigational drugs
* Requirement for anticoagulant medication or use of dual anti-platelet therapy Significant bleeding risk or coagulation disorders,
* History of gastrointestinal bleeding
* Major surgery within 8 weeks prior to screening
* History of hypersensitivity to any of the study drugs or excipients
* Pregnant or nursing (lactating) female participants, prior to randomization
* Women of childbearing potential not using highly effective contraception
* Sexually active males not agreeing to use condom
* Have received any live or live-attenuated vaccines within 6 weeks of randomization or requirement to receive these vaccinations during study
* Use of strong CYP3A4 inhibitors or use of moderate or strong CYP3A4 inducers within two weeks prior to randomization

Inclusion to Extension part:

• Participants who complete the Core Part of the study on double-blind study treatment and conduct the Accelerated Elimination Procedure (AEP)

Other inclusion and exclusion criteria may apply

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