Abstract
A-22-03673

Abstract FAQs

Withdraw

Information

Event
Congress Europe 2022 (/s/event/a1M3Y000007KjnwUAC/congress-europe-2022)

Stage
Submitted

Type
Poster

Status
Pending

Abstract Topic
MS and related disorders

Date Submitted
12.01.2022 10:20

Body

Title
REMODEL I/II Trials: Efficacy, Safety, and Tolerability of Remibrutinib in Patients With Relapsing Multiple Sclerosis

Introduction
Inhibition of Bruton's Tyrosine Kinase (BTK), a cytoplasmic tyrosine kinase and member of the TEC kinase family, results in reduced activation of B cells and innate immune cells. This offers an alternative mechanism to modulate immune regulatory networks and related neuroinflammation via inhibiting B cells and myeloid cells. Remibrutinib is a potent, highly selective, covalent BTK inhibitor with a short plasma half-life, and a promising pharmacological and safety profile. Here, we summarise the design of the REMODEL I/II Phase 3 trials, which aim to evaluate the efficacy, safety, and tolerability of remibrutinib versus teriflunomide in patients with relapsing multiple sclerosis (RMS).

Methods
REMODEL I/II are identical randomised, double-blind, double-dummy, active comparator-controlled, parallel-group, event-driven, multicentre studies. Patients aged 18–55 years having at least one/two relapses within the previous one/two years, or one active Gadolinium-enhancing lesion in the 12 months prior to screening, with an EDSS of 0.0–5.5 will be enrolled. The studies consist of an initial double-blind core part (Adaptive design, up to 30 months) followed by an open-label extension (up to 5 years). The primary endpoint is annualised relapse rate. Key secondary/exploratory endpoints are listed in Table-1.

Results
Both studies are currently recruiting participants (n=800/study). A planned futility interim analysis will be based on pooled 6-month MRI data (new/newly enlarging T2 lesions) from a subset of 200 participants.

Conclusion
The REMODEL I/II studies will investigate the efficacy, safety, and tolerability of remibrutinib versus teriflunomide to support regulatory approval worldwide as a potential new oral treatment for patients with this disabling disease.

Disclosure
The study was supported by Novartis Pharma AG, Switzerland. The detailed author disclosures will be presented in the subsequent presentation.

Author Details
H. Wiendl [1], L. Airas [2], T. Chitnis [3], M. Williams [4], J. Nakahara [5], R. Bermel [6], A. Mann [7], M. Ziehn [8], A. Bhatt [9], B. Hunter [8], Y. Zhang [7], R. Karan [8], B. Kieseier [8], X. Montalban [10]; [1] Department of Neurology with Institute of Translational Neurology, University of Münster, Münster, Germany, [2] Turku University Hospital and University, Finland, [3] Brigham and Women's Hospital, Department of Neurology, Boston, Massachusetts, United States, [4] Joi Life Wellness Group, Atlanta, Georgia, United States, [5] Department of Neurology, Keio University School of Medicine, Tokyo, Japan, [6] Mellen Center for MS, Cleveland Clinic, Cleveland, Ohio, United States, [7] Novartis Pharmaceutical Corporation, East Hanover, New Jersey, United States, [8] Novartis Pharma AG, Basel, Switzerland, [9] Novartis Healthcare Private Limited, Hyderabad, India, [10] Department of Neurology-Neuroimmunology, Centre d'Esclerosi Múltiple de Catalunya (Cemcat), Hospital Universitari Vall d'Hebron, Barcelona, Spain

Attached Files

Title	Caption	Section	Preview	Download

Table 1. Phase 3 REMODEL I and II study endpoints

Preview

Download