

A Study to Evaluate the Efficacy, Safety, Pharmacokinetics (PK), and Pharmacodynamics (PD) of Satralizumab in Participants With Anti-N-methyl-D-aspartic Acid Receptor (NMDAR) or Anti-leucine-rich Glioma-inactivated 1 (LGI1) Encephalitis

NCT05503264

Status	RECRUITING
Phase	Phase 3
Sponsor	Hoffmann-La Roche
Enrollment	152 participants

Key Eligibility Criteria

Inclusion (11)

- Reasonable exclusion of tumor or malignancy before baseline visit (randomization)
 - Onset of AIE symptoms < 9 months before randomization
 - Meet the definition of "New Onset" or "Incomplete Responder" AIE
 - For women of childbearing potential: agreement to remain abstinent (refrain from heterosexual intercourse) or use adequate contraception during the treatment period and for at least 3 months after the final dose of satralizumab or placebo
 - For participants enrolled in the extended China enrollment phase at China's sites: participants who are current residents of mainland China, Hong Kong, or Taiwan, and of Chinese ancestry
- ... and 6 more (see full listing online)

Exclusion (33)

- Any untreated teratoma or thymoma at baseline visit (randomization)
 - History of carcinoma or malignancy, unless deemed cured by adequate treatment with no evidence of recurrence for > 5 years before screening
 - For participants with NMDAR AIE, history of negative anti-NMDAR antibody in cerebrospinal fluid (CSF) using a cell-based assay within 9 months of symptom onset
 - Historically known positivity to an intracellular antigen with high cancer association or glutamate decarboxylase 65 (GAD-65)
 - Historically known positivity to any cell surface neuronal antibodies other than NMDAR and LGI1, in the absence of NMDAR and LGI1 antibody positivity
- ... and 28 more (see full listing online)

Locations (93 total)

University of Alabama at Birmingham, Birmingham, Alabama, United States
UC San Diego, La Jolla, California, United States
Hoag Memorial Hospital, Newport Beach, California, United States
... and 90 more locations

<https://clinicaltrials.gov/study/NCT05503264>

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