ForPatients
by Roche

Schizophrenia

A Trial of the Efficacy and the Safety of RO6889450 vs Placebo in Patients With an Acute Exacerbation of Schizophrenia or Schizoaffective Disorder

Trial Status	Trial Runs In	Trial Identifier
Completed	4 Countries	NCT04512066 BP41743

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:

A Phase II, Multi-Center, Randomized, Double-Blind, Parallel Group, Placebo-Controlled Trial of the Efficacy and the Safety of RO6889450 (Ralmitaront) vs Placebo in Patients With an Acute Exacerbation of Schizophrenia or Schizoaffective Disorder

Trial Summary:

This study will investigate the efficacy and safety of RO6889450 as monotherapy in participants experiencing an acute exacerbation of symptoms of schizophrenia or schizoaffective disorder.

Hoffmann-La Roche	Phase 2
Sponsor	Phase

NCT04512066 BP41743
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	#18 Years & # 45 Years	No

Inclusion Criteria:

- Participant must be 18 to 45 years of age inclusive
- Participants with a Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5) diagnosis of schizophrenia or schizoaffective disorder as confirmed by the Mini International Neuropsychiatric Interview (MINI)
- Disease duration </=10 years

- Have a current acute exacerbation of schizophrenia of no more than 8 weeks before screening visit and no current signs of apparent lack of treatment response
- At the time of screening, the participant needs to be either hospitalized or requiring inpatient psychiatric care according to clinical judgment. If the participant has been hospitalized for the current exacerbation, the hospitalization has to be of a maximum of 1 week prior to screening.
- In previous exacerbations and hospitalizations, the subject has shown a pattern of response to appropriate antipsychotic treatment
- Medically stable over a period of 3 months (non-psychiatric conditions) prior to screening visit and not expected to require hospitalization or change of treatment for non-psychiatric conditions for the duration of the study
- Screening and baseline CGI-S >/=4 (moderate or worse)
- Screening and baseline PANSS total score >= 80
- Based on screening and baseline PANSS, scores of >/= 4 (moderate or worse) on 2 or more of the following items: delusions, conceptual disorganization, unusual thought content, hallucinatory behavior, or suspiciousness/persecution
- Body mass index between 18 and 35 kg/m2 inclusive
- Male and female participants; female participants agree to remain abstinent or use acceptable contraceptive methods during the treatment period and for at least 28 days after the last dose of study drug

Additional inclusion criteria for optional 36-Week Safety Extension Phase

- Successful completion of the 12-week treatment period
- No signs or symptoms of worsening of the psychiatric or medical status that would preclude the patient from the participation in the 36-Week Safety Extension Phase or affect their ability to comply with the study requirements.

Exclusion Criteria:

- Has been inpatient for > 1 week or had any other hospitalization for acute exacerbation of schizophrenia or schizoaffective disorder within the prior 8 weeks or signs of lack of response to antipsychotic treatment
- Disease duration > 10 years
- Is currently an inpatient on an involuntary basis
- Subject answers "yes" to "Suicidal Ideation" Item 4 (active suicidal ideation with some intent to act, without specific plan) or item 5 (active suicidal ideation with specific plan and intent) or any suicidal behavior on the Columbia-Suicide Severity Rating Scale (C-SSRS) assessment within one month from screening or between screening and baseline
- Lifetime history of homicidal behavior
- Moderate to severe substance use disorder within six months (excluding nicotine) as defined by DSM-5
- Other current DSM-5 diagnosis (e.g., bipolar disorder, major depressive disorder)
- A prior or current general medical condition that might be impairing cognition or other psychiatric functioning (e.g., migraine headaches requiring prophylaxis treatment, head trauma, dementia, seizure disorder, stroke; or neurodegenerative, inflammatory, infectious, neoplastic, toxic, metabolic, or endocrine conditions)
- Clinically significant abnormalities in laboratory safety test results (including hepatic and renal panels, complete blood count, chemistry panel and urinalysis), including a) Aspartate aminotransferase (AST), OR alanine aminotransferase (ALT) 2 x upper limit of normal (ULN), OR total bilirubin > 1.5 ULN with the exception of known Gilbert syndrome. b) Serum creatinine > 1.5 ULN
- Positive result at screening for hepatitis B surface antigen (HBsAg), hepatitis C virus (HCV, untreated), or human immunodeficiency virus (HIV)-1 and -2. HCV participants who have been successfully treated and who test negative for HCV RNA are eligible for entry into the study

- Tardive dyskinesia that is moderate to severe or requires treatment
- History of neuroleptic malignant syndrome
- Average triplicate QTcF interval greater than 450 msec for males and 470 msec for females or other clinically significant abnormality on screening ECG based on centralized reading
- Participant for whom risperidone is contraindicated or who have a documented history of lack of response or intolerance to risperidone or paliperidone or participants with known hypersensitivity to risperidone, paliperidone, or to any excipients in Risperdal
- Participant treated with a long acting injectable antipsychotic or other antipsychotics that cannot be washed-out within the allotted screening period
- History of electro-convulsive therapy (ECT) for any reason
- Participant treated with clozapine at any dose within 12 months of screening visit or participants treated with clozapine at 200 mg/day or above at any time; low dose (< 200mg/day) use for insomnia or dyskinesia longer than 12 months prior to screening visit is permitted
- Participants currently receiving a psychotropic or other medication used as a psychotropic, which cannot be discontinued during the screening period
- Positive urine drug screen for amphetamines, methamphetamines, opiates, buprenorphine, methadone, cocaine and barbiturates. In case of positive urine drug screen for cannabinoids, the participant may be allowed to enter the study if approved by Medical Monitor
- Participant has previously received RO6889450
- Participant received an investigational drug within 28 days or five times the half-life of the investigational drug prior to the first study drug administration
- Diagnosis of COVID-19 infection (confirmed or presumptive) 4 weeks prior to screening or during screening. Participants can be re-screened after 4 weeks of full recovery in addition to investigator and/ or institutional approval to enroll