ForPatients
by Roche

Schizophrenia

A Study to Assess the Effects of RO6889450 in Participants With Schizophrenia or Schizoaffective Disorder and Negative Symptoms

Trial Status	Trial Runs In	Trial Identifier
Terminated	4 Countries	NCT03669640 BP40283

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:

Phase 2, Randomized, Double-Blind, Placebo-Controlled Study to Assess the Effects of RO6889450 (Ralmitaront) in Patients With Schizophrenia or Schizoaffective Disorder and Negative Symptoms

Trial Summary:

This study investigates the effects of RO6889450 on the negative symptoms associated with schizophrenia and schizoaffective disorder.

Hoffmann-La Roche	Phase 2
Sponsor	Phase

NCT03669640 BP40283
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	# 18 Years & # 55 Years	No

Inclusion Criteria:

- Patients with a Diagnostic and Statistical Manual of Mental Disorders (DSM-5) diagnosis of schizophrenia or schizoaffective disorder as confirmed by the Mini International Neuropsychiatric Interview (MINI)
- Part B only: Stable treatment with a dopamine/serotonin (D2/5HT2A) antagonist or pure D2 antagonist(s), or a D2 partial agonist for a minimum of 6 months and receiving no more than two antipsychotics
- Medically stable during the 3 months prior to study entry
- Participant is an outpatient with no psychiatric hospitalizations within the prior 6 months

- PANSS negative symptom factor score of 18 or higher
- The following rating on items of the PANSS: (a) less than 5 on G8 (uncooperativeness), P1 (delusions), P3 (hallucinations), P4 (excitement/hyperactivity), and P6 (suspiciousness/persecution); (b) less than 4 on P7 (hostility), and G14 (poor impulse control)
- Has an informant who is considered reliable by the Investigator
- Body mass index (BMI) between 18-40 kg/m2 inclusive
- Female participants are eligible to participate if not pregnant, not breastfeeding and 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

Exclusion Criteria:

- Moderate to severe substance use disorder within six months of study entry (excluding nicotine or caffeine) as defined by DSM-5
- Extrapyramidal symptom rating scale (ESRS-A CGI) subscore greater than or equal to 3
- Other current DSM-5 diagnosis (e.g., bipolar disorder, major depressive disorder)
- PANSS item G6 (depression) greater than or equal to 5
- Significant risk of suicide or harming him- or herself or others according to the Investigator's judgment
- A prior or current general medical condition that might be impairing cognition or other psychiatric functioning
- Positive result at screening for hepatitis B surface antigen (HBsAg), hepatitis C (HCV), or HIV-1 and HIV-2. HCV antibody positive participants are eligible if HCV RNA is negative
- Tardive dyskinesia that is moderate to severe or requires treatment
- History of neuroleptic malignant syndrome
- Average triplicate Fridericia's Correction Formula (QTcF) interval greater than 450 milliseconds (msec) for males and 470 msec for females or other clinically significant abnormality on screening electrocardiogram (ECG) based on centralized reading
- Clinically significant abnormalities in laboratory safety test results
- Significant or unstable physical condition that in the investigator's judgment might require a change in medication or hospitalization during the course of the study
- On more than one antidepressant, or if on one antidepressant, a change in dose within 28 days prior to screening
- History of clozapine treatment
- History of treatment with electroconvulsive therapy (ECT)
- Concomitant use of prohibited medications
- Positive urine drug screen for amphetamines, methamphetamines, opiates, buprenomorphine, methadone, cannabinoids, cocaine, and barbiturates
- Receipt of an investigational drug within 28 days or five times the half-life of the investigational drug (whichever is longer) before the first study drug administration
- Donation of blood over 400 mL within 3 months prior to screening
- 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