

Phase 3, Open Label Extension Study of ACP-204 in Lewy Body Dementia Psychosis

Status: RECRUITING

Eligibility Criteria

Age: 55 years to 84 years old

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

* The subject may benefit from long-term therapy with open-label ACP-204 treatment in the judgment of the Investigator * Subject has completed Visit 6 (EOT) of the antecedent ACP-204-012 study and did not have an early discontinuation from the antecedent study * Can complete all study visits with a study partner/caregiver * Can understand the nature of the study and protocol requirements and provide written informed consent. If the subject is deemed not competent to provide informed consent, the following requirements for consent must be met: 1. The subject's LAR (or study partner/caregiver, if local regulations allow) must provide written informed consent. 2. The subject must provide written (if capable) informed assent per local regulations * If the subject is a female, she must be of nonchildbearing potential * If the subject is male, he must agree to the following during the study intervention period and for at least 90 days after the last dose of study drug: 1. Refrain from donating sperm, AND 2. Either * Be abstinent from sexual intercourse where pregnancy can occur (abstinent on a long-term and persistent basis) and agree to remain abstinent OR * Use a condom and subject's female partner (if of childbearing potential and not pregnant) must use an additional contraceptive method

Exclusion Criteria:

* Is judged by the Investigator or the Medical Monitor to be inappropriate for the study for any reason * Is in hospice, is receiving end-of-life palliative care, or is bedridden * Has a heart rate ≤ 50 beats per minute, as measured by vital signs at Baseline (EOT visit of the antecedent study). If bradycardia is secondary to iatrogenic or treatable causes and these causes are addressed, a heart rate assessment can be repeated. * Has a BMI ≤ 18.5 kg/m² or known unintentional weight loss $\geq 7\%$ of body weight over past 6 months * Has a clinically significant laboratory abnormality in the antecedent ACP-204-012 study, excepting at ACP-204-012 EOT, that in the judgment of the Investigator or Medical Monitor, will either: 1. jeopardize the safe participation of the subject in this study; OR 2. interfere with the conduct or interpretation of safety or efficacy evaluations in the study * Is actively suicidal at Visit 1 (Baseline, EOT visit of the antecedent study) * Has a neurologic, cardiovascular, respiratory, gastrointestinal, renal, hepatic, hematologic, or other medical or mental disorder, including cancer or malignancies that, in the judgment of the Investigator, would increase the risk associated with taking study medication or significantly interfere with the conduct or interpretation of the study * Requires treatment with a medication or other substance that is prohibited by the protocol or will be used in a way that violates a use restriction

Conditions & Interventions

Interventions:

DRUG: ACP-204

Conditions:

Lewy Body Dementia Psychosis

More Information

Contact(s): Kristin Kidd - Kristin.kidd@acadia-pharm.com

Principal Investigator:

IRB

Number:

System ID: NCT07095465

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