

Phase 2 Trial Evaluating the Efficacy and Safety of RBD5044 in Patients With Mixed Dyslipidemia

NCT06797401

Status	RECRUITING
Phase	Phase 2
Sponsor	Ribocure Pharmaceuticals AB
Enrollment	120 participants

Key Eligibility Criteria

Inclusion (5)

- Willing to comply with protocol required visit schedule and visit requirements and provide written informed consent.
- Male or female participants, aged 18 to 80 years inclusive.
- Fasting TG level of ≤ 150 mg/dL (≤ 1.69 mmol/L) and < 499 mg/dL (5.61 mmol/L).
- Fasting levels at screening of non-HDL-C ≤ 100 mg/dL (2.59 mmol/L), or low-density lipoprotein cholesterol (LDL-C) ≤ 70 mg/dL (1.8 mmol/L) after at least 4 weeks of stable diet and stable optimal statin therapy (+ or - ezetimibe) if indicated.
- Body mass index between 18 and 40 kg/m².

Exclusion (6)

- Any uncontrolled or serious disease, or any medical or surgical condition, that may interfere with participation in the clinical trial and/or put the participant at significant risk (according to the investigator's judgment) if he/she participates in the clinical trial.
- Uncontrolled hypertension (blood pressure $> 160/100$ mmHg at screening). (If untreated, participant may be re-screened once hypertension is treated and controlled).
- Active or history of serious mental illness or psychiatric disorder, including but not limited to schizophrenia, bipolar disorder, or severe depression, which require current pharmacological intervention. Participants with a history of severe depression who are no longer on medication.
- Any of the following laboratory values at screening:
 - Hepatic: ALT or AST $> 2 \times$ ULN at screening, eGFR < 30 mL/min/1.73 m² (using the Modification of Diet in Renal Disease [MDRD] equation) at Screening, HbA1c $> 9.0\%$ (or > 75 mmol/mol International Federation of Clinical Chemistry [IFCC] units) at screening.

... and 1 more (see full listing online)

Locations (4 total)

Lunds Universitetssjukhus, Lund, Sweden
Ribocure Clinic/Ribocure Pharmaceuticals AB, Mölndal, Sweden
AkardoMedSite, Stockholm, Sweden
... and 1 more locations

<https://clinicaltrials.gov/study/NCT06797401>

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