

Efficacy and Safety of JS002 as Monotherapy in Patients With Primary Hypercholesterolaemia and Mixed Dyslipidemia

NCT05621070

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| Status | RECRUITING |
| Phase | Phase 3 |
| Sponsor | Shanghai Junshi Bioscience Co., Ltd. |
| Enrollment | 582 participants |

Key Eligibility Criteria

Inclusion (5)

- Signed informed consent
- Age 18~80 years old
- Subject who has not achieve LDL-C goal as categorized by their CV risk at screening
- Fasting TGd4.5mmol/L by central laboratory at screening
- Statin intolerance subject must have a history of statin intolerance as evidenced

Exclusion (8)

- History of hemorrhagic stroke
- NYHA III or IV heart failure, or known LVEF< 30% within 1 year before randomization
- Uncontrolled serious cardiac arrhythmia defined as recurrent and highly symptomatic ventricular tachycardia, atrial fibrillation with rapid ventricular response, or supraventricular tachycardia that are not controlled by medications, within 90 days prior to randomization
- Myocardial infarction, unstable angina, percutaneous coronary intervention (PCI), coronary artery bypass graft (CABG) or stroke, deep vein thrombosis or pulmonary embolism within 90 days prior to randomization
- Planned cardiac surgery or revascularization
- ... and 3 more (see full listing online)

Locations (1 total)

Peking University Third Hospital, Beijing, Beijing Municipality, China