

A Study of TAK-781 in Healthy Volunteers and in Participants With Non-Cirrhotic Primary Sclerosing Cholangitis (PSC)

NCT07229911

Status	RECRUITING
Phase	Phase 1
Sponsor	Takeda
Enrollment	134 participants

Key Eligibility Criteria

Inclusion (27)

- The participant is willing and able to fully comply with all trial procedures and requirements, in the investigator's opinion.
- The participant has provided informed consent (that is, in writing, documented via a signed and dated informed consent form (ICF) or electronic consent [e-consent] if applicable) and any required privacy authorization prior to the initiation of any trial procedures.
- Male at birth and female at birth participants aged 18 to 68 years, inclusive, at the time of consent.
- The participant is judged to be in good health (for example, no evidence of cardiovascular, liver, metabolic, gastroenterological, or kidney disease) by the investigator, based on clinical evaluations including laboratory safety tests, medical history, physical examination, ECG, and vital sign measurements performed at the first screening visit.
- The participant must have a body mass index (BMI) of less than 30.0 kilograms per square meter (kg/m^2) at the time of screening.

... and 22 more (see full listing online)

Exclusion (81)

- The participant is an employee of the sponsor or trial site, or an immediate family member (for example, spouse, parent, child, sibling) of an employee of the sponsor or trial site who is directly involved in the conduct of the trial.
- The participant has a known hypersensitivity to any component of the formulation of TAK-781 or related compounds.
- The participant has a history of significant multiple and/or severe allergies (for example, food, drug, latex allergy) or has had an anaphylactic reaction or significant intolerance to prescription or nonprescription drugs or food.
- The participant has a history or clinical evidence of bleeding diathesis or any coagulation disorder.
- The participant has a medical history of prior cholecystectomy.

... and 76 more (see full listing online)

Locations (1 total)

ICON, Salt Lake City, Utah, United States