ascent
CLINICAL TRIALS

# Single- and Multiple-Dose Clinical Trials (ASCENT-1 and ASCENT-2) for Dose Finding of PRX012 in Participants With Biologically Confirmed Alzheimer's Disease

## ascent-1

### Single-Dose Clinical Trial

**Treatment:** Single SC injection of PRX012 or placebo

**Participants With Early AD:** Amyloid PET positive, MMSE ≥18

| Healthy Volunteers (Aged 20-45 years) | | Participants With Early AD (Aged 60-85 years) | | |
|---|---|---|---|---|
| **Randomization 3:1** (PRX012:Placebo) | | **Randomization 3:1** (PRX012:Placebo) | | |
| **70 mg** | **200 mg** | **70 mg** | **200 mg** | **400 mg** |

1 **Primary Objective**
To evaluate the safety and tolerability of PRX012 administered as a single dose

2 **Secondary Objective**
To characterize the PK profile of PRX012 after SC administration as a single dose

**Study Duration**
~3 months

## ascent-2

### Multiple-Dose Clinical Trial

**Treatment:** Multiple SC injections of PRX012 or placebo

**Participants With Early AD:** Aged 55-85 years, amyloid PET eligible, MMSE ≥18

| Participants With Early AD - *APOE4* Non-carriers or Heterozygous (Group A) | | | | Participants With Early AD - *APOE4* Homozygous (Group B)* | | | |
|---|---|---|---|---|---|---|---|
| **Randomization 3:1** (PRX012:Placebo) | | | | **Randomization 3:1** (PRX012:Placebo) | | | |
| **45 mg** | **70 mg** | **200 mg** | **400 mg** | **45 mg** | **70 mg** | **200 mg** | **Up to 400 mg** |

1 **Primary Objective**
To evaluate the safety, tolerability, and immunogenicity of PRX012 after multiple SC doses

2 **Secondary Objective**
To characterize the PK profile and PD effects on brain amyloid plaque deposition of PRX012 after multiple SC doses

**Study Duration**
~6 months

## ascent-3

### Open-Label Extension Trial

Participants who complete ASCENT-1 or ASCENT-2 may be eligible to enter into the open-label extension study, **ASCENT-3**

*Group B increases representation of participants who are homozygous for *APOE4* to ~2× that of the general AD population.
PRX012 is an investigational drug and not approved by any regulatory authority.
AD, Alzheimer's disease; APOE4, apolipoprotein E4; MMSE, Mini-Mental State Examination; PD, pharmacodynamic; PET, positron emission tomography; PK, pharmacokinetic; SC, subcutaneous.
Swanson C, et al. Poster presentation at AAIC 2024; July 28-August 1, 2024; Philadelphia, PA, USA. Data as of August 1, 2024.