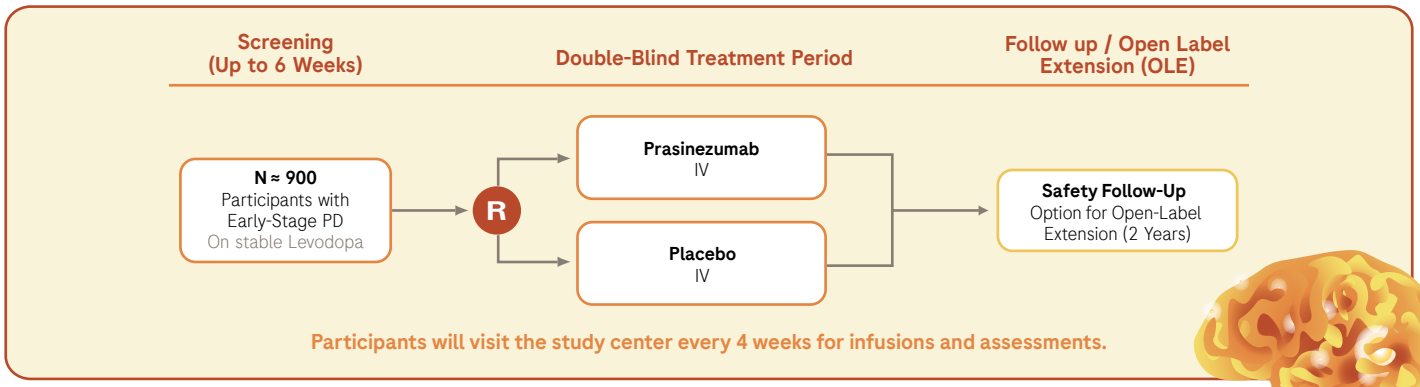
PARAISO

Recruiting

Clinical trial in early-stage Parkinson's disease

Protocol BN44715 (NCT07174310)
A Phase III, double-blind, placebo controlled study to evaluate the efficacy and safety of **Intravenous (IV) Prasinezumab** in participants with early-stage Parkinson's Disease on stable levodopa monotherapy.

Please call Genentech/Roche Trial Information Support at 1-888-662-6728 (US only) or email **global.rochegenentechtrials@roche.com**. Refer to Study: **PARAISO / BN44715**



Inclusion criteria

- Aged **50 to 85 years** at screening.
- Diagnosis of **idiopathic Parkinson's Disease** (MDS criteria) with bradykinesia plus resting tremor or rigidity.
- Diagnosis of PD for at least 3 months to maximum 3 years at screening.
- **Stable Monotherapy with Levodopa.**
- Hoehn & Yahr Stage 1 or 2 (*off* medication).
- No motor complications (MDS-UPDRS Part IV score of 0).
- No anticipated changes in PD medication from baseline throughout the study.

Primary endpoint

Time to Confirmed Motor Progression
Measured by MDS-UPDRS Part III score from the randomisation date.

Key secondary endpoints

- Change in motor function from baseline at Week 104 (MDS-UPDRS Part III *off* medication).
- Time to worsening of motor function (MDS-UPDRS Part II).
- Time to meaningful worsening in Clinician Global Impression of Change (CGI-C).
- Time to increase in Levodopa Equivalent Daily Dose (LEDD).

Select exclusion criteria

- History of other parkinsonian syndromes (e.g., MSA, PSP, vascular parkinsonism) or drug induced parkinsonism.
- Known carriers of PD gene mutations (*PRKN*, *PINK1*, *DJ1*. Note: *GBA*, synuclein *LRRK2* allowed).
- History of motor fluctuations or dyskinesias.
- Diagnosis of PD Dementia.
- History of significant neurological disease other than PD (e.g., stroke, epilepsy).
- Clinically significant psychiatric symptoms (e.g. hallucinations).
- Use of prohibited medications (e.g., MAO-B inhibitors, Dopamine Agonists, COMT inhibitors) within 3 months of baseline.
- History of clinically significant brain MRI abnormality.

Investigational Use Only: Product under investigation has not been approved by the FDA and the safety or effectiveness has not been established. This information is presented for the purpose of providing an overview of the clinical trial and should not be construed as a recommendation for use.

PD=Parkinson's Disease; MDS-UPDRS=Movement Disorder Society Unified Parkinson's Disease Rating Scale; IV=Intravenous; R=Randomization.

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