Efficacy and Safety of REC-2282 in Patients with Progressive Neurofibromatosis Type 2 (NF2) Mutated Meningiomas (POPLAR-NF2)

If you are an adult or adolescent (12 years of age or older) and have a disease called Neurofibromatosis Type 2 (NF2) you may be eligible to participate in a study to investigate the safety and efficacy of an investigational drug called REC-2282. About 90 participants will take part in this study.

This study will occur in two parts. Part 1 (Cohort A) will provide early data on efficacy and safety of REC-2282 in participants with progressive NF2 mutated meningiomas and provide guidance for the dose. In Cohort A, 20 adult participants will be randomized to one of two doses of REC-2282. Additionally, up to 9 adolescent participants will receive REC-2282.

Cohort B will assess the efficacy and safety of REC-2282 compared with placebo in participants with progressive NF2 mutated meningiomas. 60 adult and adolescent participants will be assigned to receive either REC-2282 or a placebo (an identical-looking capsule that contains no study drug); there is a 66% chance (2 in 3) of receiving REC-2282, so people who join the study will have a 33% chance (1 in 3) of receiving placebo.

In both cohorts, there will be a screening period of up to 8 weeks, a treatment period, a 4-week safety follow-up period after the end of treatment, and a 6-month post-study follow-up. At the end of the study period, participants may be offered participation in an open-label extension (OLE) period.

If you are interested in participating, please visit clinicaltrials.gov (search for POPLAR-NF2) or visit poplarnf2.com