Transcript Details
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Evaluating AR1001: A Phase 3 Trial in Early Alzheimer's Disease

Announcer:
You're listening to *Neurofrontiers* on ReachMD, and on this episode, we'll hear from Dr. Sharon Sha. She'll be discussing a novel therapy for Alzheimer's disease called AR1001, which is being examined in the phase 3 clinical trial POLARIS-AD. Dr. Sha is a Clinical Professor of Neurology and Neurological Sciences at Stanford University in Palo Alto, where she also serves as Chief for the Memory Disorders Division and the Stanford Memory Disorders Center. This research was recently presented as a poster at the 2025 CTAD conference.

Let's hear from Dr. Sha now.

Dr. Sha:
AR1001 is a novel phosphodiesterase 5 inhibitor, and this is an oral therapy that has multimechanistic actions, including improving cerebral perfusion, neuro anti-inflammatory effects, potentially reduction of tau phosphorylation, and neuroprotection in general to target people with mild cognitive impairment and mild dementia due to Alzheimer's disease. It's being used in a large phase 3 clinical trial based on the prior trends for improvement in biomarkers on a phase 2 trial. So this phase 3 trial is really looking to determine efficacy and safety of AR1001 in a global, large phase 3 study.

This clinical trial is relatively unique. It's one of the largest phase 3 clinical trials using an oral multipharmacologic or multimechanistic potential therapy for Alzheimer's disease. And the way people were recruited into this study allowed for confirmation of Alzheimer's biomarkers agnostic to modality, meaning that most clinical trials in the past have required amyloid PET positivity or CSF positivity or something like that. Some current trials are using plasma-based enrollment. This was agnostic to that, so participants were allowed to use PET scan or CSF, and a variety of assays were allowed. And so, actually, this is one of the largest clinical trials that had over 50 percent of participants contribute CSF for the analysis, and that allows us, potentially, to conduct biomarkers based on CSF throughout the trial.

The baseline demographics of the people who participated and enrolled into this large phase 3 clinical trial were really on par with other large phase 3 clinical trials, namely TRAILBLAZER and Clarity AD, which, now, those drugs have been FDA approved for use in the same population of mild cognitive impairment and mild dementia due to Alzheimer's disease. This clinical trial enrolled over 1,500 participants with underlying Alzheimer's disease, and that's very similar to these other large phase 3 trials, which enrolled close to 1,800 participants. The demographics in terms of age, baseline cognitive status, and baseline functional independence status were all similar to these other large phase 3 trials, meaning that we can't predict what the findings will be based upon these demographic information, but we think that any results from this large phase 3 clinical trial may be enough and sufficient to demonstrate true efficacy and safety for AR1001.

Announcer:
That was Dr. Sharon Sha talking about how POLARIS-AD is assessing AR1001 for Alzheimer's disease. To access this and other episodes in our series, visit *Neurofrontiers* on ReachMD.com, where you can Be Part of the Knowledge. Thanks for listening!