**ASPECT (Avanir Pharmaceuticals)**

**What is the study about?**

Alzheimer’s disease, the most common form of dementia, is a progressive neurodegenerative disease of which agitation is widely recognised as a common clinical feature. Agitation in patients with dementia is associated with increased functional disability, worse quality of life and increased caregiver burden. There are no approved treatments to specifically manage agitation in patients with Alzheimer’s disease. Current treatments include off-label use medications for other conditions however these only provide modest effectiveness therefore there is an unmet medical need for safe and effective treatment for patients with agitation in Alzheimer’s disease.

This study is looking at a drug called AVP-786, it is anticipated that AVP-786 will have a positive effect on agitation in patients with Alzheimer’s dementia. The study drug has been tested in 15 completed neuropsychiatric studies and has been safe and generally well tolerated so far. This study will assess the effectiveness, safety and tolerability of two doses of AVP-786 compared to placebo. The study will include approximately 750 participants aged between 50-90 years old. Duration of participation is approximately 20 weeks including a 4 week screening period, 12 week treatment period and one month safety follow up period. Treatment will be blinded, meaning no-one will know which treatment participants receive. Participants will undergo procedures such as blood samples, questionnaires and ECGs. Each participant must have an appointed caregiver who has direct and regular contact with them (at least 2 hours a day for 4 days a week), to provide reliable answers to questions related to the participant and also themselves.

**Who can take part?**

1. Males and females 50 to 90 years of age (inclusive) at the time of informed consent.

2. Diagnosis of probable Alzheimer's disease according to the 2011 NIAAA working groups criteria. Either outpatients or residents of an assisted living facility, a skilled nursing home, a dementia unit, or any other type of facility providing long-term care.

3. MMSE score between 8 and 24 (inclusive) at Screening and Baseline.

4. Patient has clinically significant, moderate-to-severe agitation for at least 2 weeks prior to Screening that interferes with daily routine per the Investigator's judgment.

**To find out more please contact:**

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