Ceretas

ASX Announcement

Ethics Committee Approval Secured for Additional CERE-CALM Trial Sites

- St Vincent's Hospital Sydney Human Research Ethics Committee has approved the Phase 2 CERE-CALM trial
- Approval enables two additional Australian clinical trial sites to be activated: St Vincent's Hospital Sydney and John Hunter Medical Research Institute
- Site initiation visit completed at first clinical site, Cognivus Research

31 August 2026

Ceretas Limited (ASX:CTS) ("Ceretas" or "the Company"), an Australian medical technology company developing a portable, non-invasive therapeutic ultrasound platform to treat Alzheimer's disease and other neurodegenerative conditions, is pleased to announce that the St Vincent's Hospital Sydney Human Research Ethics Committee (HREC) has approved the Company's Phase 2 CERE-CALM trial. The approval enables additional Australian clinical trial sites to participate, and follows earlier approval granted by Bellberry HREC for the lead clinical site, Cognivus Research (Refer Replacement Prospectus, ASX Announcement 21 July 2026).

CERE-CALM is a Phase 2 trial evaluating neuromodulation as a treatment for the behavioural and psychological symptoms of dementia (BPSD) in participants with Alzheimer's disease. It follows a successful first-in-human Phase 1 trial in patients with Alzheimer's disease run by the Queensland Brain Institute in 2024 which found the treatment fast, safe and well tolerated, with early signs of benefit for behavioural symptoms.

St Vincent's Hospital Sydney will now progress to governance and start-up activities. The same HREC approval also covers the John Hunter Medical Research Institute, which will proceed through the same process. Ceretas expects to add further Australian sites in the coming months as additional governance approvals are received.

The first clinical site, Cognivus Research, has completed governance and is progressing start-up activities, with a site initiation visit completed in mid-August.

Ceretas CEO/MD Dr Rachel de las Heras said: *"This additional HREC approval is an important milestone for the CERE-CALM clinical trial. St Vincent's Hospital Sydney and John Hunter are highly regarded sites that will help us reach our recruitment targets in a timely manner. With Cognivus site initiation also now complete, we're on the cusp of enrolling our first patients, a defining moment for Ceretas and for patients with Alzheimer's disease living with BPSD."*

CERE-CALM Trial Overview

CERE-CALM is a Phase 2 randomised, double-blind, sham-controlled trial evaluating low-intensity focused ultrasound neuromodulation for the treatment of the behavioural and psychological symptoms of dementia (BPSD) in adults aged 50 and over with probable Alzheimer's disease and BPSD. Participants receive six treatments over 12 weeks, comprising four weekly sessions followed by two monthly sessions.

The primary endpoint is the change in overall neuropsychiatric symptom burden as measured by Neuropsychiatric Inventory (NPI) total score from baseline to week 6, comparing active treatment with sham control. Secondary endpoints include caregiver distress at week 6 and week 12, durability of treatment effect at week 12, and overall safety and tolerability. The trial targets 66 participants (minimum 60), randomised 2:1 to active treatment or sham control.

The details of the CERE-CALM trial are provided on the Australian and New Zealand public clinical trial registry: www.anzctr.org.au, with the trial code ACTRN12626000738325.

Enquiries can be directed via email to Ceretas clinicaltrialenquiries@ceretas.com.au.

This announcement is authorised for release by the Board of Directors.

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About Ceretas

Ceretas (ASX:CTS) is a clinical-stage medical technology company developing a portable, non-invasive therapeutic ultrasound platform to treat Alzheimer's disease and other neurodegenerative conditions.

The Ceretas device directs low-intensity focused ultrasound through the skull to act on brain tissue via two mechanisms: neuromodulation, targeting neural circuits involved in memory, cognition and the behavioural and psychological symptoms of dementia; and

blood-brain barrier opening, which may facilitate clearance of disease-associated proteins and enhance delivery of therapeutic agents to the brain.

The technology is based on more than a decade of research at The University of Queensland and the Queensland Brain Institute (QBI). In 2024, QBI researchers completed a first-in-human Phase 1 trial of low-intensity focused ultrasound neuromodulation in 12 Alzheimer's participants, finding the treatment to be fast, safe and well tolerated, with encouraging early signals of benefit for behavioural symptoms. The results were published in Brain Communications in December 2025.

Ceretas is preparing to commence its Phase 2 CERE-CALM trial (ACTRN12626000738325), evaluating the platform in Alzheimer's patients with behavioural and psychological symptoms of dementia. QBI researchers are separately running their Phase 2 AGIFUS trial (ACTRN12626000687392), evaluating the same technology in Alzheimer's-related agitation, funded independently by Queensland Health.