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S2N.Bio begins Alzheimerâ??s cell therapy technology transfer to Cell Therapiesâ?? Melbourne GMP facility

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Transfer will establish GMP manufacturing and analytical processes ahead of clinical production for S2Nâ??s planned first-in-human Australian study in 2027

Cell Therapies Pty Ltd (CTPL) and S2N.Bio have commenced technology transfer of S2N's cell therapy candidate for Alzheimer's disease. The transfer will enable GMP manufacture of clinical trial material for S2N's first-in-human study in Australia.

CTPL and S2N are collaborating members of the Solutions for Manufacturing Advanced Regenerative Therapies (SMART) Cooperative Research Centre (CRC) ("SmartCRC"), which is co-funding elements of the project as part of its mission to accelerate the translation of innovative health technologies from research through to clinical and commercial outcomes.

The technology transfer will establish S2N's cell manufacturing process under GMP conditions, establish GMP analytical methods and documentation within Cell Therapies' quality system, ahead of GMP clinical production for the 2027 clinical trial.

S2N is an Australian regenerative medicine company developing an autologous cell therapy intended to replace neurons lost through neurodegeneration. The therapy is based on hair follicle-derived neuroprecursor (HFN) cells, a cell population isolated from a patient's own hair follicles. The cells are unipotent, differentiating only into neurons and related cells, and are not genetically modified.

S2N's approach is mechanistically distinct from Alzheimer's therapies currently on the market. The two recent agents approved by the Therapeutic Goods Administration (TGA), donanemab and lecanemab, are anti-amyloid antibodies that slow cognitive decline by clearing amyloid. The slowing of disease by these agents is modest, and they cannot recover function that has already been lost. S2N's cell therapy targets that gap directly: it is designed to replace the neurons lost to the disease.

S2N's preclinical foundation includes a proof-of-concept veterinary trial published in Stem Cell Research & Therapy in 2022.

According to S2N, this veterinary trial sets it apart from other companies dedicated to treating Alzheimer's, many of which rely on rodent models that have limitations in predicting human outcomes. The company says its canine trial provides evidence of functional recovery in a naturally occurring disease that shares pathological and clinical aspects with human Alzheimer's. These findings are preclinical and do not establish safety or efficacy in humans.

Before transferring to Cell Therapies, S2N refined its cell manufacture process in the University of Technology Sydney's (UTS) Biologics Innovation Facility (BIF). The BIF is an ISO 9001:2015-certified, Good Manufacturing Practice (GMP)-like pilot biomanufacturing facility.