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Regeneus clears procedures to initiate Progenza trial for osteoarthritis treatment

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Sydney-headquartered Regeneus announced the completion of enrolment of all 20 patients in the STEP trial. Further, a review of the cumulative study safety data by the study safety oversight committee identified no safety concerns. The STEP trial (Safety, Tolerability and Efficacy of Progenza) is the first clinical trial of Progenza, the company's allogeneic off-the-shelf stem cell product for the treatment of knee osteoarthritis.

The completion of enrolment Cohort 2 ahead of schedule is a positive milestone for the clinical development of the company's allogeneic stem cell therapy. The lack of safety concerns identified from the pre-specified review of the cumulative safety data from all 20 patients is also encouraging. The review included a minimum of 1-month safety data for all patients, and substantially more data for earlier enrolled Cohort 1 patients.
The trial is entitled as: 'A phase 1 randomized, double-blind, placebo-controlled single ascending dose study to evaluate the safety, tolerability and preliminary efficacy of intra-articular Progenza in adults with symptomatic knee osteoarthritis'.

The company has revealed that leading Sydney-based sports medicine specialist, Dr Donald Kuah, is the Principal Investigator on the trial. Dr Kuah, a principal of Sydney Sportsmed Specialists, is known to have extensive experience in the diagnosis and treatment of patients with osteoarthritis.

The study will complete once the last patient completes 12 months of post treatment follow up, concluding with a second MRI. All 20 participants have knee osteoarthritis and received ultrasound-guided injections of Progenza or placebo directly into their arthritic knee joint. One in five patients received a placebo injection.

The primary objective of the trial is to evaluate the safety and tolerability of Progenza. The secondary objectives are to investigate the effect of Progenza on knee pain and function; quality of life; knee joint structures using magnetic resonance imaging; and osteoarthritis biomarkers. Participants will be monitored for 12 months.