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Singapore: Australia based, Circadian Technologies, through its wholly owned subsidiary Opthea has received USFDA approval for the application to initiate its Phase 1 clinical trial of Investigational New Drug (IND) OPT-302 in patients with wet age-related macular degeneration (wet AMD).

Dr Megan Baldwin, CEO and managing director, Circadian, "The FDA's acceptance of our IND for the Phase 1 clinical trial of OPT-302 is a major milestone for the Company. It is the result of a detailed review by the FDA of our non-clinical data package including preclinical safety/toxicology, efficacy testing and manufacturing processes for OPT-302, as well our Phase 1 study design. We look forward to bringing this important novel therapy to wet AMD patients for whom there remains a significant unmet medical need."

Opthea's first-in-human multi-centre clinical trial is a sequential dose escalation study of OPT-302 administered to patients with wet AMD on a monthly basis for three months by ocular injection either alone or in combination with ranibizumab (Lucentis).

Wet AMD is the leading cause of blindness caused by excessive growth and leakage of blood vessels at the back of the eye that leads to a chronic and often rapid loss of vision.