Azure Health Technology Limited
ABN: 35 111 082 485
Address: Level 45, MLC Centre, 19 Martin Place, Sydney NSW 2000
www.azureht.com.au | Tel: +61 2 8279 8908

MEDIA RELEASE

Azure Health Technology completes study protocol for NAFLD/NASH Phase II clinical study

Sydney, Australia 31 July 2020 – Azure Health Technology Limited (AZT) today announced that it has completed the preparation of a study protocol for a Phase II clinical study on Non-Alcoholic Fatty Liver Disease and Non-Alcoholic SteatoHepatitis (NAFLD/NASH).

The protocol relates to a randomised, double-blind, placebo-controlled Phase II clinical study on NAFLD/NASH to analyse the efficacy and safety of IVB001, a drug candidate based on the non-invasive and direct delivery of tocotrienols using the Company's proprietary and patented transmucosal delivery platform. The study will seek to enrol 80 patients and be conducted at 8 sites in Australia.

The active pharmaceutical ingredient is a formulation of delta tocotrienol which has been demonstrated in a previous Phase Ia Clinical Study to be efficiently delivered transmucosally, achieving improved bioavailability compared to orally administered tocotrienols when patients are in the fasted state.

The Investigational Product will be IVB001 and the matching placebo, 60mg doses of IVB001 will be self-administered sublingually three times a day for 168 days (24 weeks).

The primary endpoints will be safety measured by incidence of treatment emergent Adverse Events (AEs) and Serious Adverse Events (SAEs) and efficacy measured by mean change from Baseline to Week 24 of hepatic steatosis using Magnetic Resonance Imaging – Proton Density Fat Fraction (MRI-PDFF) which measures the percentage of fat in the patient's liver. A secondary endpoint (amongst others) will be the measure of change from baseline in liver elasticity as measured by Fibroscan at Weeks 12 and 24. The study will be powered to achieve a *p* value of 0.05.

Patients who are likely to have NASH (where the accumulation of fat in the liver has caused inflammation and some liver cell damage) but not cirrhosis (scarring of the liver which is often irreversible) will be selected by investigators based on history, examination, imaging and laboratory results.

Professor Edward Gane, a Member of AZT's Scientific Advisory Board, said "Tocotrienols address multiple steps in the NAFLD/NASH cascade including the abnormal retention of fat in liver cells (steatosis), the inflammation caused by the steatosis and the generation of scar tissue (fibrosis/cirrhosis) that results from inflammation. Clinical studies in another group have demonstrated that orally delivered tocotrienols have shown efficacy in addressing NAFLD/NASH. By delivering the tocotrienols directly and in a non-invasive

way using AZT's transmucosal delivery platform, we are exploring an exciting potential new therapy for NAFLD/NASH. The non-invasive delivery method maximises patient compliance which is really important for a chronic disease like NAFLD/NASH."

The protocol is now ready to be included in the rest of the dossier for submission to the Human Research Ethics Committees (HREC) of the clinical study sites.

For more information please contact:

Dr Glenn Tong
CEO and Managing Director
Tel: +61 (0) 412 193 350

Ms Catriona Glover
Company Secretary
Tel: +61 (0) 402 328 200

About Azure Health Technology Limited

Azure Health Technology Limited (AZT) is an Australian public unlisted biotechnology company developing and commercialising novel dietary supplements and prescription medicines based on natural products (tocotrienols) which have wide therapeutic potential, including: Delayed Onset Muscle Soreness, muscle recovery, exercise endurance, Non-Alcoholic Fatty Liver Disease (NAFLD), Non-Alcoholic SteatoHepatitis (NASH), pancreatic cancer, hyperlipidaemia, hypertension and diabetes. AZT owns and controls patent and other intellectual property rights for novel approaches to non-invasively delivering tocotrienols directly to the target tissues. The Company has a product development program for evidence-based nutraceuticals and a clinical development program for prescription medicines. For more information see: www.aztht.com.au