

## MEDIA RELEASE

### **Azure Health Technology Limited commences preparations for NAFLD/NASH Phase II clinical study**

**Sydney, Australia 15 June 2020** – Azure Health Technology Limited (AZT) today announced that it has commenced preparations for a Phase II clinical study on Non-Alcoholic Fatty Liver Disease and Non-Alcoholic SteatoHepatitis (NAFLD/NASH).

After discussions with a number of Australian and international Clinical Research Organisations (CROs), AZT is pleased to engage Datapharm Australia as the CRO for 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 and New Zealand.

There are no approved treatments for NAFLD/NASH. If left unchecked, NAFLD/NASH can progress to liver cirrhosis and liver cancer. The global market for NAFLD/NASH is expected to grow to about US\$20-35B by 2025. NAFLD/NASH is a great unmet need which AZT hopes to address.

Tocotrienols act as strong antioxidants in the body, have anti-fibrotic activity and distribute preferentially to the liver. They 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) that results from inflammation. Orally delivered tocotrienols have shown efficacy in clinical studies on NAFLD/NASH. AZT expects that improving the delivery of the tocotrienols using the Company's proprietary and patented transmucosal delivery platform holds great promise in the development of an efficacious treatment for NAFLD/NASH.

AZT and Datapharm Australia have begun the task of selecting clinical study sites and preparation of documentation for submission to Human Research Ethics Committees (HREC).

AZT's Chief Scientific Officer, Dr David Kingston said, "The way that tocotrienols target multiple parts of the disease cascade for NAFLD/NASH points to some exciting prospects for AZT's drug candidates. Using a non-invasive and direct method for delivering these drugs also makes a lot of sense in the context that this is a chronic disease and patient compliance over an extended period of time is a major issue for therapies that are invasive."

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**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.azureht.com.au](http://www.azureht.com.au)