

## MEDIA RELEASE

# Azure Health Technology Limited commences preparations for pancreatic cancer Phase II clinical study

**Sydney, Australia 22 June 2020** – Azure Health Technology Limited (AZT) today announced that it has commenced preparations for a Phase II clinical study on pancreatic adenocarcinoma (pancreatic cancer).

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 pancreatic cancer to analyse the efficacy and safety of IVB003, a drug candidate based on the non-invasive and direct delivery of tocotrienols using AZT's proprietary and patented transmucosal delivery platform. The study will seek to enrol 40 patients and be conducted at 6 sites in Australia and New Zealand. As previously announced, AZT has also engaged Datapharm Australia to conduct an NAFLD Phase II clinical study.

Pancreatic cancer is uncommon but since the majority of these cancers are in an advanced stage by the time of diagnosis, it is the third leading cause of cancer-related deaths in the US, claiming an estimated 44,000 lives per annum in the US. The global pancreatic treatment market is expected to reach US\$4.11B by 2023.

The present standard of care for pancreatic cancer provides only limited improvements to overall survival, progression-free survival and quality of life. These factors create a great unmet clinical need for pancreatic cancer.

AZT's Chief Scientific Officer, Dr David Kingston said "Tocotrienols, delivered orally, have been shown in both animal and clinical studies to induce programmed cancer cell death (apoptosis) and inhibit transmigration of stem-cell like cancer cells (a key process in the spread of cancer cells or metastasis). IVB003 delivers tocotrienols directly to the target organs and tissues non-invasively through AZT's proprietary and patented transmucosal delivery platform and has a good safety and toxicity profile. We are excited to explore this as a novel way of targeting pancreatic cancer".

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

AZT's IVB003 drug candidate has been through a formal Pre-IND Consultation process with the US FDA and the drug development pathway presented by AZT was broadly endorsed by the FDA.

AZT is also preparing a submission to the FDA for orphan drug status for IVB003 which could potentially secure an additional seven years of market exclusivity for this drug candidate.

AZT's member of the Scientific Advisory Board and leader of the pancreatic cancer program, Professor Richard Pestell AO said, "Pancreatic cancer patients often suffer from pre-operative and post-operative difficulties in digestion (malabsorption) and AZT's IVB003 has the potential to achieve therapeutic levels of tocotrienols in these patients through its non-invasive and direct delivery platform".

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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)