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MEDIA RELEASE

Azure Health Technology completes study protocol for Pancreatic Cancer Phase II clinical study

Sydney, Australia 21 September 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 Pancreatic Adenocarcinoma (Pancreatic Cancer) and has received supportive feedback from Key Opinion Leaders (KOLs).

The protocol relates to a randomised, double-blind, placebo-controlled Phase II clinical study on Pancreatic Cancer to assess the efficacy and safety of IVB003, 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 to 10 sites in Australia. The study has been designed to be able to demonstrate a statistically significant difference between the two arms.

The active pharmaceutical ingredient is a formulation of predominantly delta with a minor component of gamma 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.

Patients diagnosed with locally advanced or metastatic pancreatic adenocarcinoma will be randomised to Standard of Care (SOC) therapy plus IVB003 or SOC plus placebo. Patients will be followed until disease progression, toxicity or investigator's decision to stop therapy.

The Investigational Product will be IVB003 and the matching placebo; 60mg doses of IVB003 will be self-administered sublingually three times a day.

The primary endpoints will be to compare the Progression Free Survival (PFS) and Objective Response Rate (ORR) between SOC plus IVB003 and SOC plus placebo. The secondary endpoint will be to compare Overall Survival (OS) between groups. Additional endpoints will be to compare rates of Complete Response (CR), Partial Response (PR), Stable Disease (SD) and Progressive Disease (PD) between groups based on Recist 1.1 (Response Evaluation Criteria for Solid Tumours Version1.1). This study will also compare the decrease in CA19-9 between groups. CA19-9 is a tumour marker used in the management of pancreatic cancer. Lower values indicate less active disease.

AZT and the Clinical Research Organisation appointed by the Company to manage this study, DataPharm Australia Pty Ltd, are in the advance stages of selecting clinical study

sites. The Investigator's Brochure and draft clinical study protocol have been discussed with KOLs who will lead the clinical studies at these sites.

Dr David Kingston, the Chair of AZT's Scientific Advisory Board and its Chief Scientific Officer, said "The over-whelmingly positive and supportive feedback that AZT has received from KOLs together with the broad endorsement of our study design through a formal Pre-IND Consultation with the US FDA provides AZT with a high level of confidence that there is a compelling case for conducting this clinical study".

Professor Richard Pestell AO, a Member of AZT's Scientific Advisory Board, said "There is encouraging evidence that tocotrienols show activity against pancreatic adenocarcinoma. Gamma and delta tocotrienols have been shown to have activity against pancreatic cancer by targeting a number of cell signalling pathways including NF-Kappaβ, STAT and apoptosis and angiogenic pathways[1]. Husain has published that delta tocotrienol inhibits pancreatic cancer stem-like cells and prevents metastasis[2]. Also in a phase 1 clinical study, delta tocotrienol has been shown to induce apoptosis in human pancreatic cancer cells but not in adjacent normal tissue[3]. Together with the good safety profiles of these molecules and AZT's direct and non-invasive delivery method, the proposed study has exciting potential for the development of an efficacious therapy for pancreatic cancer and I am delighted to support this study".

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.

References:

1. Kannappan R et al. Tocotrienols fight cancer by targeting cancer cell signalling pathways. Genes Nutr. 2017; 7 (1); 43-52

2. Husain K et al. Delta tocotrienol inhibits pancreatic cancer stem-like cells and prevents metastasis. Oncotarget. 2017; 8 (19); 31554-67.

3. Springett G et al. A phase 1 safety, pharmacokinetic and pharmacodynamic presurgical trial of delta tocotrienol in patients with pancreatic ductal adenocarcinoma. EBioMedicine. 2015; 2 (12); 1978-95.

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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.aztht.com.au