

VGI Health Technology Limited – HREC Approval for Pancreatic Cancer Phase II Clinical Study

Sydney, New South Wales, 11 January 2024 – VGI Health Technology Limited is pleased to announce that its wholly owned subsidiary, Invictus Ops Pty Ltd (**Invictus**), has received human ethics approval from the Human Research Ethics Committee of The Peter MacCallum Cancer Centre for its Phase II clinical study in Pancreatic Adenocarcinoma (**Pancreatic Cancer**). The first clinical study site recruited for this study is the Northern Health Network and the Lead Principal Investigator is Dr Belinda Lee, Consultant Medical Oncologist & Head of Cancer Clinical Trials, Northern Health. Dr Lee commented “The Northern Health Network is excited to lead this multi-site Phase II clinical study on **Pancreatic Cancer**. This is one of the most intractable cancers and therefore has a great unmet need that has to be addressed urgently. My team and I are delighted to be working in partnership with Invictus to assess their transmucosal tocotrienol drug candidates for Pancreatic Cancer.”

This study will comprise a multi-centre, randomised, double-blind exploratory efficacy and safety study of Invictus' transmucosal (sublingual) tocotrienols (**IVB003**) or placebo added to standard of care therapy in locally advanced or metastatic pancreatic cancer. The study will enrol eighty **Pancreatic Cancer** patients across at least eight sites in Australia.

Patients will be dosed three times daily with 120mg of IVB003 (a total of 360mg daily dose). The primary endpoint is Progression Free Survival (**PFS**) and the secondary endpoints are the Objective Response Rate (**ORR**), tumour marker CA 19-9 changes and Overall Survival (**OS**).

Pancreatic Adenocarcinoma is the most common form of pancreatic cancer and begins in the cells that line the ducts of the pancreas. This type of cancer is often detected late, spreads rapidly and has a poor prognosis. Pancreatic Cancer is the third largest cause of cancer death in the USA (American Cancer Society), it is usually not diagnosed until late because the early symptoms are non-specific. The 5-year survival of advanced pancreatic cancer is only 12%. The market size for pancreatic cancer medicines is expected to reach \$4.2 billion in 2025 (www.prnewswire.com/newsreleases/pancreatic-cancer-treatment-market-size-worth-42-billion-by-2025-grand-view-research-inc). There is obviously a need for new medicines to improve these survival figures.

Dr David Kingston, the Chief Medical Officer of VGI Health Technology Limited, said “The really exciting thing about this study is there is already evidence from animal and human studies in other groups that orally-administered tocotrienols selectively kill pancreatic cancer cells and leaves the surrounding healthy cells intact, metastasis (the spreading of the cancer cells) is inhibited and the efficacy of a common chemotherapy agent, Gemcitabine, is increased. Consequently, we have good reason to form the view that Invictus' **IVB003**, which has better bioavailability than orally administered tocotrienols, has the potential to perform even better.”

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About VGI Health Technology Limited

VGI Health Technology Limited trading as VGI Health Technology is an Australian public listed company (NSX:VTL). VTL refers to recent announcements about the divestment of its wholly owned subsidiary Invictus BioPharma Pty Ltd. Post completion of this transaction, VTL will be focussed on manufacturing, marketing and selling novel dietary supplements based on natural products (tocotrienols) which have wide therapeutic potential, including: Delayed Onset Muscle Soreness, muscle recovery and exercise endurance. The Company has a product development program for evidence-based nutraceuticals.

For more information see: <https://www.vgiht.com>

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