

VGI Health Technology approves study protocol for NE1-Elite® clinical study in the US

Sydney New South Wales, 13 September 2021 – VGI Health Technology Limited (NSX:VTL) is pleased to announce that its operational subsidiary, Invictus Ops Pty Ltd., has approved a clinical study protocol for a clinical study to be conducted by Altipure R&D in Ohio, USA on its patented nutraceutical product NE1-Elite®.

The clinical study will be led by VTL's Scientific Advisory Board Member Dr Jordan Moon who is an expert in exercise, nutritional, and dietary supplement clinical trials. NE1-Elite® has been shown in previous clinical studies to reduce Delayed Onset Muscle Soreness (DOMS), improve muscle recovery after exercise and maintenance of peak muscle power. The first part of the present study will be a randomised, double-blind and placebo-controlled study on 30 healthy volunteers. The subjects will be administered one 40mg dose of NE1-Elite® per day for 21 days or a placebo. The primary endpoint will be a reduction of muscle soreness with secondary endpoints being reduction in muscle swelling after heavy exercise, improvement of muscle function, improvement in force development and strength in both lower and upper body following high effort and heavy exercise.

A second part of the clinical study will assess the pharmacokinetics and bioavailability of NE1-Elite®. The study will involve three arms with 8 healthy volunteers in each arm. The three arms will be administered 40mg of a previous formulation of NE1-Elite®, 40mg of the current formulation of NE1-Elite® and 80mg of the current formulation of NE1-Elite®. The objective of this study is to assess the bioequivalence between a previous formulation of NE1-Elite® and the current formulation of NE1-Elite® and also assess the upper limit of dosage using VTL's MELT3™ technology.

VTL's Chief Scientific Officer and Chair of the Scientific Advisory Board, Dr David Kingston said "This study, which was developed and will be led by Dr Moon as Principal Investigator, will greatly strengthen the clinical evidence that VTL has to substantiate the marketing claims for NE1-Elite® and add to the considerable body of data that we already have on the pharmacokinetics and bioavailability of tocotrienols delivered using our MELT3™ platform. We are delighted that a well-recognised expert in exercise and sports nutrition clinical studies like Dr Moon has agreed to lead this study as Principal Investigator."

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About VGI Health Technology Limited

VGI Health Technology Limited trading as VGI Health Technology is an Australian public listed biotechnology company (NSX:VTL) 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. VTL 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: <https://www.vgiht.com>

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