

ASX Announcement | 24 January 2022  
Vioneering Technologies (ASX:VTI)

## Vioneering Technologies Initiates Landmark International Clinical Trial of NaturalVue® Multifocal Contact Lens in Myopia Progression Control

Company believes trial will be an important value driver beginning with the release of interim 1-year data in mid-2023

### Highlights:

- VTI has enrolled the first patient in its international randomised controlled clinical trial (RCT) to test its NaturalVue® Multifocal Contact Lenses in myopia progression control
- Study data expected to solidify the Company's strong international market leadership in myopia progression control
- Important interim 1-year data expected mid-2023

**Atlanta, Georgia, Sunday, 23 January 2022 (Sydney Monday, 24 January 2022):** US-based medical device company and pioneer in myopia progression control, [Vioneering Technologies, Inc \(ASX: VTI\)](#) ('Vioneering', 'VTI' or 'the Company'), today announced that the first patient has completed the initial visit in its landmark international multi-center study to provide an additional measure of the effectiveness of its NaturalVue® (etafilcon A) Multifocal 1-Day Contact Lenses ('NaturalVue MF') for myopia progression control. The study, referred to as '**PROTECT**' (**PRO**gressive Myopia **T**reatment **E**valuation for NaturalVue Multifocal **C**ontact Lens **T**rial), is a multi-center, randomised, double-masked clinical trial with participating investigators in centers in Canada, the United States, and Hong Kong.

The trial is designed to enroll 144 healthy nearsighted children (myopes) of 7 to 13 years of age whose current prescription is between -0.75D and -5.00D. Participants will be randomly assigned to wear NaturalVue Sphere single vision contact lenses (the control lens) or NaturalVue Multifocal contact lenses (the test lens). Primary outcomes will be determined by the changes in refractive error progression and eye length over time, both important markers of myopia progression. One-year follow-up data has been shown to be a strong predictor of the overall outcomes in other myopia control studies. VTI expects that the data will demonstrate the superiority of NaturalVue MF over the control in managing myopia progression, thus providing an important data point for practitioners and VTI's corporate partnering activities. One-year follow up data is expected to be released mid-2023, with longer-term data expected mid-2024 and mid-2025.

**VTI's Chief Medical Officer, Dr. Ashley Tuan, commented:** "With 2 billion myopes in the world, and 5 billion expected by 2050, now is a prime time for VTI to be at the forefront of innovation, development, and clinical validation in this industry. We are an early leader in the rapidly expanding area of myopia progression

control, with safe and effective products that are available in over eleven countries. The results from PROTECT will allow us to have head to head comparison in terms of treatment effectiveness against other products that went through similarly designed multicentered studies. The results from PROTECT, starting with the 1-year interim results in mid-2023, will add to our extensive real-world data, providing practitioners and parents with greater knowledge of their choices in the management of paediatric myopia.”

**VTI non-executive Chairman, David J. Mazzo, added:** "Myopia is a pressing global health issue that negatively impacts the quality of life of billions of children, with up to 90% of children in some Asian nations and over a quarter of children in the US being myopic. Additionally, the degree of near-sightedness reached by the end of childhood correlates to a lifetime risk of blindness and other debilitating eye diseases, so limiting the progression of myopia in childhood is an important part of myopia management. We anticipate that the results of the PROTECT study, starting with the interim 1-year data, will convince greater numbers of practitioners and parents worldwide to use NaturalVue MF as a key part of myopia management."

PROTECT represents VTI’s renewed commitment to invest in research and development and to leverage its leadership position in the rapidly growing area of myopia progression control. The news of the study’s initiation comes on the heels of VTI’s recent release of 6-year real-world data on the impact of its NaturalVue MF in children with myopia (see [ASX release on 4 November 2021](#)). That study showed the significant positive impact of NaturalVue MF in 196 real-world subjects followed over up to six years in 15 practices<sup>1</sup>. The data showed that 95% of subjects wearing NaturalVue MF experienced a decrease in myopia progression, and 78% of wearers had a decrease in myopia progression of 70% or greater. The average myopia progression slowed by approximately 0.85D or 85% compared to baseline, which was statistically significant at all points in time (P<0.05.) The average myopia progression while wearing NaturalVue MF never exceeded more than about 0.25D from baseline. Eye experts generally believe that minimizing the progression of myopia is a critical intervention aimed at minimising lifetime risks of blindness and other serious ocular diseases related to myopia. VTI expects that the results of its rigorous PROTECT study will corroborate the belief that NaturalVue MF slows myopia progression and is an excellent choice for the management of myopia.

**Ends**

**This release was authorized by the CFO, Brian Lane.**

**For more information, please contact:**

<i><b>Company</b></i>	<i><b>Investor and media relations</b></i>
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### **About Visioneering Technologies**

Visioneering Technologies Inc. (ASX:VTI) is an innovative eye care company committed to redefining vision. A pioneer in myopia management, VTI merges advanced engineering with a relentless drive to achieve superior results for patients and practitioners. VTI’s flagship product is the NaturalVue® (etafilcon A) Multifocal 1-Day Contact Lens, an extended depth of focus lens that is one of the most significant innovations in the eye care industry in more than 20 years. For more information, please visit

[www.vtvision.com](http://www.vtvision.com).

### Foreign ownership restrictions

VTI's CHES Depositary Interests (**CDIs**) are issued in reliance on the exemption from registration contained in Regulation S of the US Securities Act of 1933 (**Securities Act**) for offers that are made outside the US. Accordingly, the CDIs have not been, and will not be, registered under the Securities Act or the laws of any state or other jurisdiction in the US. As a result of relying on the Regulation S exemption, the CDIs are 'restricted securities' under Rule 144 of the Securities Act. This means that you are unable to sell the CDIs into the US or to a US person for the foreseeable future except in very limited circumstances after the expiration of a restricted period, unless the re-sale of the CDIs is registered under the Securities Act, or an exemption is available. To enforce the above transfer restrictions, all CDIs issued bear a 'FOR US' designation on the Australian Securities Exchange (**ASX**). This designation restricts any CDIs from being sold on ASX to US persons. However, you are still able to freely transfer your CDIs on ASX to any person other than a US person. In addition, hedging transactions with regard to the CDIs may only be conducted in accordance with the Securities Act.

### Forward-Looking Statements

This announcement contains or may contain forward-looking statements that are based on management's beliefs, assumptions and expectations and on information currently available to management.

All statements that address operating performance, events or developments that we expect or anticipate will occur in the future are forward-looking statements. These include, without limitation, U.S. commercial market acceptance and U.S. sales of our product, as well as our expectations with respect to our ability to develop and commercialize new products.

Management believes that these forward-looking statements are reasonable when made. You should not place undue reliance on forward-looking statements because they speak only as of the date when made. VTI does not assume any obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise. VTI may not actually achieve the plans, projections or expectations disclosed in forward-looking statements. Actual results, developments or events could differ materially from those disclosed in the forward-looking statements.

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<sup>1</sup> Benoit, DP; Dillehay, SM. (2021, November 4). New Clinical Evidence Through 6 years: NaturalVue Multifocal for Myopia Management [Poster]. American Academy of Optometry, Boston. <http://www.aaopt.org>.