

## ASX Announcement | 19 January 2024 Visioneering Technologies (ASX:VTI)

# VTI Continues Release of 1-Year Data from the ongoing PROTECT Clinical Trial for Myopia Progression Control at the Global Specialty Lens Symposium

No Meaningful Progression of Myopia in 2/3 of Patients in NaturalVue® Multifocal 1 Day Contact Lenses

#### **Highlights:**

- New and updated data released:
  - 45% of patients had no progression (change <= 0 Diopters ("D")) and ~2/3 of patients or 64% experienced no meaningful progression of myopia (defined as -0.25 D or less of progression per year).
  - o 71% or 0.41 D reduction in refractive error progression, versus the control group.
    - Children wearing NaturalVue Multifocal Contact lenses showed an average refractive error change of 0.18 D.
  - 0.17mm or 61% average reduction in axial elongation, versus the control group.
    - The average axial length change in children wearing NaturalVue Multifocal Contact lenses was 0.11 mm.
- The 1-year results of the NaturalVue Multifocal 1 Day contact lenses are observed to be consistent with those of the only treatment approved by the U.S. Food and Drug Administration (FDA) for myopia progression control.
- This 1-year data set corroborates the NaturalVue Multifocal 1 Day real-world data analyses.

The PROTECT study is ongoing and data will continue to be reviewed, analyzed, and shared as available.

<u>Visioneering Technologies, Inc.</u> (ASX:VTI) ('Visioneering,' 'VTI' or 'the Company'), producer of the NaturalVue<sup>®</sup> Multifocal 1 Day Contact Lenses (NVMF), announces the full 1-year results of its ongoing multi-center, double-masked, randomized controlled trial (RCT). **PROTECT** (<u>PROgressive Myopia Treatment Evaluation for NaturalVue Multifocal Contact Lens Trial) is designed to demonstrate the safety and effectiveness of NVMF for myopia progression control in children. PROTECT is a 3-year study with interim analyses planned after the 1-year and 2-year marks.</u>

The 1-year data shows that 45% of subjects in the test group had no myopia progression at all and nearly two-thirds of subjects in the test group, or 64%, experienced no meaningful progression (defined as 0.25D or less per year).

Analysis of the full data set\* re-confirmed previously released results regarding axial length and refractive error change (minimal and insignificant changes noted). Children wearing NVMF contact lenses showed an average myopia change of 0.17 D. The average refractive error reduction was 71%, or 0.41 D vs. control group. The average axial length reduction was 61%, or 0.17 mm vs. control group. Children wearing NVMF contact lenses showed an average axial length change of 0.11 mm.



Combined with the 6-year data published in Clinical Ophthalmology (2022)<sup>1</sup> and two other independent studies published in 2023<sup>2,3</sup>, this one-year data supports that NVMF effectively manages eye growth and refractive error change among progressing myopic children in diverse populations and clinical settings. To date, a low drop-out rate of 4% has been reported.

One-year data from studies of similar design to PROTECT have been predictive of the final 3-year results. The PROTECT study data will continue to be reviewed and analyzed with additional details to be shared as available. The final results of the study and any regulatory uses thereof will be based on the analysis of the complete 3-year data set.

#### VTI Chief Medical Officer, Dr. Ashley Tuan, commented:

"Further analysis of the full data set indicates that initial results announced in October are holding, further validating our confidence in the safety and effectiveness of NaturalVue Multifocal Contact Lenses for patients. NaturalVue Multifocal 1 Day also provides clear vision for myopia correction and effectively slows myopia. The interim 1-year treatment effects are consistent with those of the only treatment approved by the FDA for myopia progression control, which we view as a positive result. We look forward to sharing more data from the study in the future."

#### Chief Executive Officer and Executive Director of VTI, Dr. Juan Carlos Aragón, added:

"Now that we have the full data set analysis, we are excited that eye care professionals around the world have a strong myopia intervention that provides excellent vision for patients while also helping to slow the progression of their patients' myopia."

VTI expects to release longer-term 2- and 3-year data when available.

\* Note: This reflects the 1-year data set. The PROTECT study is ongoing and data will be reviewed, analyzed, and shared as available. Data is based on a modified PP (Per Protocol) analysis including children between ages 8 and <13 with refractive error between -0.75 and -4.00 D versus age-matched controls wearing spherical lenses.

This information may describe uses for this product, i.e., Myopia Progression Control, which have not been approved by the FDA for use in the United States. It is intended for educational purposes only. NaturalVue<sup>®</sup> Multifocal is part of an ongoing randomized clinical trial (RCT) studying its effectiveness for myopia progression control.

- 1. Cooper J, Aller T, Smith EL 3rd, Chan K, Dillehay SM, O'Connor B. Retrospective Analysis of a Clinical Algorithm for Managing Childhood Myopia Progression. Optom Vis Sci. 2023 Jan 1;100(1):117-124.
- 2. Lederman, CR. Myopia Control With Extended Depth of Focus Multifocal Contact Lenses. In: American Association for Pediatric Ophthalmology and Strabismus; 2023 Mar 29; New York, USA.
- 3. Walline JJ, Walker MK, Mutti DO, et al. Effect of High Add Power, Medium Add Power, or Single-Vision Contact Lenses on Myopia Progression in Children: The BLINK Randomized Clinical Trial. JAMA. 2020;324(6):571–580. doi:10.1001/jama.2020.10834

#### **Ends**

### This release was authorized by the CEO, Dr. Juan Carlos Aragón.

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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 presbyopia and 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) Enhanced Multifocal 1-Day Contact Lens, an extended depth of focus lens that the Company believes is one of the most significant innovations in the eye care industry in more than 20 years. For more information, please visit <a href="https://www.vtivision.com">www.vtivision.com</a> or call +1 844-884-5367, ext. 104.

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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.

Given the current uncertainties regarding the on-going impact of COVID-19 on the trading conditions impacting VTI, the financial markets and the health services world-wide, there can be no assurance that future developments will be in accordance with VTI's expectations or that the effect of future developments on VTI will be those anticipated.

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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