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New Data from VTI's PROTECT Clinical Trial for Myopia Progression Control Presented at ARVO

58% of Patients had Similar Physiological Axial Length Growth as Age-Related Emmetropic Children

Highlights:

- New data released:
 - The majority (58%) of patients had similar physiological axial length growth as age-related emmetropic children
 - Average daily wearing time with NaturalVue was 11-12 hours per day, equal to control (single vision lenses) and greater than study protocol (10 hours/day, 6 days/week)
 - These longer wearing times indicate that vision and comfort were acceptable to children and strongly supported compliance.
 - The compliance factor for children in the PROTECT study is a contributor to the strong efficacy results reported.
 - To date, a low drop-out rate of 4% has been reported.
- These new data points further support that NaturalVue may effectively manage eye growth and refractive error change among children under diverse clinical settings and populations.

The PROTECT study is ongoing and data will continue to be reviewed, analyzed, and shared as available. Data presented here are limited by the range of age, race, geographical locations and study duration.

Seattle, Washington, 6 May 2024: [Visioneering Technologies, Inc \(ASX:VTI\)](#) ('Visioneering,' 'VTI' or 'the Company'), producer of the NaturalVue® Multifocal 1 Day Contact Lenses (NVMF), continued its release of the 1-year prospective data of its ongoing multi-center, randomized, double-masked, controlled trial (RCT) at the Association for Research in Vision and Ophthalmology (ARVO) today. **PROTECT (PROgressive Myopia Treatment Evaluation for NaturalVue Multifocal Contact Lens Trial)** was designed to demonstrate the safety and effectiveness of NVMF for myopia progression control in children. PROTECT is a 3-year study involving 145 children with analyses planned after the 1-year and 2-year marks.

Dr. Ashley Tuan, Chief Medical Officer for VTI, presented new data from the PROTECT trial that focused on details of axial length and wearing time. Dr. Tuan also summarized data released earlier in the year on refractive error change and reduction. The poster entitled, "A Randomized Controlled Trial for Myopia Progression Control Using Catenary Power Profile Contact Lenses: 12-month Effectiveness and Safety," was prepared by Dr. Tuan and Dr. Sally Dillehay.

The new data that outlines the distribution of change in axial length (mm) in patients showed that 58% of patients wearing NaturalVue had axial growth similar to age-matched emmetropic children. This data point, especially when paired with the previously release distribution of change in refractive error

(D) data showing that 2/3 of patients or 64% experienced no meaningful progression of myopia (defined as -0.25 D or less of progression) further suggests NaturalVue Multifocal may effectively manage myopia among children under diverse clinical settings and populations.

Compliance is believed to be essential for myopia control success and is influenced by the quality of vision and comfort.¹ Given that children on average wore NaturalVue for 11-12 hours per day is indicative that the lens provides excellent vision and comfort and a positive quality of life experience. We believe that these factors did contribute to the positive results seen thus far in the PROTECT study.

In addition to the new learnings listed above, the 1-year data set has revealed the following results thus far:

- 45% of patients had no progression (change ≤ 0 Diopters (“D”)) and $\sim 2/3$ of patients or 64% experienced no meaningful progression of myopia (defined as -0.25 D or less of progression per year).
- 71% or (0.41D) 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.

One-year data from studies of similar design to PROTECT have been predictive of the final 3-year results.² 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:

“For the majority of patients, the study showed that NaturalVue held axial length growth to that of age-matched emmetropic children. Additionally, the wearing time results are important as these are directly related to the results seen across the study. These new data continue to validate our confidence in the effectiveness of NaturalVue Multifocal Contact Lenses. NaturalVue Multifocal 1 Day will continue to mine the study and share results with the industry and eye care practitioners around the world.”

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

“As we continue to glean new learnings from this extensive data set, it is evident that NaturalVue represents a powerful tool for eye care practitioners to use to manage myopia. These results should provide confidence to both eye care practitioners and parents that NaturalVue will provide excellent vision for patients while also helping to slow the progression of patients’ myopia.”

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

To download a Fact Sheet summarizing the findings to date, [click here](#).

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 www.vtivision.com or call +1 844-884-5367, ext. 104.

* Note: This reflects the 1-year data set. The PROTECT study is ongoing and data will be reviewed, analyzed, and shared as available. Data presented here are limited by the range of age, race, geographical locations and study duration. 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. SD = standard deviation

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® Multifocal is part of an ongoing randomized clinical trial (RCT) studying its effectiveness for myopia progression control.

1. Bullimore MA, Jong M, Brennan NA. Myopia control: Seeing beyond efficacy. *Optom Vis Sci.* 2024 Mar 1;101(3):134-142. doi: 10.1097/OPX.0000000000002119. PMID: 38546754.
2. Brennan N, Toubouti Y, Cheng X et al. Efficacy in myopia control. *Progress in Retinal and Eye Research* 83 (2021) 100923

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