

ASX Announcement | 16 January 2025 Visioneering Technologies (ASX:VTI)

Visioneering Announces Positive Interim 2-Year Data for their NaturalVue® Multifocal 1 Day Contact Lens from the PROTECT Multi-center, Randomized, Double-Masked Clinical Trial for Myopia Progression Control

Key Highlights:

- **Study Design:** PROTECT is a three-year multicenter, randomized, double-masked clinical trial (RCT) that adheres to the highest scientific standards for pediatric myopia control.
- Year 2 Findings so far:
 - Preliminary data shows sustained myopia progression control from both refractive error (0.60 D) and axial length (0.25 mm)* perspectives.*
 - Results align with the treatment effects of the only FDA-approved therapy for myopia progression control.*
- Real-World Corroboration: Findings reinforce prior real-world data and six-year studies on NaturalVue Multifocal 1 Day contact lenses.
- **Safety and Comfort:** The study reports a low dropout rate, which is attributed to the lenses' comfort and vision performance.

Visioneering Technologies, Inc. (ASX: VTI), manufacturer of NaturalVue® (etafilcon A) Multifocal 1 Day Contact Lenses, today announces the preliminary year 2 data from the ongoing PROTECT (<u>PROgressive Myopia Treatment Evaluation for NaturalVue Multifocal Contact Lens Trial</u>) study. The results will be presented at the Global Specialty Lens Symposium (**GSLS**) in Las Vegas on Thursday, 16 January 2025 (US time). Dr. Ashley Tuan, VTI's Chief Medical Officer, will share these results during her presentation, entitled "The Latest Findings from the PROTECT Myopia Management RCT".

The preliminary two-year data highlight the safety and efficacy of NaturalVue Multifocal 1 Day Contact Lenses in managing myopia progression in children. The results demonstrate a significant reduction in refractive error and axial length growth compared to the control group. The two-year adjusted treatment effect* in refractive error progression was 0.60 D (diopters), representing a 53% reduction compared to the control group. The two-year adjusted treatment effect* in axial length elongation was 0.25 mm, indicating an 86% retardation relative to the control group. Both two-year adjusted treatment effect values are consistent with the two-year values achieved by the only FDA-approved therapy for myopia progression control in a separate study

Combined with previously published six-year retrospective (real-world) data in Clinical Ophthalmology (2022) and independent studies released in September 2023, these findings affirm NaturalVue



Multifocal's effectiveness in controlling myopia progression in children.

VTI remains committed to analyzing and sharing additional details as the study progresses. This announcement of the preliminary 2-year data follows the release of the interim 1-year data (refer to ASX announcements on 10 and 13 October 2023) and the full 1-year results (refer to ASX announcement on 19 January 2024.)

Looking Ahead:

VTI expects to release more detailed 2-year data and the 3-year data when available. These findings, combined with earlier data from independent studies, support NaturalVue Multifocal's effectiveness in controlling myopia progression across diverse patient populations thus far.

About PROTECT

'PROTECT' (PROgressive Myopia Treatment Evaluation for NaturalVue Multifocal Contact Lens Trial) is a 3-year, prospective, double-masked multi-national trial evaluating the safety & effectiveness of NaturalVue® Multifocal Contact Lenses for slowing myopia progression (participating investigators in the United States, Canada, Hong Kong, and Singapore) involving 145 kids.

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.

*Data is based on 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. Adjusted data was equalized for key variables such as age, sex, and pupil size. Results noted actual values (vs. percentage; in diopters for refractive error and millimeters for axial length) that better represent the treatment effect which is helpful when comparing across studies.

Note: this announcement may describe uses for NaturalVue®, i.e., myopia progression control, which has not been approved by the FDA for use in the United States. As stated above, NaturalVue® Multifocal is part of an ongoing randomized clinical trial (RCT) studying its effectiveness for myopia progression control.

Ends

This release was authorized by the CEO, Dr. Juan Carlos Aragón. For more information, please contact:

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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. To the extent applicable, these may include, without limitation, commercial market acceptance of NaturalVue® Multifocal Contact Lenses and its adoption for the correction of pediatric myopia.

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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