

For More Information:

Layna L. Mendlinger info@vtivision.com

For immediate release

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

Visioneering Technologies, Inc. Highlights Myopia Management Advancements with NaturalVue® Multifocal from Ongoing PROTECT Study at GSLS

Las Vegas, Nevada, January 16, 2025: Visioneering Technologies, Inc. (ASX: VTI), manufacturer of NaturalVue® (etafilcon A) Multifocal 1 Day Contact Lenses, presented preliminary year 2 data from the ongoing 3-year PROTECT (PROgressive Myopia Treatment Evaluation for NaturalVue Multifocal Contact Lens Trial) study at the Global Specialty Lens Symposium (GSLS). Dr. Ashley Tuan, VTI's Chief Medical Officer, shared the glimpse of preliminary data during her presentation, entitled "The Latest Findings from the PROTECT Myopia Management RCT".

Year 2 Preliminary Data Highlights:

- 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.

The 2-year data underscores 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 Dr. Tuan also shared a summary from the year 1 data set.

PROTECT Year 1 Data Summary:

- Vision & Comfort:
 - Maintained 20/20 or better high-contrast visual acuity at all distances, comparable to spectacles, with no clinically significant low-contrast reduction.

30 Mansell Court • Suite 215 • Alpharetta, GA 30076 • 1-844-VTI-LENS (1-844-884-5367)



- Results from the validated Patient-Reported Outcome PREP2** showed that children reported the same high level of satisfaction as those wearing single-vision contact lenses, with no perceived trade-offs in vision or comfort.
- o Preserved stereoacuity.
- Astigmatic compatibility.
 - Indicated to correct up to 2.00 D of astigmatism.
 - Demonstrated efficacy to correct 100% astigmatism at 2.00 D and 83% at 3.00 D¹
- **Normalized accommodative accuracy.** To date, children have achieved relief from accommodative stress and improved performance for near tasks and digital device usage.
- Continuous Treatment Effect Across Pupil Sizes: Proven efficacy through year 1 across pupil sizes
 (2–7 mm), ideal for children active outdoors or on digital devices. Nearly 2/3 of children achieved nearemmetropic change.

Combined with previously published six-year retrospective data and independent studies, these findings affirm NaturalVue Multifocal's effectiveness in controlling myopia progression.

"Year 1 findings from the 3-year trial demonstrate clear vision, safety, and comfort, leading to high compliance and effective outcomes and we expect to see this continue as we analyze more of the year 2 data", said **Dr. Ashley Tuan, VTI's Chief Medical Officer.**"

Chief Executive Officer and Executive Director of VTI, Dr. Juan Carlos Aragón concluded, "Based on the results from all recent clinical studies, NaturalVue Multifocal may be the only myopia management lens that can reduce vision challenges in all types of children."

To download a Fact Sheet summarizing the findings to date, click here.

Looking Ahead:

VTI plans to release year 2 data from the 3-year PROTECT trial in early 2025. These findings, combined with earlier data from independent studies, support NaturalVue Multifocal's effectiveness in controlling myopia progression across diverse patient populations thus far.

Looking Ahead:

VTI expects to release more detailed 2-year and 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.

Note: This reflects the 1-year data set (of a 3-year study). 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 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.

**Pediatric Refractive Error Profile 2

This information may describe uses for this product, i.e., Myopia Progression Control, which has 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.

References

1. Carracedo, G. Evaluation of Visual Acuity with Multifocal Catenary Curve-Based Contact Lens Design in Different Degrees of Astigmatism. Poster presented at Global Specialty Lens Symposium; January 17, 2025; Las Vegas, NV, USA.

VTI-RCT-PR8