

ASX Announcement | 4 November 2021
Visioneering Technologies (ASX:VTI)

6-Year Myopia Progression Data for NaturalVue Multifocal Announced at American Academy of Optometry's Annual Meeting

- Retrospective cohort analysis - 196 real-world subjects, 6 years of data, 15 practices
- 95% of subjects showed a decrease in myopia progression, with 78% showing a decrease of 70% or more, as compared to baseline
- The average rate of myopia progression slowed by 85% as compared to baseline from 6-72 months
- Axial lengthening was slowed to normal rate of change expected for non-myopic children of a similar age range

Atlanta, Georgia, Thursday, 4 November 2021 (Sydney Friday, 5 November 2021): US-based medical device company and producer of the NaturalVue® Multifocal 1 Day Contact Lenses ('NaturalVue MF') **Visioneering Technologies, Inc (ASX: VTI)** ('Visioneering', 'VTI' or 'the Company') announced the positive results of an extensive, retrospective cohort analysis spanning over six years, on the impact of its NaturalVue MF in children with myopia, or near-sightedness. VTI's NaturalVue MF contact lenses feature the innovative Neurofocus Optics® Technology, which uses an extended-depth-of-focus design to address known optical risk factors associated with the progression of myopia.

The study results were released at the **American Academy of Optometry's** annual meeting in Boston, MA, USA, and documents findings in 196 real-world subjects followed over six years in 15 practices¹. The data showed that 95% of subjects wearing NaturalVue MF experienced a decrease in myopia progression as compared to baseline; additionally, 78% of wearers showed 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.

An age and ethnicity matched group of children ($N=188$) would have been expected to progress by -1.09D if not wearing NaturalVue MF,²⁻⁶ versus -0.06D observed with NaturalVue MF over 3 years - a difference of greater than 1.00D less myopia increase with NaturalVue MF. Every 1 Diopter less of myopia means much better vision and a 40% decrease in risk of a major cause of vision loss across a lifetime.⁷ 67% of the children had complete halting of myopic progression during the period of the study.

Myopia progression is caused by eyes growing abnormally in length from front to back which is termed "axial length." Axial length change was measured for a subset of the study subjects.** Significantly, the average axial elongation change was approximately 0.10 mm per year through 47 months of follow-up, which approximates that expected for a non-myopic child of a similar age range⁸ and shows that NaturalVue MF contact lenses help to reduce the anatomical cause of myopia progression.¹ To be able to compare the effectiveness of NaturalVue MF to changes observed in children not wearing the lenses, an age and ethnicity matched virtual control group ($N=188$) developed from 63 randomized clinical trials was used.²⁻⁶ This analysis demonstrated a Cumulative Absolute Reduction of axial Elongation (Termed a 'CARE' value) of 0.44 mm less

axial elongation over 3 years for NaturalVue MF than would be expected for age and ethnicity matched children.²⁻⁶ The CARE value for NaturalVue MF compares very favorably to those of other myopic progression interventions such as orthokeratology lenses, with a CARE value of 0.44 over 7 years, or other soft contact lenses with a CARE value of 0.30 at 3 years.⁹

These findings are particularly significant in that the number of children with myopia has continued to increase, with a 3x Increase in myopia prevalence during the 2020 coronavirus pandemic.¹⁰ Another study found that school-aged children are now spending 7+ hours per week using computers and mobile video games, which tripled their risk for myopia.¹¹ These factors have far-reaching implications since myopia has been identified as the second leading cause of blindness globally,¹² and has been shown to be associated with increased risks of myopic macular degeneration, retinal detachment, glaucoma, and cataract.¹³

This retrospective analysis shows real-world results with the NaturalVue Multifocal 1 Day contact lens in slowing or stopping myopia progression, and for the first time, the impact of NaturalVue MF in slowing axial length growth in myopic children. These data are helpful to eye care practitioners and parents in deciding which intervention to recommend for a patient. The small number of subjects for the axial length data is an acknowledged limitation of the study.

To provide the eye care community and potential corporate partners with additional data, VTI will soon initiate in the US, Canada, and Hong Kong, a double-blinded, randomized, and controlled study of NaturalVue MF in myopic children, with 1-year data, expected mid-2023.

“Nearly 5 billion people are predicted to be affected by myopia by 2050,¹⁴ with a large number of them being children. Combined with the enormous medical and economic costs of treating serious eye diseases that potentially come with myopia, myopia deserves the respect of a global epidemic,” said Stephen Snowdy, PhD, VTI CEO and Executive Director. “These data combined with VTI’s recently granted patents in the US and China, and other major markets, further strengthen VTI’s position as a leader in managing myopia in children.”

Ends

This release was authorized by the CEO, Stephen Snowdy, PhD.

For more information, please contact:

<i>Company</i>	<i>Investor and media relations</i>
Stephen Snowdy CEO, Visioneering Technologies, Inc. Email: ssnowdy@vtivision.com	Haley Chartres H^CK Digital Tel: +61 423 139 163 Email: haley@hck.digital

About Visioneering Technologies

Visioneering Technologies Inc. (ASX:VTI) is an innovative eye care company committed to redefining vision. Since its founding in 2008, Visioneering has brought together clinical, marketing, engineering, manufacturing, and regulatory leaders from top vision care businesses to provide new solutions for presbyopia, myopia, and astigmatism.

Headquartered in the US, Visioneering designs, manufactures, sells, and distributes contact lenses. Its flagship product is the NaturalVue® Multifocal contact lens, and VTI has expanded its portfolio of technologies to address a range of eye care issues. The company has grown operations across the United States, Australia, and Europe and is expanding into Asia with a focus on markets with high rates of myopia.

About the American Academy of Optometry

The American Academy of Optometry (AAO) inspires excellence in optometric practice by fostering research and disseminating knowledge in vision science through its journal, Optometry, and Vision Science, and the continuing education presented at its annual meeting. Fellows of the Academy are committed to the premise that learning is a lifelong obligation of a professional, as is the commitment to expand the profession's knowledge base through ongoing fellowship and exchange. For more information, visit the website: <http://www.aaopt.org>.

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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. These include, without limitation, ⁱ 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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**Data was less for axial length measurements due to lack of measurement instrumentation available in some practices at the time the study began. Data calculated through 3 years (35 months) in a smaller sample.

¹ 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>.

² Myopia Profile. How Can We Set Myopia Control Expectations? <https://www.myopiaprofile.com/how-can-we-set-myopia-control-expectations/>. Accessed July 16, 2021.

³ Brennan N, Cheng X, Toubouti Y, Bullimore M. Influence of Age and Race on Axial Elongation in Myopic Children. *American Academy of Optometry* 2018: E-Abstract 180072. <https://www.aaopt.org/detail/knowledge-base-article/influence-of-age-and-race-on-axial-elongation-in-myopic-children>. Accessed July 16, 2021.

⁴ Meng W, Butterworth J, Malecaze F *et al.* Axial length of myopia: a review of current research. *Ophthalmologica* 2011;225(3):127-134.

⁵ Parssinen O, Kauppinen M, Viljanen A. The progression of myopia from its onset at age 8-12 to adulthood and the influence of heredity and external factors on myopic progression. A 23-year follow-up study. *Acta Ophthalmol* 2014;92(8):730-739.

⁶ Johnson & Johnson Vision. Managing Myopia A Clinical Response to the Growing Epidemic. https://s3-us-west-2.amazonaws.com/covalentcreative/jjv/media/documents/Managing_Myopia_Clinical_Guide_Dec_2020.pdf. Accessed July 17, 2021.

⁷ Bullimore MA, Brennan NA. Myopia Control: Why Each Diopter Matters. *Optom Vis Sci*. 2019 Jun;96(6):463-465.

⁸ Zadnik, K; Mutti, D O; Mitchell, L G; Jones, L; Burr, D; Moeschberger, M. PhD Normal Eye Growth in Emmetropic Schoolchildren, *Optometry and Vision Science*: November 2004 - Volume 81 - Issue 11 - p 819-828
doi: 10.1097/01.OPX.0000145028.53923.67

⁹ Brennan N. Why 'CARE' for Myopia. <http://reviewofmm.com/why-care-for-myopia/>. Accessed October 1, 2021

¹⁰ Wang J, Li Y, Musch DC, et al. Progression of Myopia in School-Aged Children After COVID-19 Home Confinement. *JAMA Ophthalmol*. 2021;139(3):293–300. doi:10.1001/jamaophthalmol.2020.6239.

¹¹ Saxena R, Vashist P, Tandon R, Pandey RM, Bhardawaj A, Gupta V, et al. (2017) Incidence and progression of myopia and associated factors in urban school children in Delhi: The North India Myopia Study (NIM Study). *PLoS ONE* 12(12): e0189774.
<https://doi.org/10.1371/journal.pone.0189774>

¹² Holden BA, Wilson DA, Jong M, et al. Myopia: a growing global problem with sight-threatening complications. *Community Eye Health*. 2015;28(90):35.

¹³ Flitcroft DI. The complex interactions of retinal, optical and environmental factors in myopia aetiology. *Prog Retin Eye Res*. 2012;31(6):622-660.

¹⁴ Holden BA, Fricke TR, Wilson DA, Jong M, Naidoo KS, Sankaridurg P, Wong TY, Naduvilath TJ, Resnikoff S. Global prevalence of myopia and high myopia and temporal trends from 2000 through 2050. *Ophthalmology*. 2016;123(5):1036-1042.