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**ASX Announcement** 

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# Clinical Research Update of 141 Children Wearing Natural Vue Multifocal Presented At Global Specialty Lens Symposium (GSLS)

Data Consistently Shows 90% Decrease in Myopic Progression Refractive Error in a Large Sample Followed for up to 4 years

## **Highlights of the Clinical Research Update**

- Updated data with 141 children wearing NaturalVue Multifocal for up to 4 years, demonstrated approximately 90% decrease (1.00 Diopters) in myopic progression refractive error (RE) consistently at each time point examined
- Additionally, in a subset of 36 children, axial length (AL) progression decreased by 54.8%, a
  decrease in progression of 0.23 mm, at the 12-17 month point

Las Vegas, Nevada, 26 January 2019: US-based medical device company and producer of the NaturalVue® (etafilcon A) Multifocal 1 Day Contact Lenses Visioneering Technologies, Inc (ASX: VTI) ('Visioneering' or 'The Company') has presented at the Global Specialty Lens Symposium (GSLS) an update of clinical data of 141 children wearing NaturalVue Multifocal and followed for up to 4 years.

Pediatric Myopia, or nearsightedness in children, has undergone explosive growth on a global scale over the past four decades and has become a major worldwide eye health issue. Eye experts generally believe that minimizing the progression of nearsightedness is an important intervention aimed at minimizing life-time risks of blindness and other serious ocular diseases that are related to nearsightedness. Based in part on the clinical research presented at GSLS, Visioneering Technologies, Inc., the makers of NaturalVue® (etafilcon A) Multifocal 1 Day Contact Lenses, believe their product helps to slow the worsening of myopia, and markets the lenses internationally.

Previously, multiple eye care practices contributed to a publication of peer-reviewed data showing that NaturalVue Multifocal slowed the progression of nearsightedness by 96% on an annualized basis in a cohort of 32 children. Similar data on a second cohort of 27 children were presented at GSLS in 2018. At GSLS 2019 held this past week, several of the same investigators updated the dataset to include additional children in the retrospective observational case series. The key investigators included Jeffrey Cooper MS, OD, FAAO, Professor Emeritus SUNY College of Optometry (New York), Brett O'Connor, OD, FAAO (Florida), Thomas Aller, OD, FBCLA, Visiting Scholar, University of California, School of Optometry (California) and Sally M. Dillehay, OD, EdD, FAAO (Georgia). Other practitioners involved with the expanded cohort data included Ronald Watanabe, OD (Massachusetts), Nadine Eisenberg, OD (New York), Hal Ostrom, OD, FIAO (Connecticut), Jeff Jeruss, OD, FIAO (Georgia), and Amber Zaunbrecher, OD (Georgia).

The updated data include 141 children (mean age  $12.38 \pm 3.18$  years) being followed for 6 to 48 months (mean  $18.5 \pm 11.6$  months). The data were very consistent at each time point, demonstrating approximately 90% decrease (1.00 Diopters, D) in myopic progression, as compared to the rate of progression prior to wearing NaturalVue Multifocal (0.90D (84.1%) at 12-17M; 0.97D (90.7%) at 24-29M; 1.04D (97.2%) at 36-41M; 0.99D (92.5%) at 48M). All timepoints were

statistically significantly different from baseline (p < 0.00001). Within a subset of 36 children, axial length was measured. Axial length change from baseline averaged 0.19  $\pm$  0.17 mm at 12-17M (p < 0.005, a 0.23mm (55%) reduction as compared to a similar group of children from the same practice). The investigators reported that their patients indicated few or no complaints of visual or comfort issues, that nearly all of the children continued wearing the lenses, and there were no adverse events.

The consistency of the decreased myopia progression reported in this data set reflects the potential of NaturalVue Multifocal 1 Day contact lenses in slowing the progression of myopia in children. Continuing this research will further substantiate these findings, and add to the body of knowledge for myopia progression control.

Visioneering CEO Stephen Snowdy, PhD, said: "We'd like to thank the investigators and their teams for their continuing efforts and passion in the fight to address myopia progression in children. The 90% effectiveness shown in these most recent longer term data for NaturalVue Multifocal is very encouraging, especially when combined with the excellent vision experienced by the children wearing our lenses. The prevalence and severity of myopia has been increasing at a rapid rate in nearly all industrialized nations, with some Asian nations having 90 or more percent of their children affected by myopia. Our goal is to expand the availability of NaturalVue Multifocal globally and to minimize the amount of myopia progression in as many children as possible.

#### For more information, please contact:

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NaturalVue® (etafilcon A) Multifocal 1 Day Contact Lens Indication for Use in Europe and Australia and New Zealand: NaturalVue (etafilcon A) Multifocal Daily Disposable Soft (Hydrophilic) Contact Lenses are indicated for daily wear for the correction of refractive ametropia (myopia and hyperopia) and/or presbyopia, and myopia progression control in aphakic and/or non-aphakic persons with non-diseased eyes in powers from -20.00 to +20.00 dioptres and with non-diseased eyes who may require a reading addition of up to +3.00D. The lenses may be worn by persons who exhibit astigmatism of 2.00 dioptres or less that does not interfere with visual acuity.

#### **About VTI:**

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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 the EU and is expanding into Asia with a focus on markets with high rates of myopia.

### **Foreign Ownership Restriction:**

VTI's CHESS Depositary Interests (CDIs) are issued in reliance on the exemption from registration contained in Regulation S of the US Securities Act of 1933 (Securities Act) for offers or sales which are made outside the US.

Accordingly, the CDIs have not been, and will not be, registered under the Securities Act or the laws of any state or other jurisdiction in the US. The holders of VTI's CDIs are unable to sell the CDIs into the US or to a US person unless the re-sale of the CDIs is registered under the Securities Act or an exemption is available. Hedging transactions with regard to the CDIs may only be conducted in accordance with the Securities Act.

#### **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, 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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<sup>&</sup>lt;sup>1</sup> Cooper, J, O'Connor, B, Watanabe, R, Fuerst, R, Berger, S, Eisenberg, N, & Dillehay, SM. Case Series Analysis of Myopic Progression Control With a Unique Extended Depth of Focus Multifocal Contact Lens. Eye & Contact Lens. 44(5):e16-e24, September 2018

<sup>&</sup>lt;sup>2</sup> O'Connor, B, Jeruss J, Aller T, Dillehay SM. Myopia Management with A Unique Extended Depth of Focus Contact Lens: A Case Series Analysis. Paper presented at Global Specialty Lens Symposia. January, 2018.