

## **ASX Announcement**

# Prospective Study Shows Slower Vision Degradation in Fast-Progressing Near-Sighted Children Wearing Visioneering Technologies' NaturalVue Multifocal Contact Lens

Atlanta, GA – November 7, 2018 – Thomas Aller, OD, FBCLA, an internationally recognized expert in nearsightedness in children, has presented updated findings from a prospective clinical trial of NaturalVue<sup>®</sup> (etafilcon A) 1 Day Multifocal Contact Lenses from Visioneering Technologies, Inc. Dr. Aller presented the data at the American Academy of Optometry (AAO) Conference in San Antonio Texas on November 9.

Dr Aller, who is a practicing optometrist and Visiting Scholar at the UC Berkeley School of Optometry, highlighted how VTI's unique contact lens design continues to show promise in managing nearsightedness in children (paediatric myopia).

Between October 2017 and January 2018, multiple eye care practices released peer-reviewed data showing nearly 60 children for whom NaturalVue Multifocal had slowed the progression of nearsightedness by 96% on an annual basis.<sup>1,2</sup> It is generally thought 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.

Starting in 2017, Dr. Aller spearheaded a prospective, registered clinical trial (NCT03358862) with the objective of quantifying changes in vision (refractive error) and eye shape (axial length) in myopic children wearing NaturalVue Multifocal contact lenses. To date, 24 children have completed at least one 6-month follow up visit, and 19 children have worn the lenses for more than one year. The average age of this sample population was 10.8 years old (range 7-17), with approximately half of the children (50%) having some Asian ethnicity.

Prior to wearing NaturalVue Multifocal, the children were worsening in their myopic vision by  $1.28 \pm 0.79$  diopters per year, a rate of worsening that many practitioners consider to be quite aggressive, given that the average amount of progression is approximately 0.50 diopters per year.<sup>3</sup> In contrast, children wearing NaturalVue Multifocal experienced a rate of worsening of 0.24 diopters per year, a decreased change of 1.04 diopters per year (statistically significant, P<0.01), representing an 81% decrease in the rate of myopia progression.

In addition, the children in Dr. Aller's study who wore NaturalVue Multifocal experienced slower changes to the shape of their eyes, compared to the rate of change one would expect in children with a similar level of aggressive worsening of myopia. Using published estimates of axial length change based on the prior year's refractive error change (1 mm=3.00 D),<sup>4</sup> these children would have been predicted to have shown an increase in axial length of  $0.43 \pm 0.26$  mm in the year prior to wearing NaturalVue MF. With NaturalVue MF, the 19 children who have worn the lens for at least one year demonstrated an axial length change of  $0.20 \pm 0.19$  mm in one year. This level of axial length growth in these fast-progressing children wearing NaturalVue Multifocal is very encouraging.

Combining Dr. Aller's data with previous studies on NaturalVue Multifocal, the average follow up period was 12 months, with some children reaching 36 months of NaturalVue Multifocal wear in

2018. On average, 97% of more than 80 children showed a decrease in their rate of myopia progression, with an average decrease of 0.93 diopters per year.

"The prevalence of myopia is increasing among children globally at alarming rates, and identifying better ways to manage myopia has become a top priority for vision care experts worldwide," said Dr. Aller. "The NaturalVue Multifocal data are very encouraging based on the level of decrease in changes in both refractive error and expected axial length growth, especially in a group of very fast progressing myopic children. To achieve more than 1.00 diopters of decrease in myopic refractive error change on a prospective basis after one year is quite remarkable and promising. The unique design of NaturalVue Multifocal offers intervention for multiple potential causes of myopic progression, and its availability as a daily disposable contact lens makes it ideal for use in children. I am excited to continue this research and follow these children into their second year of wear."

## 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 Visioneering Technologies, Inc.

Visioneering Technologies, Inc. (VTI) is a US-based medical device company primarily engaged in the design, manufacture, sale and distribution of a revolutionary new contact lens: the NaturalVue<sup>®</sup> Multifocal (MF) contact lens. The NaturalVue MF contact lens employs VTI's Neurofocus Optics<sup>®</sup> technology, which was developed, refined and tested over many years. The characteristics of the NaturalVue MF contact lens allow it to be used in two of the largest eye-care markets globally: adults with presbyopia (age-related difficulty in seeing close objects) and children with myopia (near-sightedness, or difficulty seeing distant objects).

NaturalVue lenses were cleared by the FDA in late 2014 and received the CE Mark, as well as TGA approval in early 2018. VTI recently commenced its US market expansion for NaturalVue MF contact lenses, and has broadened its reach into international markets in 2018. VTI also sells and plans additional contact lens products.

### 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.

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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>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>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.

<sup>3</sup> Smith MJ, Walline J. Controlling myopia progression in children and adolescents. Adolesc Health Med Ther. 2015;6:133–140.

<sup>4</sup>Lam AK, Chan R, Pang PC. The repeatability and accuracy of axial length and anterior chamber depth measurements from the IOLMaster. *Ophthalmic Physiol Opt.* 2001;21(6):477-483.