Q&A With VTI Chief Medical Officer

Visioneering Technologies (ASX:VTI) recently announced enrolment of its first patient into a new clinical study to investigate the effectiveness of NaturalVue MF for myopia management in children - PROTECT (PROgressive Myopia Treatment Evaluation for NaturalVue Multifocal Contact Lens Trial). In this Q&A, VTI Chief Medical Officer Dr Ashley Tuan examines how this study will be conducted - and why it is such a significant clinical and commercial milestone.

VTI has six-years of real-world efficacy and safety evidence on NaturalVue Multifocal to support its use in myopia management. How will the data from PROTECT be different from that data, and why is it needed?

Our post-market surveillance data from 15 clinical practices in the last 6 years was very encouraging as it relates to the efficacy and safety of NaturalVue Multifocal for myopia management. The data gives us great confidence that NVMF is very effective in slowing the progression of myopia in children. However, the real-world study does not have a built-in control group to benchmark with the natural progression of myopia from other children in an "everything else being equal" manner, and the clinical practices did not use consistent methodologies.

The research community views a Randomized Control Trial (RCT) study as the Gold Standard of clinical research. An RCT has standardized testing methods and enrolment criteria and it eliminates confounding factors and biases. We have hired an independent contract research organization to administer the PROTECT study. Together, we believe the standardized methods and third-party administration of the PROTECT study will deliver results of the highest accuracy and integrity.

Several RCT studies have been performed in myopia management using contact lenses. The industry and eye care practitioners are impressed with the NVMF real-world data and have been requesting that we improve its credibility through the use of an RCT. We expect that our RCT data will corroborate our real-world data and confirm the effectiveness of NVMF in managing myopia. We believe the systematic nature of the PROTECT study will convince more practitioners and families to consider NVMF when selecting a product for myopia management and will generate greater opportunities for VTI to enter into strategic partnerships with other companies in the eye care industry.

Briefly describe the design of the PROTECT study and how it is structured to support the acquisition of quality data to inform and progress VTI's R&D program? What are the key endpoints and when can we expect the first data read-out?

PROTECT is a multi-national, randomized, double masked, 3-year prospective study. That means we will collect data from different geographical areas (the US, Canada, and Hong Kong) to ensure a good representation of different ethnicities and living environments. We are enrolling at least 144 myopic children. The children will be randomly assigned to either the Treatment Group (wearing NV Multifocal) or the Control Group (wearing NV Sphere). The children and the examining practitioners will not know which kind of lenses they are wearing ("double masked") to eliminate bias. The key endpoints are the amount of change in refractive error and the amount of change in eyeball length.

PROTECT's study design is closely mirroring two significant myopia progression control RCTs, namely MiSight and BLINK. MiSight is the first contact lens approved by the US FDA indicated to slow the progression of near-sightedness in children. BLINK is a study conducted by researchers at two research universities in the US that was funded by the US National Eye Institute. By following the design of these two studies, we believe PROTECT will generate high quality data.

We expect to have one-year follow-up data in mid-2023. The first-year outcome will be a strong predictor of our treatment effectiveness, and we expect to release longer-term data in mid-2024 and mid-2025.

Who are some of the principal investigators and institutions participating in the PROTECT study and what is the significance of their involvement?

We are planning to have seven study sites. The first site is Toronto Eye Care in Canada, with Dr. Barbara Caffery as Principal Investigator. For the remaining sites, we aim to balance academic institutions with private practices to gain a diverse population from diverse settings. All planned Principal Investigators are well respected members of the optometric or ophthalmology academic arena and are Key Opinion Leaders in the field of Myopia Progression Control. They each have experience in conducting clinical trials and in treating pediatric patients.

VTI has enrolled the first patient in its international study to test the merits of its NaturalVue® Multifocal Contact Lenses in myopia management. Why is this such a significant clinical milestone?

The PROTECT study demonstrates VTI's commitment to Myopia Progression Control. VTI has invested significant time and resources in planning this study. The first patient in signifies that most of the planning is complete, including regulatory approval of the trial protocol, selection and engagement of the contract research organization and contracting with the study site. We anticipate completing our enrolment in six months and announcing our interim 1-year data in mid-2023.

What are your expectations for the PROTECT study and on what basis have you formed your expectations (e.g., on previously generated data)?

From our early clinical studies and large-scale post-market surveillance data, we have seen repeatable outcomes that NVMF is safe and significantly slowed the progression of myopia of the children who were wearing it. We are confident that the PROTECT study will further support and validate NVMF's use in myopia management.

How will the study data be used to strengthen the Company's position as a global leader in myopia management? Will the data be useful globally?

An RCT study is considered the gold standard of clinical study designs and it allows head-to-head comparison to other similarly designed RCT studies in terms of treatment effectiveness. We are confident our study outcomes will justify our leadership in this area in the most credible manner.

PROTECT will have participants from the US, Canada, and Hong Kong, representing a large geographical, racial and ethnic diversity. We believe the findings will represent expected outcomes in global populations.

The results from PROTECT, starting with the one-year interim results in mid-2023, will add to our extensive real-world data, providing global practitioners and parents with greater knowledge of their choices in the management of pediatric myopia.

Why is VTI so dedicated to creating novel solutions for the management of myopia progression (e.g. what is the medical need)?

Although sometimes viewed solely as a "visual deficiency" or a refractive error, myopia is in fact a debilitating disease or condition that has substantial impact on day-to-day functioning and can continue to worsen without treatment.

Myopia is the second largest cause of blindness in the world. It is widely recognized as a substantial public health issue causing significant visual loss and is a risk factor for a range of other serious ocular conditions, particularly related to excessive ocular elongation. These risks increase as myopia worsens, so it's important to identify myopia early and slow or stop its progression to limit the negative health consequences it presents. Our early clinical studies and real-world data show that VTI's innovative optics can slow the progression of myopia and ocular elongation, thereby decreasing the likelihood of serious ocular conditions for NVMF wearers.

With 2 billion myopes in the world, and 5 billion expected by 2050, now is a prime time for VTI to be at the forefront of myopia progression control, contributing positively to a public health issue that increased substantially in the past several decades, accelerated during the COVID-19 pandemic and likely will continue to worsen in the future.

How do NaturalVue MF contact lenses fit into VTI's overall strategy for providing treatments for pediatric myopia?

We believe that successful management of myopia will require a suite of products, with soft contact lenses such as NVMF being one of the most important. Other products include orthokeratology, specialized glasses and eye drops. Our strategy is to expand our product line to include multiple treatments for myopia as well as other vision care needs.

From a commercial perspective, why is this such a compelling market opportunity?

There is a large and rapidly growing addressable market for myopia progression control today. Interest in understanding the causes and impacts of myopia has grown significantly in the past several years. China recently issued an implementation plan for the prevention and control of myopia in children and adolescents. The Singapore National Eye Centre, the Singapore Eye Research Institute and Johnson & Johnson Vision recently announced a public-private strategic partnership focused on myopia. These and other developments are helping to educate practitioners and parents about the need to manage myopia.

In addition, corporate interest in myopia management has increased dramatically over the past several years.
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- Menicon, the largest contact lens company in Japan, licensed NVMF from VTI for its Menicon Bloom Day product as part of its Menicon BloomTM Myopia Control Management System
- The FDA recently approved CooperVision's MiSight contact lenses, the first contact lens indicated to slow the progression of myopia in children
- Johnson & Johnson Vision, the world's largest contact lens company, collaborated with Menicon to produce ACUVUE® AbilitiTM Overnight Therapeutic Lenses, the first and only FDA-approved orthokeratology contact lens for myopia management
- EssilorLuxottica, the world's largest eye care company, and CooperCompanies recently announced a joint venture for the acquisition of SightGlass Vision, a U.S. based life sciences company focused on developing innovative spectacle lenses to reduce the progression of myopia in children
- Bausch Health and BHVI recently announced an exclusive global licensing agreement for myopia control contact lenses

VTI is a leader in myopia management as is evident from our sales growth and our license agreement with Menicon. We believe the high integrity of the PROTECT study will increase partnership and collaboration opportunities for VTI in the increasingly collaborative myopia management field.

- Dr Ashley Tuan