ASX Announcement | 13 October 2023
Visioneering Technologies (ASX:VTI)

Visioneering Provides Addendum to Interim 1-Year Data for the PROTECT Clinical Trial

Visioneering Technologies, Inc (ASX:VTI) ('Visioneering,' 'VTI' or 'the Company'), producer of the NaturalVue® Multifocal 1 Day Contact Lenses, today provided additional details of the interim 1-year results from its multi-center, randomized, double-masked, clinical trial known as '**PROTECT'** (**PRO**gressive Myopia **T**reatment **E**valuation for NaturalVue Multifocal **C**ontact Lens **T**rial). The study objective is to demonstrate safety and quantify the effectiveness of its NaturalVue Multifocal 1 Day Contact Lenses for myopia progression control in children.

The PROTECT Clinical Trial, investigational plan number VTI-NVMF-MPC-RCT-001, is a Phase IV (post-market approval) clinical trial being conducted in accordance with Good Clinical Practice (GCP) and any regional or national regulations, as appropriate. The study population includes myopic children between the ages of seven and less than 13 years old at the time of enrollment with Spherical Equivalent Refractive Error between -0.75 and -5.00 Diopters (**D**) inclusive, astigmatism less than or equal to -0.75D and anisometropia of less than 1.000. Subjects were randomly assigned to wear NaturalVue Sphere single vision contact lenses (**Control Group**) or NaturalVue Multifocal soft contact lenses (**Test Group**) in a 2:1 test to control ratio for two years. Subjects in the Control Group will cross over to NaturalVue Multifocal at 24 months and all subjects will continue wearing the contact lenses for an additional 12 months.

This multicentered clinical trial has participating investigators in Canada, the United States, Hong Kong, and Singapore. PROTECT is a 3-year study with interim analyses stipulated after the 1-year and 2-year subject follow-ups. One year data from studies of similar design to PROTECT have been predictive of the 3-year results. The final results of the study and any regulatory uses thereof will be based on the analysis of the complete 3-year data set.

The primary efficacy endpoint is the change in refractive error relative to baseline at 24 months, measured as the mean change in refractive error measured with cycloplegic auto-refraction (**CSER**) in Diopters at 24 months, relative to baseline. The primary safety endpoint is adverse events, including biomicroscopic findings, for the test and control groups at 24 months, relative to baseline. Secondary endpoints include, but are not limited to, CSER at 12 and 36 months, as well as change in axial length at 12, 24 and 36 months.

The study enrolled 145 subjects in total, randomized into either the Test Group (103 subjects) or the Control Group (42 subjects). The preliminary 1-year results are based on 127 of 136, or 93%, of the active subjects completing their 1-year visit. Nine subjects have exited the study, of which six were voluntary, representing a dropout rate of 4%.

The preliminary 1-year primary efficacy endpoint results were as follows:

Per Protocol: -0.55D Control Group, -0.23D Test Group, 0.32D change, or 58% efficacy,
Subgroup analysis*: -0.59D Control Group, -0.18 Test Group, 0.41D change, or 69% efficacy.

The preliminary 1-year secondary endpoint results for change in axial length in millimeters (**mm**) included:

Per Protocol: 0.27 mm Control Group, 0.13 mm Test Group, -0.15 mm change, or 56%.

Subgroup analysis*: 0.29 mm Control Group, 0.12 Test Group, -0.17 mm change, or 59%.

There were no device-related serious adverse events in the study through the initial measurement date from the Intention-to-Treat (ITT) dataset. Device related adverse events were low and balanced between two study groups and are considered typical observations in normal contact lens wearing population. Further, distance and near vision were stable over time. The test and control products both may be considered safe for use in children as young as seven years old.

Statistical significance was not measured due to the preliminary nature of the findings. The Company will continue to review and analyze the interim 1-year data set and plans to share full 1-year results, including statistical significance, in January 2024 after all subjects have completed their first-year visits.

VTI expects to release longer-term 2- and 3-year data when available.

*Modified Population to match current FDA predicate device enrollment criteria, including children between ages 8 and <13 with refractive error between -0.75 and -4.00D versus age-matched controls wearing spherical lenses, matching common study populations.

Ends

This release was authorized by the CEO, Dr. Juan Carlos Aragón.

For more information, please contact:

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About Visioneering Technologies

Visioneering Technologies Inc. (ASX:VTI) is an innovative eye care company committed to redefining vision. A pioneer in presbyopia and myopia management, VTI merges advanced engineering with a relentless drive to achieve superior results for patients and practitioners. VTI's flagship product is the NaturalVue® (etafilcon A) Enhanced Multifocal 1-Day Contact Lens, an extended depth of focus lens that the Company believes is one of the most significant innovations in the eye care industry in more than 20 years. For more information, please visit www.vtivision.com or call +1 844-884-5367, ext. 104.

Foreign ownership restrictions

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 that 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. As a result of relying on the Regulation S exemption, the CDIs are 'restricted securities' under Rule 144 of the Securities Act. This means that you are unable to sell the CDIs into the US or to a US person for the foreseeable future except in very limited circumstances after the expiration of a restricted period, unless the re-sale of the CDIs is registered under the Securities Act, or an exemption is available. To enforce the above transfer restrictions, all CDIs issued bear a 'FOR US' designation on the Australian Securities

Exchange (**ASX**). This designation restricts any CDIs from being sold on ASX to US persons. However, you are still able to freely transfer your CDIs on ASX to any person other than a US person. In addition, 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.

Given the current uncertainties regarding the on-going impact of COVID-19 on the trading conditions impacting VTI, the financial markets and the health services world-wide, there can be no assurance that future developments will be in accordance with VTI's expectations or that the effect of future developments on VTI will be those anticipated.

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.

VTI-IR-ASX84