ASX Announcement | 19 November 2019
Visioneering Technologies (ASX:VTI)

FDA approves first contact lens indicated to slow the progression of nearsightedness in children

Highlights

- The U.S. Food and Drug Administration (FDA) granted approval on November 18, 2019 for CooperVision's MiSight contact lens
- The approval helps to clarify the regulatory path for Visioneering and other companies
- Resources that CooperVision invests in education and marketing in the U.S. regarding the importance of treating myopia progression should benefit Visioneering as well

Atlanta, Georgia, Tuesday, 19 November 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') is pleased to announce that the U.S. FDA has granted approval for the first contact lens specifically cleared in the US to slow the progression of nearsightedness in children. The registration was granted to CooperVision's MiSight® 1 day contact lens.

This approval represents a major step forward for the field of myopia progression control and demonstrates the rapidly emerging interest in the U.S. for new products that treat myopia progression. The approach used to gain U.S. clearance of MiSight may indicate a relaxation of some clinical trial guidelines that previously had been suggested by the FDA, but were prohibitive to the execution of efficient clinical trials in myopia progression. With this potential shift of requirements towards more achievable clinical trials for myopia progression control products, Visioneering is considering its next steps with regard to pursuing a specific claim for myopia progression control for its NaturalVue Multifocal (NVMF) contact lenses in the U.S.

NVMF currently is approved, or registered, specifically for the treatment of myopia progression in Europe, Australia, New Zealand, Hong Kong, and Singapore. In the U.S., NVMF is approved for the correction of myopia, but not specifically for myopia progression control. However, many eye care professionals in the U.S. currently use NVMF for treating myopia progression as it employs a unique optical design that has been shown in peer reviewed, published data to slow the progression of myopia in children by over 90%.[i]

MiSight is available in distance powers up to -6.00 diopters. NVMF is available in a full range of distance powers, up to -12.25 diopters, enabling treatment of a greater portion of the myopic population than MiSight.

Visioneering Technologies CEO Stephen Snowdy, PhD, said: "The U.S. approval of MiSight is very positive for Visioneering and the industry, and an exciting time for practitioners of myopia progression in the U.S. This achievement may establish a pathway to FDA approval specifically for myopia progression control in the U.S. for other innovators like Visioneering. We estimate that the addressable market for myopia progression in the U.S. is approximately US$2 billion. This FDA announcement should help to highlight the need for myopia progression control, and therefore benefit patients, practitioners and innovators."

Ends.

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. 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.

To learn more, please visit: www.vtivision.com

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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,

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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[i] 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