

## Visioneering Technologies Receives Regulatory Approval from Australia's Therapeutic Good Administration (TGA) for its NaturalVue® Family of 1 Day Contact Lenses

Indications include unique NaturalVue Multifocal lens for myopia progression control

Atlanta, Georgia, USA, 2 March 2018: Visioneering Technologies, Inc. (ASX: VTI), an innovative US-based medical device company dedicated to developing advanced products that improve vision, announced today it has received approval from the Australian Therapeutic Goods Administration (TGA) for its portfolio of proprietary NaturalVue® (etafilcon A) brand 1 Day Contact Lenses, including Sphere, Toric, Multifocal and Multifocal Toric. VTI's CE Mark includes an indication for VTI's unique NaturalVue Multifocal (NVMF) for myopia progression control (the control of progressive nearsightedness), allowing the Company to market and sell the device in Australia. NVMF contact lenses feature VTI's innovative Neurofocus Optics® Technology, which employs a patented extended depth-of-focus design to address known optical risk factors associated with myopia progression. The innovative NVMF lens design allows it to be used for both myopia progression control and presbyopia (the age-related loss of ability to see near objects).

Dr Kate Gifford, PhD, BAppSc(Optom)Hons, GCOT, an optometrist, clinical researcher and peer educator, is currently in practice in Brisbane, Australia, where she works in contact lens fitting, binocular vision, pediatrics, and myopia control. "The addition of NaturalVue Multifocal lenses to the portfolio of therapy options eye care professionals have for the management of myopia is a milestone in the treatment of this condition," said Dr. Gifford. "The scientific data increasingly points to contact lenses as among the best options for myopia control, especially for children. Optometrists now have new clinically valid information to present to their patients to help them make the best decision about how to proceed with myopia prevention and treatment."

The TGA approval is awarded by the Therapeutic Goods Association, a part of Australia's Department of Health, whose primary purpose is to safeguard and enhance the health of the Australian community through effective and timely regulation of therapeutic goods. Export certification for therapeutic goods can only be issued for a product that has been registered, listed, included or is exempt from the requirement to be on the Australian Register of Therapeutic Goods (ARTG). This allows VTI to commercialize its contact lens products in Australia, as well as to prepare other Asia Pacific regulatory submissions to gain approval for commercial launch of its products in additional countries, including New Zealand, Hong Kong and Singapore, among others.

"TGA's approval of VTI NaturalVue contact lenses for inclusion on the ARTG represents an important milestone. We are clearly very pleased to have received regulatory approval for the marketing and sale of our NaturalVue product line of daily disposable contact lenses with indications for both myopia progression control and presbyopia for the NaturalVue Multifocal lens design," said Dr. Stephen Snowdy, CEO and Executive Director. "TGA approval paves the way for expansion into the broader Asia Pacific market. Australia is a highly regarded market by many in the global medical community as it boasts a robust healthcare system, as well as having a history of embracing innovative technology for the management of paediatric myopia."

Paediatric myopia progression affects a high percentage of children in industrialized nations. A recent study published in the peer-reviewed journal, *Eye and Contact Lens*, documented that VTI's NaturalVue MF lens delivered approximately 96% reduction (average of both eyes) of annualized myopic progression in children aged 6 to 19, with 98.4% of the children showing a decrease in the rate of worsening of their myopia.<sup>i</sup>

## For more information, please contact:

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## **About VTI:**

Visioneering Technologies, Inc. (ASX:VTI), headquartered in Atlanta, Georgia, is an innovative company dedicated to developing products that improve vision. With a portfolio of technologies, the Company uses creative and differentiated design approaches to develop products that enhance practitioner and patient experiences. Its revolutionary new contact lens, the NaturalVue™ Multifocal (MF) contact lens, can be used in two of the largest eye-care markets globally: presbyopia (age-related difficulty in seeing close objects) and myopia (near-sightedness, or difficulty seeing distant objects). VTI optical designs have been awarded twelve patents worldwide, with an additional seven pending. For more information, visit www.vtivision.com.

## 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 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. 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.

<sup>i</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*. 2017;(e-pub prior to publication, Oct).