Visant Medical Earns FDA Clearance For Proprietary Dry Eye Disease Therapy

MENLO PARK, CA, USA, January 17, 2023 /EINPresswire.com/ -- Visant Medical, Inc., a clinical-stage medical device company, today announced receipt of U.S. Food and Drug Administration (FDA) 510(k) clearance for its patented canalicular occlusive device. The device blocks tear drainage through the canalicular system in patients experiencing dry eye symptoms.

To achieve 510(k) clearance, the Visant device underwent rigorous FDA premarket review, including extensive clinical evaluation in the United States through a prospective, multicenter, randomized, double-masked, controlled clinical trial designed to evaluate the device's clinical utility and safety. The pivotal study outcomes summarized in the FDA-cleared labeling demonstrate the ability of the Visant device to improve both signs and symptoms of dry eye disease over a sustained period of six months.

"We are pleased to have received FDA clearance for our innovative dry eye product, which is based on a proprietary formulation of cross-linked hyaluronic acid", said Vartan Ghazarossian, PhD, Co-founder, President, and CEO of Visant Medical. "Upon commercialization, the product will be offered as a kit that includes the device in a sterile syringe, along with compatible cannulas for delivery of the device."

"Through collaborative engagement with FDA, Visant conducted a rigorous clinical investigation of canalicular occlusion for the treatment of dry eye," said Mark Packer, MD, Chief Medical Officer of Visant Medical. "The results of this clinical trial provide the highest quality of evidence demonstrating the safety and effectiveness of this innovative device for patients with dry eye."

"Clinicians are all too familiar with the limitations of current rigid punctal and canalicular plugs," said Paul Karpecki, OD, Associate Professor, University of Pikeville, Kentucky College of Optometry, Kentucky Eye Institute; Gaddie Eye Centers, Total Eyecare Partners. "The Visant Medical device is a gel, consisting of 98% water, that conforms to the shape of the canaliculus. I look forward to treating my dry eye patients with this unique device."

About Visant Medical
Visant Medical is a spin-out of vision care accelerator StepWise Medical. More than 16 million people in the U.S. have been diagnosed with dry eye disease. Dry eye disease represents the second most frequent reason that patients visit their eye care professional. Based on the etiology of the disease, many of these patients would be candidates for the Visant Medical canalicular occlusive device.

For more information, visit www.visantmedical.com.

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