SightGlass Vision Receives Breakthrough Device Designation from U.S. Food and Drug Administration

Decision is the Latest Milestone for Diffusion Optics Technology™ (DOT™) Spectacle Lenses Designed to Slow Myopia Progression in Children

LOS ALTOS, CALIF, February 14, 2024—SightGlass Vision, a joint venture of CooperCompanies and EssilorLuxottica that develops innovative technologies and science-based treatments to address the global myopia epidemic, today announced that the U.S. Food and Drug Administration (FDA) has granted Breakthrough Device designation to its Diffusion Optics Technology™ (DOT™) spectacle lenses, which are intended to slow myopia progression in children. The unique design is the first to use the contrast management mechanism of action, incorporating thousands of elements that gently scatter light across the retina.

The FDA's Breakthrough Devices Program is for highly innovative devices that provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating human disease or conditions. Manufacturers are given more frequent opportunities for FDA feedback during the premarket review phase, as well as a prioritized submission review. Since the program's introduction in 2015, only 18 other ophthalmic devices have received the Breakthrough Device designation.*

"The FDA Breakthrough Device designation for Diffusion Optics Technology™ (DOT™) spectacle lenses is a milestone for our organization—and for the broader fight against the pediatric myopia epidemic. Recent studies[1,2] illustrate that about half of U.S. children are myopic, yet most are not receiving treatments proven to slow myopia progression," said Andrew Sedgwick, CEO of SightGlass Vision. "We are enthusiastic about more closely collaborating with the FDA as we pursue U.S. market clearance."

SightGlass Vision's patent-protected technology has demonstrated proven efficacy and safety through rigorous clinical evaluation.[3,4,5,6] As reported in September 2023, full four-year outcomes from the pivotal CYPRESS study showed statistically significant slowing of axial length progression and cycloplegic spherical equivalent refraction.[7]

Diffusion Optics Technology™ (DOT™) spectacle lenses have made their commercial debut in several markets, including China, the Netherlands, and Israel, as well as through

preliminary market trials in other countries. For more information, visit SightGlassVision.com.

About SightGlass Vision
SightGlass Vision develops innovative technologies and science-based treatments to address the global myopia epidemic, backed by novel and comprehensive research. Its unique Diffusion Optics Technology™ (DOT™) is based on ground-breaking discoveries surrounding myopia progression. Spectacle lenses using its patent-protected approach incorporate thousands of light-scattering elements designed to mimic more natural contrast on the retina—a method intended to reduce myopia progression in children. The treatment has completed the three years pivotal multisite clinical study. Founded in 2016, the company now operates as a joint venture of CooperCompanies and EssilorLuxottica to accelerate commercialization opportunities and expand the myopia management category worldwide.

SightGlass Vision™ Diffusion Optics Technology™ (DOT™) spectacle lenses are not available for sale in the United States.

** As of June 30, 2023. FDA Breakthrough Devices Program. Graph 2: Number of Granted Breakthrough Device Designations by Clinical Panel. https://www.fda.gov/medical-devices/how-study-and-market-your-device/breakthrough-devices-program#metrics*

Media Contact
Mike McDougall, APR, Fellow PRSA, FAAO
McDougall Communications for SightGlass Vision
+1-585-545-1815 or mike@mcdougallpr.com

[1] Kwan J, et al. *Current Trends in Pediatric Eye Examinations and Contact Lens Prescribing in the U.S.* Poster presentation at the Global Specialty Lens Symposium, January 2024.

[2] Myopia Management 2024 Report, Jobson Optical Research, January 2024. https://reviewofmm.com/2024-myopia-report/

[3] Control of myopia using Diffusion Optics Technology™ spectacle lenses: 12-month results of a randomised controlled, efficacy and safety study (CYPRESS). British Journal of Ophthalmology Published Online First: 01 September 2022. DOI: 10.1136/bjo-2021-321005

[4] Rappon J., et al. Two-year effectiveness of a novel myopia management spectacle lens with full-time WEARERS. Invest. Ophthalmol. Vis. Sci. 2022;63(7):408.

[5] Chalberg T., et al. Control of Myopia Using Diffusion Optics Spectacle Lenses: Efficacy and Safety Study (CYPRESS) 42-month results. ARVO 2023 Annual Meeting presentation. 27 April 2023.

[6] Laughton, D et al. Safety and Efficacy of a Novel Spectacle Lens for Myopia Control Over Three Years. 2022 American Academy of Optometry annual meeting. 27 Oct 2022.

[7] Xiaoying Zhu, Deborah Laughton, Jennifer S. Hill, Marcella McParland, Vanessa Tasso, Jay Neitz, Maureen Neitz, Thomas W. Chalberg. Control of Myopia using Diffusion Optics Technology Spectacle Lenses: Efficacy and Safety Study (CYPRESS) 4 Year Results. Presented at CCOS 2023.