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Nanoscope Therapeutics Initiates Rolling Submission of Biologics License Application to FDA for MCO-010, the First Gene-Agnostic Therapy to Treat Retinitis Pigmentosa

- *First modules of BLA submitted to FDA under rolling review, with full submission anticipated in early 2026*
- *MCO-010 BLA for retinitis pigmentosa is eligible for priority review based on fast-track designation*
- *If approved, MCO-010 has the potential to be the standard of care for retinitis pigmentosa, delivered via a one-time, in-office intravitreal injection with the ability to restore vision in patients with severe vision loss regardless of their underlying genetic mutation*

DALLAS, TX, July 14, 2025 – Nanoscope Therapeutics Inc., a biotechnology company committed to developing and commercializing novel gene-agnostic therapies for patients suffering severe vision loss from retinal degenerative diseases, today announced the initiation of a rolling submission of a Biologics License Application (BLA) to the U.S. Food and Drug Administration (FDA) for its lead investigational therapy, MCO-010, for the treatment of severe vision loss due to retinitis pigmentosa (RP).

This marks a significant regulatory milestone as the **first BLA submitted for a gene-agnostic gene therapy for retinal disease**. Being gene-agnostic means that MCO-010 is designed to address the broad genetic diversity of RP—a condition linked to over 100 known genes and more than 1,000 different mutations—**regardless of the underlying mutation**.

The FDA has granted Nanoscope rolling review of its BLA, with the first modules already submitted and completion of the full BLA submission anticipated in early 2026. The application is eligible for priority review under the program's fast-track designation.

If approved, MCO-010 would be the first gene-agnostic therapy to restore vision in legally blind RP patients, potentially providing a significant market opportunity and, more importantly, establishing the standard of care for patients suffering from vision impairment due to RP.

"For the first time, patients who are considered to be on a path to permanent blindness may have a chance to regain sight," said Sulagna Bhattacharya, CEO and Co-Founder of Nanoscope. "We are deeply thankful to the FDA for their guidance as we remain steadfast in our mission to restore vision and bring light back into the lives of those living in darkness."

MCO-010, Nanoscope's proprietary multi-characteristic opsin (MCO), is delivered via a one-time, in-office intravitreal injection. After injection, MCO-010 activates highly dense bipolar retinal cells to become light sensitive, utilizing remaining visual circuitry following photoreceptor death. MCO-010 is designed to offer a distinct approach in that it does not require genetic testing, surgical intervention, or repeat dosing, making it applicable to a broad population of RP patients, while also fitting into existing retina office workflows.

"We've been working on the MCO platform for more than a decade," added Samarendra Mohanty, PhD, President, Chief Scientific Officer, and Co-Founder of Nanoscope. "We've seen this investigational therapy surpass our expectations in the lab and in patients in clinical trials, and we believe we're now one step closer to potentially bringing this pioneering therapy to all RP patients."

RP is one of the leading causes of blindness in the working-age population in the U.S., affecting more than 100,000 people and leaving over 25,000 legally blind. Vision loss due to RP is highly dependent on the underlying mutation present, and, on average, RP patients lose 1 line of vision on an eye chart approximately every three years, and a majority are legally blind (worse than 20/200 vision) by the age of 60.

"One of the most challenging aspects of my entire career has been telling patients with RP there is no restorative treatment available as they experience progressive, irreversible, permanent vision loss," said Dr. Allen C. Ho, MD, Director of Retina Research at Wills Eye Hospital and Chief Medical Advisor for Nanoscope. "Based on the preclinical science and evidence in clinical trials, MCO-010 represents a potential,

important paradigm shift for patients and retina specialists, providing hope for meaningful improvement in the quality of life for the neediest retina patients of all."

In Nanoscope's pivotal RESTORE Phase 2b trial, MCO-010 met its Best Corrected Visual Acuity primary endpoints in both dose groups at 52 weeks versus sham-control, with vision gains from baseline of >0.3 LogMAR, a result equivalent to three or more lines on an eye chart. In ongoing long-term follow-up, visual acuity gains were observed through 3 years, with no serious adverse events reported in treated eyes. Further multi-year follow up is scheduled with these patients to evaluate longer-term efficacy and safety.

"It's the first time the FDA will be evaluating an application for a gene-agnostic therapy for inherited retinal disease," concluded Glenn Sblendorio, Chairman of the Board of Directors for Nanoscope. "We feel confident in our clinical data, which we believe will mark the dawn of a new era in retinal care. Our goal is to bring back the light of hope for RP patients —and eventually for many other retinal degenerative conditions."

For more information on MCO-010 and Nanoscope Therapeutics visit: www.nanostherapeutics.com.

About Nanoscope Therapeutics

Nanoscope Therapeutics is developing gene-agnostic, vision-restoring optogenetic therapy for millions of patients blinded by retinal degenerative diseases. Following positive results from the RESTORE Phase 2b multicenter, randomized, double-masked, sham-controlled clinical trial for retinitis pigmentosa (RP) (NCT04945772), a rolling BLA submission to the FDA has been initiated. If approved, MCO-010 has the potential to be the standard of care for RP patients, administered as a one-time, in-office injection without the need for genetic testing. The company has also shown promising results in the STARLIGHT Phase 2 clinical trial of MCO-010 in Stargardt disease (SD) (NCT05417126) and plans to initiate a Phase 3 registrational trial in 2025. MCO-010 has received FDA Fast Track and Orphan Drug designations for both RP and SD. Preclinical programs include Leber congenital amaurosis (LCA), in IND-enabling studies, as well as an IND-ready asset for geographic atrophy (GA).

Contact:
Nanoscope Therapeutics
(817) 857-1186
PR@nanostherapeutics.com