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SpyGlass Pharma's Novel BIM-IOL System Demonstrated a Statistically Significant Reduction in Mean IOP at 24 Months

- 42% reduction in mean intraocular pressure (IOP) compared to baseline ($p<0.0001$)
- 100% of patients were off all topical IOP-lowering medications at 24 months
- 100% of treated patients achieved 20/30 or better Best Corrected Distance Visual Acuity (BCDVA) at 24 months

ALISO VIEJO, Calif., Oct. 14, 2025 (GLOBE NEWSWIRE) -- SpyGlass Pharma, a late-stage biopharmaceutical company, today announced interim 24-month data from its first-in-human trial of the Bimatoprost Drug Pad-IOL System (the BIM-IOL System). The BIM-IOL System, comprising novel, proprietary non-bioerodible drug pads attached to SpyGlass Pharma's intraocular lens (IOL), is designed to be implanted during routine cataract surgery to reduce IOP in patients with open-angle glaucoma (OAG) or ocular hypertension (OHT). The system is designed to consistently deliver multiple years of bimatoprost, a prostaglandin analog approved for the reduction of elevated IOP in patients with OAG or OHT.

The interim clinical trial data demonstrated sustained improvements in IOP and visual acuity outcomes, underscoring the potential of the BIM-IOL System to transform care for OAG and OHT patients.

"Adherence with daily topical IOP-lowering medications is one of the most consistent challenges for patients in the management of glaucoma and ocular hypertension," said Malik Kahook, M.D., Co-founder of SpyGlass Pharma. "The findings at 24 months demonstrated that patients can achieve meaningful and durable reduction in IOP without the burden of daily drops. We are pleased to share these interim results and continue our objective of delivering a long-term, drop-free solution for patients in need."

The single-center, prospective first-in-human trial is designed to evaluate the BIM-IOL System for the treatment of elevated IOP in patients with OAG or OHT undergoing routine cataract surgery. At 24 months, the BIM-IOL System demonstrated:

- 42% reduction in mean IOP, from 25.1 ± 2.5 mmHg at baseline post-washout to 14.5 ± 3.0 mmHg ($p<0.0001$), with no statistically significant difference in IOP reduction across the three dosage groups tested.
- 100% of patients were off all topical IOP-lowering medications.
- Best corrected distance visual acuity (BCDVA) improved to 20/30 or better in all patients.

Overall, the BIM-IOL System was observed to be well-tolerated. All observed adverse events were considered to be related to the cataract procedure and none were deemed to be associated with the BIM-IOL System. No serious adverse events were observed.

“The 24-month findings from our first-in-human trial add to our growing body of data supporting the long-term durability of the BIM-IOL System,” added Patrick Mooney, Chief Executive Officer of SpyGlass Pharma. “With an implantation technique familiar to all cataract surgeons, including the two-thirds of physicians who do not routinely perform minimally invasive glaucoma surgery, we believe our system has the potential to become a widely-implemented solution for reducing reliance on topical medication."

ABOUT THE BIM-IOL SYSTEM

SpyGlass Pharma’s lead product candidate, the BIM-IOL System, comprising novel, proprietary non-bioerodible drug pads attached to its intraocular lens, is designed to be implanted during routine cataract surgery to reduce elevated intraocular pressure (IOP) in patients who have either open-angle glaucoma (OAG) or ocular hypertension (OHT). The BIM-IOL System is designed to consistently deliver multiple years of bimatoprost, a prostaglandin analog approved for topical use by the U.S. Food and Drug Administration (FDA) in 2001, for the reduction of elevated IOP in patients with OAG or OHT.

The company is planning initiation of two registrational Phase III clinical trials of the BIM-IOL System by end of year and continues long-term follow-up of patients in its first-in-human trial. SpyGlass Pharma completed enrollment in a Phase I/II study to investigate the safety and efficacy of the BIM-IOL System in a larger patient pool. SpyGlass Pharma plans to work with the FDA to advance the program through Phase III clinical trials, New Drug Application (NDA) submission, and ultimately to potential commercial approval.

ABOUT SPYGLASS PHARMA

SpyGlass Pharma is a late-stage biopharmaceutical company dedicated to transforming the treatment paradigm for patients living with chronic eye conditions through long-acting, sustained drug delivery of approved medicines. The company’s mission is to redefine the management of these conditions by developing durable drug delivery solutions that can empower patients and surgeons with confidence in long-term disease control and vision preservation.

The SpyGlass Platform, a novel, non-bioerodible drug delivery technology, is designed to be used with various well-established, approved medicines, including bimatoprost and other small molecules, providing flexibility to potentially treat a range of conditions in the front and back of the eye.

The company was founded in 2019 by Malik Y. Kahook, M.D. and Glenn Sussman to solve the lack of ophthalmic innovations that capitalize on durable treatment options. The SpyGlass Platform was originally developed in the Sue Anschutz-Rodgers Eye Center of the University of Colorado School of Medicine.

For more information, visit: www.spyglasspharma.com.

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