# SpyGlass Pharma Announces Positive 36-Month First-in-Human and 3-Month Phase I/II Trial Results for Its Novel BIM-IOL System

November 10, 2025

*First-in-Human (FIH) Trial at 36 Months*:

- 37% reduction in mean intraocular pressure (IOP) in evaluable patients across all dose groups with 95% of patients off all topical IOP-lowering drops
- 100% of evaluable patients achieved 20/30 or better Best Corrected Distance Visual Acuity (BCDVA)
- No product-related adverse events (AEs) were reported

*Phase I/II Trial at 3 Months*:

- 37% and 36% reduction in mean IOP with 98% and 96% of patients off topical IOP-lowering drops in 78 mcg and 39 mcg dose groups, respectively
- 100% of patients achieved 20/40 or better BCDVA and a mean 20/20 BCDVA, in both the BIM-IOL and control groups
- Overall safety results were comparable to routine cataract surgery

ALISO VIEJO, Calif., Nov. 10, 2025 (GLOBE NEWSWIRE) -- SpyGlass Pharma™, a late-stage biopharmaceutical company, announces positive results from two clinical trials of its lead product candidate, the Bimatoprost Drug Pad-IOL System (BIM-IOL System), for the treatment of elevated IOP in patients with mild-to-moderate open-angle glaucoma (OAG) or ocular hypertension (OHT). The data were presented by Malik Kahook, M.D., co-founder and president of SpyGlass Pharma, at the Interventional Glaucoma Consortium (IGC) in Salt Lake City, Utah on Saturday, November 8th, which included 36-month follow-up data from the FIH trial and three-month interim safety and efficacy results from the Phase I/II trial.

“The FIH results demonstrate that the BIM-IOL System can deliver sustained IOP reduction, drop-free outcomes, and strong visual performance for three years,” said Dr. Kahook. “Our Phase I/II trial aims to confirm these findings across a larger patient population and has shown similar IOP reduction and drop-free outcomes three months after implantation. Together, these results represent an important milestone for both SpyGlass and patients in need of disease control while removing the adherence burden.”

"The physician community needs better sustained drug delivery options to eliminate the adherence burden of IOP-lowering drops for patients with open-angle glaucoma or ocular hypertension," said Jeffrey Kammer, M.D., associate professor of ophthalmology at Vanderbilt University Medical Center and an investigator in the Phase I/II trial. "The implantation procedure during routine cataract surgery is straightforward, and the three-month IOP reduction results and improved visual performance are highly compelling. I am excited to continue to work with SpyGlass to monitor longer-term results of the BIM-IOL System.”

**FIH Results at 36 Months:**

- 37% reduction in mean IOP in evaluable patients across all dose groups from 25.1 ± 2.5 mmHg at baseline post-washout to 15.9 ± 2.7 mmHg.
- 95% of evaluable patients were off all topical IOP-lowering medications.
- 100% of evaluable patients achieved 20/30 or better BCDVA.
- No product-related AEs were reported.

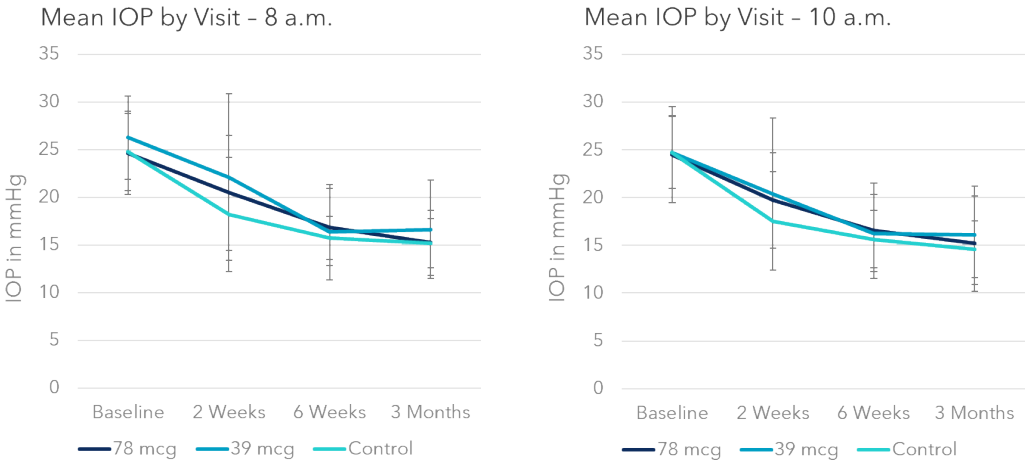
**Phase I/II Efficacy Results: Sustained IOP Control, Elimination of Drops, and Improved Visual Performance**
The primary endpoint of the Phase I/II trial is mean IOP reduction from baseline at the 2 Week, 6 Week, and 3 Month timepoints following implantation of the SpyGlass BIM-IOL System delivering bimatoprost at two dose levels (78 mcg and 39 mcg). The BIM-IOL System achieved a mean reduction in IOP that was comparable to the control group, which received a commercially available monofocal intraocular lens (IOL) with twice-daily timolol eye drops.

At three months:

- Patients achieved a 37% and 36% reduction in mean IOP from baseline in the 78-mcg and 39-mcg dose groups, respectively, compared to a 37% reduction in the control group at 8 a.m. Results were similar at the 10 a.m. timepoint (Figure 1).
- 98% of patients (49 of 50) in the 78-mcg dose group and 96% of patients (22 of 23) in the 39-mcg dose group were free from all topical IOP-lowering medications.

- Patients demonstrated vision improvement, reaching 20/40 or better BCDVA and mean BCDVA of 85 to 86 letters (~20/20 vision).

Figure 1: Mean IOP Reduction Sustained Over Three Months Across Doses




**Phase I/II Safety Results: Comparable to Routine Cataract Surgery**
At three months:

- Adverse event (AE) rates were similar across the 78-mcg (35.3%), 39-mcg (39.1%), and control (33.3%) groups.
- No serious ocular AEs were observed.

**ABOUT THE FIRST-IN-HUMAN TRIAL**
The first-in-human (FIH) trial is a single-center, prospective trial evaluating the BIM-IOL System for the treatment of elevated IOP in patients with OAG or OHT undergoing routine cataract surgery. A total of 23 patients were sequentially assigned 1:1:1 across three BIM-IOL System dosage groups. At the 36-month timepoint, 21 evaluable patients remained, with two discontinuing due to one relocating outside the country and the other entering palliative care following a cancer diagnosis unrelated to the BIM-IOL System.

**ABOUT THE PHASE I/II TRIAL**
The Phase I/II trial is a prospective, multicenter, randomized, double-masked, controlled clinical trial evaluating the safety and efficacy of the innovative BIM-IOL System in patients with OAG or OHT undergoing cataract surgery. A total of 104 eligible patients were randomized 2:1:1 to receive the 78 mcg BIM-IOL System (N=51) with daily administration of artificial tear drops, 39 mcg BIM-IOL System (N=23) with daily administration of artificial tear drops, or a commercially available monofocal IOL with twice-daily administration of timolol eye drops as the control group (N=30).

The primary endpoint is mean IOP reduction from baseline at the 2 Week, 6 Week, and 3 Month timepoints. Secondary endpoints include mean IOP reduction from baseline, visual performance, and typical safety assessments for both medication and IOL.

**ABOUT THE BIMATOPROST DRUG PAD-IOL SYSTEM**
SpyGlass Pharma's lead product candidate, the Bimatoprost Drug Pad-IOL System (BIM-IOL System), comprising novel, proprietary non-bioerodible drug pads attached to its intraocular lens, was 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 continues long-term follow-up of patients in both the FIH trial and Phase I/II trial. SpyGlass plans to work with the FDA to advance the program through initiation of Phase III clinical trials, 505(b)(2) 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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