SpyGlass Pharma Announces Positive Topline 12-Month Phase 1/2 Trial Results for Its Innovative BIM-IOL System

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- 97% of patients who received the BIM-IOL System off all topical IOP-lowering therapy at 12-months
- 100% of BIM-IOL System patients achieved 20/32 or better BCDVA and a mean BCDVA equivalent to 20/20 vision, demonstrating high quality of vision, performance in line with the state-of-the-art IOLs in the control group
- Overall safety results were comparable to routine cataract surgery

ALISO VIEJO, Calif., March 09, 2026 (GLOBE NEWSWIRE) -- SpyGlass Pharma, Inc. (Nasdaq: SGP) (SpyGlass Pharma), a late-stage biopharmaceutical company, today announced positive 12-month results from the Phase 1/2 trial evaluating its lead product candidate, the Bimatoprost Drug Pad-IOL System (BIM-IOL System), for the treatment of elevated intraocular pressure (IOP) in patients previously diagnosed with open-angle glaucoma (OAG) or ocular hypertension (OHT) and a concomitant cataract.

A total of 104 patients were randomized 2:1:1 to receive the 78 mcg BIM-IOL System (N=51) and 39 mcg BIM-IOL System (N=23) with daily administration of artificial tear drops, or a commercially available monofocal IOL from Alcon, Bausch + Lomb or Johnson & Johnson with twice-daily administration of timolol eye drops as the control group (N=30).

At 12 months, the BIM-IOL System achieved:

- Evaluable patients achieved a 34% and 42% reduction in mean IOP from baseline in the 78-mcg and 39-mcg dose groups, respectively, compared to a 35% reduction in the control group at 8 a.m. Results were similar at the 10 a.m. timepoint.
- 98% of evaluable patients (48 of 49) in the 78-mcg dose group and 96% of evaluable patients (22 of 23) in the 39-mcg dose group were free from all topical IOP-lowering medications.
- Evaluable patients (N=72) demonstrated vision improvement, 100% reaching 20/32 or better best corrected distance visual acuity (BCDVA) and mean BCDVA of 86 letters (equivalent to 20/20 vision).
- Adverse event (AE) rates were similar across the 78-mcg (41.2%), 39-mcg (43.5%), and control (36.7%) groups. No serious ocular AEs were observed.

“The 12-month results demonstrate the potential for the BIM-IOL System to address the key challenge of long-term adherence to ophthalmic treatments, delivering sustained IOP reduction and improved visual performance while eliminating the need for topical drops,” said Malik Kahook, M.D., chief medical officer and executive chair of the board of SpyGlass Pharma. “These positive findings from a multicenter, randomized, controlled clinical trial reinforce our previously released 3-year first-in-human data. We look forward to presenting additional Phase 1/2 trial results at a future medical conference.”

“This readout clearly demonstrates the potential for SpyGlass technology to have a life changing impact on patients, while being accessible to 100% of cataract surgeons. We’re now in a category of our own in demonstrating our ability to eliminate topical IOL-lowering medications for the vast majority of patients, while delivering the same high quality of vision that patients and surgeons expect from state-of-the-art IOLs,” said Patrick Mooney, chief executive officer of SpyGlass Pharma. “Bolstered by our confidence in the Phase 1/2 program, we remain hyper-focused on advancing enrollment for our two pivotal Phase 3 trials of the BIM-IOL System.”

In January 2026, SpyGlass Pharma announced that the first patients were randomized in two identical registrational Phase 3 trials of the 78-mcg dose of the BIM-IOL System. The Phase 3 trials are largely consistent in trial design with the SpyGlass Pharma Phase 1/2 trial with minor protocol modifications intended to improve consistency across trial arms.

About the Phase 1/2 Trial
The Phase 1/2 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 evaluable 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 two time points for each follow-up visit at the 2 Weeks, 6 Weeks, and 3 Months. Secondary endpoints include mean IOP reduction from baseline, mean IOP, time to reintroduction and number of IOP-lowering medications, and improvement of visual performance. The trial also includes 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 first-in-human trial and Phase 1/2 trial as well as patient enrollment in ongoing Phase 3 clinical trials. SpyGlass plans to work with the FDA to advance the program through 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 significantly improve the lives of patients with chronic eye 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 Pharma 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 Pharma platform was originally developed in the Sue Anschutz-Rodgers Eye Center at the University of Colorado Anschutz School of Medicine.

FORWARD-LOOKING STATEMENTS

This press release contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. All statements in this press release that are not purely historical are forward-looking statements, including, but not limited to, statements regarding: the potential benefits and impact of the BIM-IOL System on patients, anticipated presentation of additional data, and SpyGlass Pharma's plans relating to the clinical development of the BIM-IOL System towards commercial approval. The forward-looking statements contained herein are based upon SpyGlass Pharma's current expectations and involve assumptions that may never materialize or may prove to be incorrect. These forward-looking statements are neither promises nor guarantees and are subject to a variety of risks and uncertainties, including those set forth in the Risk Factors section of the Company's final 424B4 prospectus filed with the Securities and Exchange Commission (SEC) on February 6, 2026, and the other documents that SpyGlass Pharma may file from time to time with the SEC. These forward-looking statements are made as of the date of this press release, and SpyGlass Pharma assumes no obligation to update or revise any forward-looking statements, whether as a result of new information, future events, or otherwise, except as required by law. You should, therefore, not rely on these forward-looking statements as representing our views as of any date subsequent to the date of this press release.

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