SpyGlass Pharma Announces First Patients Randomized in SGP-005 and SGP-006, Two Registrational Phase III Clinical Trials of Its Novel BIM-IOL System

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ALISO VIEJO, Calif., Jan. 20, 2026 (GLOBE NEWSWIRE) -- SpyGlass Pharma, a late-stage biopharmaceutical company, today announced that the first patients have been randomized in two registrational Phase III clinical trials of its lead product candidate, the Bimatoprost Drug Pad-IOL System (BIM-IOL System), for lowering intraocular pressure (IOP) in patients with open-angle glaucoma (OAG) or ocular hypertension (OHT).

“The inconsistent use of topical IOP-lowering drops is a significant challenge in managing the estimated 1 million glaucoma and OHT patients who are expected to undergo cataract surgery in the United States this year,” said Chetan Pujara, Ph.D., Chief Research & Development Officer of SpyGlass Pharma. “Randomizing the first patients in our registrational Phase III clinical trials represents a critical step toward bringing our BIM-IOL System to market – a much-needed solution to help patients overcome this burden.”

"As an investigator in the Phase I/II clinical trial, I’ve witnessed firsthand how the BIM-IOL System can eliminate the need for drops by providing sustained IOP control in patients with OAG or OHT," said Fiaz Zaman, M.D., F.A.C.S., ophthalmologist at Houston Eye Associates. "I look forward to participating in the Phase III clinical trials and collaborating with both SpyGlass Pharma and my fellow investigators to potentially bring the BIM-IOL System to patients. The next frontier of managing and preventing glaucoma disease progression will be therapeutic technologies that remove the patient adherence challenge.”

“Today’s exciting milestone brings us one step closer to offering the roughly 10,000 cataract surgeons – including the two-thirds who do not routinely perform minimally invasive glaucoma surgery – the promise of seamlessly integrating sustained bimatoprost drug delivery into cataract surgery,” said Patrick Mooney, Chief Executive Officer of SpyGlass Pharma. “Backed by robust clinical data and an optimized Phase III trial design that builds on learnings from our earlier studies, we believe SpyGlass Pharma’s BIM-IOL System is well-positioned to advance through clinical development for potential commercial approval.”

ABOUT THE PHASE III PROGRAM

The Phase III clinical trial program consists of two prospective, multicenter, randomized, masked, controlled clinical trials, SGP-005 and SGP-006, evaluating the efficacy and safety of the BIM-IOL System in patients with OAG or OHT undergoing cataract surgery. Each trial is expected to enroll approximately 400 participants and is designed to demonstrate non-inferiority of the BIM-IOL System to a standard of care commercial intraocular lens (IOL) with twice-daily administration of timolol eye drops. The co-primary endpoints are the time-matched change in mean IOP from baseline, as well as the proportion of patients achieving best corrected distance visual acuity (BCDVA) of 20/40 or better. The studies will also measure change in mean IOP, time to postoperative introduction of IOP-lowering medications, and number of IOP-lowering medications introduced postoperatively. Participants will be monitored for up to 36 months to evaluate long-term safety, efficacy, and durability.

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 three 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 initiated two registrational Phase III clinical trials of the BIM-IOL System and continues long-term follow-up of patients in the Phase I/II study investigating the safety and efficacy of the BIM-IOL System. SpyGlass Pharma plans to work with the FDA to advance the program through completion of Phase III clinical trials, New Drug Application 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 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.

FORWARD-LOOKING STATEMENTS

This press release contains forward-looking statements including, but not limited to, statements regarding the expected number of glaucoma and OHT patients to undergo surgery in the United States this year, expected trends in management and treatment of glaucoma, our plans relating to the clinical development of the BIM-IOL System towards commercial approval, including expected enrollment, and the potential advantages of the SpyGlass platform and the BIM-IOL System. These statements are based on numerous assumptions and involve substantial risks, uncertainties and other factors that may cause actual results, levels of activity, performance or achievement to be materially different from the information expressed or implied by these forward-looking statements. The forward-looking statements in this press release are as of the date of this press release. 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.

Media Contact:
Nami Surendranath
+1 (212) 418-8981
nsurendranath@dnacommunications.com

Investor Contact:
Ami Bavishi or Nick Colangelo
Gilmartin Group LLC
investors@spyglasspharma.com