Graybug Vision Reports Full-Data Analysis from 12-Month Treatment Phase of ALTISSIMO Phase 2b Trial in Wet AMD

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- *GB-102 1mg has shown competitive durability and anatomical control versus aflibercept*
- *Trend in mean BCVA of GB-102 1mg compared to aflibercept driven primarily by a subgroup of patients*
- *Developing enhanced formulations and seeking partner funding for additional clinical trials of GB-102*
- *Focus on advancing GB-401 implant for glaucoma*
- *Current cash sufficient to support planned operations into 2023*

Management to host webcast/conference call today at 8 a.m. ET

REDWOOD CITY, Calif., May 12, 2021 (GLOBE NEWSWIRE) -- Graybug Vision, Inc. (Nasdaq: GRAY), a clinical-stage biopharmaceutical company focused on developing transformative medicines for the treatment of diseases of the retina and optic nerve, today provided full-data analysis from the 12-month treatment phase of its Phase 2b ALTISSIMO trial of GB-102 for the treatment of wet age-related macular degeneration (wet AMD), Graybug's proprietary formulation of sunitinib malate injected twice-a-year intravitreally.

The ALTISSIMO trial is a masked and controlled Phase 2b dose-ranging study of two doses of GB-102 with a single control arm of patients on aflibercept, conducted across 33 study sites in the United States. The primary endpoint is median time to first supportive therapy with a vascular endothelial growth factor (VEGF) inhibitor, and secondary endpoints are safety and pharmacodynamics, measured as mean change of best-corrected visual acuity (BCVA) and mean change of central subfield thickness (CST) of the retina.

The ALTISSIMO full-data analysis focused on the GB-102 1mg arm as compared to aflibercept and the pre-enrollment period, excluding results from the GB-102 2mg arm. As previously reported, the development of GB-102 2mg was terminated in 2020 following an interim safety analysis. The trial was not powered to assess non-inferiority to aflibercept.

Overall, GB-102 1mg was safe and well-tolerated. No drug-related serious adverse events or vision-threatening inflammation were reported. The majority of drug-related adverse events were mild to moderate. Particle migration to the anterior chamber in patients treated with GB-102 1mg was reduced by 79% as compared to GB-102 1mg patients in the ADAGIO Phase 1/2a trial (4/51 injections vs. 3/8), and no surgical interventions were required.

As previously reported, patients in the GB-102 1mg trial arm (n=21) had a median time to first supportive therapy of five months, and 48% of patients did not require supportive therapy for at least six months. An additional analysis showed the injection frequency was reduced by 58% compared to patients' treatment prior to enrollment in the trial.

"Given the constantly changing landscape of long-acting drug delivery, GB-102 has the potential to significantly reduce the treatment burden for patients compared to the current standard of care," said Parisa Zamiri, MD, PhD, Chief Medical Officer of Graybug. "The ALTISSIMO results support further exploration of enhanced formulations of GB-102 for the treatment of wet AMD."

Although ALTISSIMO was not powered to show statistical significance, control of CST in patients treated with twice-a-year GB-102 1mg compared with baseline was similar to bi-monthly aflibercept, while BCVA trended lower in GB-102 1mg patients as compared with aflibercept. This trend in visual acuity was primarily driven by six patients: two patients whose disease was not well-controlled despite frequent anti-VEGF treatment prior to enrollment, two patients who experienced adverse events unrelated to GB-102, and two patients who experienced adverse events related to dispersion of GB-102 microparticles.

Over the past 18 months, Graybug continued to optimize its technology platform and initiated the development of additional formulations, which have the potential to preserve the durability of GB-102 microparticles while minimizing the risk of dispersion. These new and enhanced formulations, including injectable implants, also have the potential to simplify the drug reconstitution process as well as minimize the injection technique variability. They have already been incorporated into the development programs of both GB-102 and GB-401. Graybug anticipates that its GB-401 implant program for glaucoma will enter a Phase 1 trial in the first half of 2022.

"We are encouraged by the ALTISSIMO full-data analysis that indicates favorable safety, extended durability, and pharmacodynamics of GB-102, and are in the process of designing an additional trial in wet AMD with enhanced formulations of GB-102 while looking for a partner to fund its further clinical development," said Fred Guerard, PharmD, Chief Executive Officer, Graybug Vision. "We will pause development of GB-103 and GB-102 for diabetic macular edema while we devote our current cash to advancing GB-401 through Phase 1 clinical development. Our opportunistic in-licensing efforts will continue targeting technologies addressing high unmet medical needs in ophthalmology."

Graybug expects to report the results from the on-going six-month extension period of ALTISSIMO in the fourth quarter of 2021.

Conference Call and Webcast

Graybug's management will host a webcast and conference call at 8 a.m. ET / 5 a.m. PT today, May 12, 2021, to discuss the ALTISSIMO clinical results. The live call may be accessed by dialing (844) 955-2748 (domestic) and (929) 517-0407 (international) and entering the conference ID# 5461708 or via webcast from the IR Events & Presentations page of the Investors and Media section of Graybug's website at https://investors.graybug.vision/news-events/events-presentations. Following the live event, a replay will be available at the same location.

About Graybug

Graybug is a clinical-stage biopharmaceutical company focused on developing transformative medicines for the treatment of diseases of the retina and optic nerve. The company's proprietary ocular delivery technologies are designed to maintain effective drug levels in ocular tissue for six months and potentially longer, improving disease management, reducing healthcare burdens and ultimately delivering better clinical outcomes. Graybug's lead product candidate, GB-102, a formulation of the pan-vascular endothelial growth factor (VEGF) inhibitor, sunitinib malate targeting a six-month or longer dosing regimen, inhibits multiple neovascular pathways for the intravitreal treatment of retinal diseases, including wet age-related macular degeneration. Graybug's other product candidates developed using its proprietary technologies also include GB-401, an injectable sustained release formulation of a beta-adrenergic blocker prodrug, for primary open-angle glaucoma, with a dosing regimen of once every six months or longer, and GB-103, a longer-acting version of GB-102, designed to maintain therapeutic drug levels in the retinal tissue for 12 months with a single injection. Founded in 2011 on the basis of technology licensed from the Johns Hopkins University School of Medicine, Graybug is headquartered in Redwood City, California. For more information, please visit www.graybug.vision.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995, including, but not limited to statements regarding the company's clinical pipeline, its ability to identify a partner to advance the development of GB-102 for wet AMD, the timing or outcomes of its interactions with regulatory authorities, its ability to advance GB-102, GB-103, GB-401, or any future product candidate through preclinical or clinical development, its ability to timely secure a partner to fund further development of GB-102 on reasonable terms if at all, achieve its anticipated milestones within the timing outlined above or at all, its ability to conduct planned operations within the evolving constraints arising from the COVID-19 pandemic, and the timing, cost, and results of its clinical trials. Forward-looking statements are subject to risks and uncertainties that may cause the company's actual activities or results to differ significantly from those expressed in any forward-looking statement, including risks and uncertainties described under the heading "Risk Factors" in the company's annual report on Form 10-K for the year ended December 31, 2020, and the other reports the company files from time to time with the Securities and Exchange Commission. These forward-looking statements speak only as of the date of this press release, and the company undertakes no obligation to revise or update any forward-looking statements to reflect events or circumstances after the date hereof.

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