Graybug Vision Reports Preliminary Topline Results from Phase 2b ALTISSIMO Trial

March 9, 2021

- *Median time to first supportive therapy was 5 months for GB-102 1mg*
- *48% of patients in the GB-102 1 mg arm were rescue-free for at least 6 months*
- *Control of retinal thickness was consistent across all trial arms*
- *Mean best-corrected visual acuity with GB-102 1mg trended lower than aflibercept arm*
- *No drug-related serious adverse events*
- *Clinical monitoring is ongoing to observe durability beyond 6 months*

REDWOOD CITY, Calif., March 09, 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 preliminary topline data 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 microparticle depot formulation of sunitinib malate injected 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 pharmacodynamics measures of mean change of best-corrected visual acuity (BCVA) from baseline and mean change of central subfield thickness (CST) of the retina from baseline.

The trial was originally designed to evaluate two separate doses of GB-102, 1mg and 2mg, injected every 6 months as compared with aflibercept injected every 2 months. Based on the results of an interim safety analysis, the 2mg dose was discontinued after the initial dose, and all patients in that arm were switched to 1mg for their second dose.

Analysis of the ALTISSIMO 1mg arm shows the primary endpoint of median time to first supportive therapy was 5 months. Furthermore, 48% of patients did not require supportive therapy for at least 6 months, and 62% of patients for at least 4 months or more, at least once during the trial. Overall, the 1mg dose performed better than the 2mg dose.

Overall, GB-102 1mg was well-tolerated. There were no drug-related serious adverse events, and the majority of drug-related adverse events were mild to moderate. Medication was detected in the anterior chamber in less than 10% of GB-102 1mg injections, and no adverse event required surgical intervention. There was no vision-threatening inflammation observed, and there was no increase in intraocular pressure reported.

CST and BCVA were measured as secondary endpoints. CST in the GB-102 1mg arm was consistent with the study control arm. The mean change from baseline for BCVA for all 20 completers was approximately 9 letters lower across all time points, on average, than that observed in the study control arm.

At the end of the treatment phase, patients were surveyed as to their satisfaction with their treatment compared to their treatment prior to entering the trial. Over 80% of responding patients who had been treated with GB-102 reported that they were equally or more satisfied with their treatment, similar to the satisfaction expressed by patients treated with aflibercept.

ALTISSIMO is continuing through a six-month extension in which 28 of the 50 patients who completed their Month 12 visit were eligible and agreed to continue masked clinical monitoring. Patients will continue with monthly visits until the point at which they require additional supportive therapy, up to a maximum of 6 months. As of today, 22 patients have successfully completed 2 months or more of this six-month extension period without the need for further treatment.

Graybug will determine next steps after completing the full analysis of the ALTISSIMO results, which is anticipated to occur in the second quarter.

"We are very grateful to all patients, investigators and staff who participated in the ALTISSIMO trial, and look forward to the read-out of the extension trial data," said Parisa Zamiri, MD, PhD, Chief Medical Officer of Graybug.

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 microparticle depot 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 is also using its proprietary technologies to develop GB-401, an injectable depot 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, interactions with regulatory authorities, its ability to advance GB-102, GB-103, GB-401, or any future product candidate through clinical development, its ability to 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 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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