Adverum Biotechnologies Provides Update on the INFINITY Trial Evaluating ADVM-022 in Patients with Diabetic Macular Edema

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REDWOOD CITY, Calif., April 28, 2021 (GLOBE NEWSWIRE) -- Adverum Biotechnologies, Inc. (Nasdaq: ADVM) announced a Suspected Unexpected Serious Adverse Reaction (SUSAR) of hypotony (clinically-relevant decrease in ocular pressure) in its INFINITY clinical trial evaluating ADVM-022 gene therapy for the treatment of diabetic macular edema (DME). This event occurred 30 weeks after randomization in one patient treated with a single intravitreal injection of the high dose (6 x 10^11 vg/eye) of ADVM-022 who has developed hypotony, with panuveitis and loss of vision in the treated eye.

In the interests of patient safety, Adverum has decided to immediately unmask the INFINITY Phase 2 study to better understand this event and to help identify and manage any similar potential risk to other patients in this study, which completed patient dosing in December 2020. Additionally, the company is conducting a thorough review of data from the ADVM-022 program and plans to report its findings as the analysis progresses.

“The safety of every patient who is participating in our clinical studies with our gene therapy is the utmost priority for us at Adverum,” said Laurent Fischer, M.D., chief executive officer of Adverum. “We are fully committed to thoroughly assessing this case and ongoing monitoring of this patient and all patients treated with ADVM-022 with our investigators, data monitoring committee (DMC), scientific advisory board, and healthcare authorities.”

The INFINITY study is evaluating two doses of a single intravitreal (IVT) injection of ADVM-022 gene therapy, either a high dose 6 x 10^11 vg/eye or low dose 2 x 10^11 vg/eye. As of December 2020, the INFINITY study was fully enrolled, and all patients completed dosing of the single IVT injection of ADVM-022. All patients continue to be evaluated regularly during the monitoring phase of this study. Adverum is working closely with the DMC and the study sites to proactively develop additional recommendations for patient monitoring and management. All clinical trial sites, as well as the U.S. Food and Drug Administration (FDA), have been advised of this case.

About the INFINITY Phase 2 Trial of ADVM-022 in DR/DME
INFINITY is a Phase 2, multi-center, randomized, double-masked, active comparator-controlled trial designed to assess a single intravitreal (IVT) injection of ADVM-022 in patients with diabetic macular edema (DME), the most common cause of vision loss in patients with diabetic retinopathy (DR).

The INFINITY trial enrolled 36 patients and is designed to demonstrate superior control of disease activity following a single IVT injection of ADVM-022 compared to a single aflibercept injection, as measured by time to worsening of DME disease activity. Participants in this double-masked trial were randomized to one of three arms for their study eye treatment: Arm 1 received high dose (6 x 10^11 vg/eye) of ADVM-022, Arm 2 received low dose (2 x 10^11 vg/eye) of ADVM-022, and Arm 3 received aflibercept at a dose of 2 mg. Additional objectives include assessments of treatment burden, visual acuity, retinal anatomy, and safety outcomes. For additional information about the INFINITY trial, please visit www.clinicaltrials.gov using Identifier NCT#04418427 or www.INFINITYclinicaltrial.com.

About Adverum Biotechnologies
Adverum Biotechnologies (Nasdaq: ADVM) is a clinical-stage gene therapy company targeting unmet medical needs in serious ocular and rare diseases. Adverum is advancing the clinical development of its novel gene therapy candidate, ADVM-022, as a one-time, intravitreal injection for the treatment of patients with wet age-related macular degeneration and diabetic macular edema. For more information, please visit www.adverum.com.

Forward-Looking Statements
Statements contained in this press release regarding the events or results that may occur in the future are “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995. Actual results could differ materially from those anticipated in such forward-looking statements as a result of various risks and uncertainties, which include risks described in Adverum’s Quarterly Report on Form 10-K for the year ended December 31, 2020 and any subsequent filings with the SEC under the heading “Risk Factors.” All forward-looking statements contained in this press release speak only as of the date on which they were made. Adverum undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made.

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