Adverum Biotechnologies Announces First Patient Randomized in Phase 2 INFINITY Trial of ADVM-022 Single Injection Gene Therapy for Diabetic Macular Edema (DME)

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-- INFINITY trial is currently enrolling patients with DME, the most common cause of vision loss in people with diabetic retinopathy --

REDWOOD CITY, Calif., July 13, 2020 (GLOBE NEWSWIRE) -- Adverum Biotechnologies, Inc. (Nasdaq: ADVM), a clinical-stage gene therapy company targeting unmet medical needs in ocular and rare diseases, today announced that the first patient was randomized in the INFINITY clinical trial to evaluate ADVM-022 for the treatment of diabetic macular edema (DME). Diabetes impacts over 30 million people in the United States and over 400 million people globally and is increasing in prevalence. Approximately 5% of adults with diabetes are impacted by DME, a vision-threatening complication of diabetic retinopathy.

Arshad M. Khanani, M.D., M.A., principal INFINITY trial investigator, and director of clinical research, Sierra Eye Associates, where the first patient was enrolled in INFINITY said, “The current gold-standard therapy for DME is burdensome and often not possible clinical practice around the world, as patients require frequent, long-term anti-VEGF intravitreal injections. Based on the transformative data presented to date in the ongoing OPTIC trial for wet AMD, I believe that, with a single intravitreal injection, ADVM-022 has the potential to change the treatment paradigm and improve outcomes for patients with DME.”

“We are excited to have randomized the first patient in INFINITY,” said Aaron Osborne, MBBS, chief medical officer of Adverum Biotechnologies. “With continued growing momentum in our OPTIC and INFINITY trials, our goal is to bring forward our novel gene therapy, ADVM-022 as a one-time treatment option for patients living with wet AMD and DME, two of the leading causes of vision loss and blindness around the world. We are grateful to the participants and investigators and expect to present data from INFINITY in the second half of 2021.”

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 will enroll approximately 33 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 activities. Additional objectives include assessments of treatment burden, visual acuity, retinal anatomy, and safety outcomes.

Across the United States, leading retinal clinical trial sites will participate in the INFINITY trial. For additional information, please visit www.clinicaltrials.gov using Identified NCT#04418427 or www.INFINITYclinicaltrial.com.

About Diabetic Retinopathy (DR) and Diabetic Macular Edema (DME)
In the United States, over 30 million people are impacted by diabetes, and the prevalence has increased significantly to 12% of adults, according to the Centers for Disease Control (CDC)[1]. On a global basis, over 400 million people have diabetes, a significant increase from approximately 100 million in 1980, with prevalence rising to over 8% of adults, according to the World Health Organization (WHO)[2].

Diabetic retinopathy (DR) affects approximately one in three adults with diabetes and can put patients at risk of vision loss. DR can be diagnosed at different severity levels, and is the most common cause of blindness in working-age adults in the U.S.

Diabetic macular edema (DME) is a vision-threatening complication of DR that can occur at any severity stage of DR. DME is characterized by retinal thickening in the area of the macula, and the risk of DME increases with the worsening of the DR severity score (DRSS). DME affects approximately 5% of people with diabetes and is the leading cause of vision loss in patients with DR.

The current standard-of-care therapy for DME is anti-VEGF intravitreal injections. These are effective but typically require frequent and long-term injections for patients to maintain good vision. Compliance with these regimens can be difficult for patients, leading to undertreatment and vision loss. Real-world outcomes in DME with anti-VEGF therapy are meaningfully worse than in clinical trials.

About ADVM-022 Gene Therapy
ADVM-022 utilizes a proprietary vector capsid, AAV.7m8, carrying an aflibercept coding sequence under the control of a proprietary expression cassette. ADVM-022 is administered as a one-time intravitreal injection (IVT), designed to deliver long-term efficacy and reduce the burden of frequent anti-VEGF injections, optimize patient compliance and improve vision outcomes for patients with wet age-related macular degeneration (wet AMD) and diabetic macular edema (DME).

In recognition of the need for new treatment options for wet AMD, the U.S. Food and Drug Administration granted Fast Track designation for ADVM-022 for the treatment of wet AMD.
Adverum is currently evaluating ADVM-022 in the OPTIC Phase 1 clinical trial in patients with wet AMD and the INFINITY Phase 2 trial in patients with DME.

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. Such statements include but are not limited to statements regarding: the potential for ADVM-022 in treating patients with wet AMD and DME; and Adverum’s expectations as to its plans to advance ADVM-022 in DME by enrolling patients in the INFINITY trial, and as to the expected enrollment numbers for the trial; and Adverum’s expectations that it will present data from the INFINITY trial in the second half of 2021. Actual results could differ materially from those anticipated in such forward-looking statements as a result of various risks and uncertainties, which include risks inherent to, without limitation: Adverum’s novel technology, which makes it difficult to predict the time and cost of product candidate development and obtaining regulatory approval; the results of early clinical trials not always being predictive of future results; the potential for future complications or side effects in connection with use of ADVM-022; obtaining regulatory approval for gene therapy product candidates; enrolling patients in clinical trials; reliance on third parties for conducting the OPTIC and INFINITY trials and vector production; the effects of the COVID-19 pandemic on the company’s operations and on the company’s ongoing clinical trials; and ability to fund operations through completion of the OPTIC and INFINITY trials and thereafter. Risks and uncertainties facing Adverum are described more fully in Adverum’s Form 10-Q filed with the SEC on May 28, 2020 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.

Investor and Media Inquiries:

Investors:
Myesha Lacy
Adverum Biotechnologies, Inc.
mlacy@adverum.com
1-650-304-3892

Media:
Cherilyn Cecchini, M.D.
LifeSci Communications
ccecchini@lifescicomms.com
1-646-876-5196

[1] https://www.cdc.gov/diabetes/pdfs/data/statistics/national-diabetes-statistics-report.pdf

[2] https://www.who.int/news-room/fact-sheets/detail/diabetes

Source: Adverum Biotechnologies, Inc.