Adverum Biotechnologies Announces Publication of Preclinical Long-Term Safety Data on ADVM-022 IVT Gene Therapy

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-- Long-term safety and sustained anti-VEGF protein expression out to 30 months following a single IVT injection of ADVM-022 in NHPs --

REDWOOD CITY, Calif., Feb. 02, 2021 (GLOBE NEWSWIRE) -- Adverum Biotechnologies, Inc. (Nasdaq: ADVM), a clinical-stage gene therapy company targeting unmet medical needs in ocular and rare diseases, today announced the publication of preclinical data on ADVM-022 intravitreal (IVT) gene therapy in *Translational Vision Science & Technology (TVST)*, an official journal of the Association for Research in Vision and Ophthalmology (ARVO). ADVM-022 is in clinical trials for wet AMD and DME, and this preclinical study in NHPs is the longest safety and expression study to date, with measurements out 30 months following a single IVT injection.

"There is a growing body of both clinical and preclinical data demonstrating durable efficacy and favorable safety profile following a single IVT injection of ADVM-022," said Laurent Fischer, M.D., chief executive officer at Adverum Biotechnologies. "In this preclinical study, we saw long-term, sustained aflibercept expression out to 30 months following ADVM-022. The levels of aflibercept were sustained at therapeutic levels, with no measurable adverse effects on normal retinal structure and function. We are excited to work on developing ADVM-022 as a potential "one and done" IVT injection therapy that may dramatically reduce the treatment burden for patients living with wet AMD and DME."

Szilárd Kiss, M.D., academic retina specialist, added, "Currently, patients with wet AMD are treated with frequent anti-VEGF intravitreal injections to maintain their vision. One of the highest priorities in research today is to develop therapies that extend the duration of efficacy following treatment, enabling patients to preserve sight for months or years following treatment. The preclinical data on ADVM-022 demonstrate long-term safety and aflibercept expression following a single intravitreal injection of this novel IVT injection gene therapy. We are excited to continue to assess ADVM-022 as it demonstrates the potential to improve real-world visual outcomes over intermittent anti-VEGF injections for patients living with wet AMD."

The publication, titled "Long-Term Safety Evaluation of Continuous Intraocular Delivery of Aflibercept by the Intravitreal Gene Therapy Candidate ADVM-022 in Nonhuman Primates," reported the following:

- A single IVT injection of ADVM-022 (2 x 10^12 vg/eye in this study) appears to be safe and well tolerated and resulted in sustained expression of aflibercept with no detectable adverse effects on normal retinal structure or function measured out to 30 months.
- Sustained therapeutic levels of aflibercept expression post IVT injection of ADVM-022 were confirmed from serial anterior chamber and vitreous humor taps
- Overall ocular health was comprehensively assessed by longitudinal anterior and posterior segment analysis by slit-lamp, fundus examination, optical coherence tomography (OCT), blue light fundus autofluorescence (FAF), as well as terminal histological evaluation; the effect on retinal function was determined by electroretinography (ERG).
- The integrity of retinal pigment epithelium (RPE) was maintained throughout the study with no histological abnormalities observed.
- Mild-to-moderate inflammatory responses were observed that did not require steroid treatment.

The full online publication can be accessed from the TVST website.

About ADVM-022 Gene Therapy
ADVM-022 utilizes a propriety 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 at 2 x 10^11 vg/eye and 6 x 10^11 vg/eye doses. The Company plans to begin a pivotal trial in mid-2021 for ADVM-022 in wet AMD.

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; the potential efficacy and safety of ADVM-022 in wet AMD and DME; Adverum's expectations as to its plans to advance ADVM-022 in wet AMD by initiating a pivotal trial mid-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. Risks and uncertainties facing Adverum are described more fully in Adverum's Form 10-Q filed with the SEC on November 5, 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.

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