Adverum Biotechnologies Completes Patient Enrollment for INFINITY Phase 2 Trial of ADVM-022 in DME and Provides 2021 Business Outlook

January 11, 2021

-- INFINITY Phase 2 trial fully enrolled; data expected in 2H21 --

-- First pivotal trial planned for ADVM-022 in wet AMD in mid-2021; regulatory agency discussion planned 1Q21 --

-- New commercial GMP manufacturing facility expected to be production-ready by YE23 --

REDWOOD CITY, Calif., Jan. 11, 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 completion of patient enrollment in the INFINITY Phase 2 trial to evaluate a single intravitreal injection of ADVM-022, for the treatment of diabetic macular edema (DME). The company will provide a corporate overview at the 39th Annual J.P. Morgan Healthcare Conference on Wednesday, January 13, 2021 at 10:50 a.m. ET. The live webcast will be accessible under Events and Presentations in the Investors section of the company's website.

“2021 is an exciting year for Adverum as we build on the tremendous progress we have made to advance ADVM-022, a potential one-time intravitreal injection gene therapy for VEGF-driven retinal diseases, into a pivotal trial for wet AMD and in Phase 2 for DME. ADVM-022 has the potential to help millions of patients at risk of losing their vision,” said Laurent Fischer, M.D., chief executive officer at Adverum Biotechnologies. “Our investigators understand the potentially transformative clinical data emerging for ADVM-022, and we have seen rapid enrollment of patients in our clinical trials. In INFINITY, we began patient enrollment during the COVID-19 pandemic, and in less than six months, we recently completed patient enrollment. We look forward to sharing data from this trial in the second half of 2021. We are grateful to the participants and investigative sites. As we move through 2021, we are in a strong position with an expert team, a promising lead therapy, and expanding manufacturing capabilities which will enable us to continue to deliver on our mission to bring novel gene therapies to patients as quickly as possible.”

Arshad M. Khanani, M.D., M.A., principal investigator in the INFINITY trial, and director of clinical research at Sierra Eye Associates, said, “Currently, patients with DME require frequent, long-term anti-VEGF intravitreal injections, which during COVID-19 is even more challenging and in many parts of the world actually impossible. ADVM-022 is a single in-office intravitreal injection therapy that has shown promising efficacy and safety for over two years in patients with wet AMD in the OPTIC trial. In INFINITY, we are excited to study ADVM-022 in our patients with DME, who are often of working age and need a more durable treatment over the long course of their disease. ADVM-022 has the potential to be a transformative treatment for patients with DME.”

Dr. Fischer continued, “We are also incredibly excited about our investment in a new GMP commercial manufacturing facility in North Carolina announced last week to support our expected commercialization for the first in-office gene therapy for wet AMD and DME.”

Our Focus in 2021

ADVM-022 in wet AMD:

- Present longer-term data from OPTIC Phase 1 trial, including additional anti-VEGF protein expression data, in the first quarter of 2021
- First pivotal study trial planned for ADVM-022 in wet AMD in mid-2021 following regulatory agency discussion planned for the first quarter of 2021
- Continue to follow OPTIC patients who reached 2-years post treatment with ADVM-022 in a 3-year extension study

ADVM-022 in DME:

- Present clinical data from INFINITY Phase 2 trial in the second half of 2021

Adverum GMP Manufacturing:

- Begin build-out of new GMP commercial manufacturing facility in North Carolina with multiple production suites with 4000L total capacity, expected to be production-ready by the end of 2023 with further expansion capabilities to support the future commercialization of ADVM-022
- Process development scale up from current 200L suspension to 1000L suspension

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 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; Adverum’s expectations that it will present longer-term data from the OPTIC Phase 1 trial for ADVM-022 in wet AMD in the first quarter of 2021 and data from the INFINITY Phase 2 trial for ADVM-022 in DME in the second half of 2021; Adverum’s plans to accelerate the development and future commercial launch plans for ADVM-022; Adverum’s expectations as to its plans to advance ADVM-022 in wet AMD by initiating a pivotal trial mid-2021; the benefits Adverum expects from its new manufacturing facility; and other of Adverum’s expectations of future events under “Our Focus in 2021”. All of these statements are based on certain assumptions made by Adverum on current conditions, expected future developments and other factors Adverum believes are appropriate in the circumstances. Adverum may not achieve any of these in a timely manner, or at all, or otherwise carry out the intentions or meet the expectations disclosed in its forward-looking statements, and you should not place undue reliance on these forward-looking statements. Actual results and the timing of events 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 preliminary or interim results of clinical trials to change as the clinical trial continues or in connection with the preparation and analysis of final 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 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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