Vera Therapeutics Reports Positive Interim Phase 2 Data Showing MAU868 Has Significant BK Antiviral Activity in Kidney Transplant Patients

Jun 4, 2022

- *MAU868, a first-in-class monoclonal antibody,* was well tolerated in kidney transplant recipients with BK viremia
- *Data presented as oral late breaker at American Transplant Congress*
- *BK Virus is a leading cause of transplant loss and transplant-associated morbidity; currently no approved treatments*

BRISBANE, Calif., June 04, 2022 (GLOBE NEWSWIRE) -- Vera Therapeutics, Inc. (Nasdaq: VERA), a late-stage biotechnology company focused on developing and commercializing transformative treatments for patients with serious immunological disease, today announced that interim data from the Phase 2 trial of MAU868 versus placebo to treat BK Virus (BKV) in kidney transplant patients showed that MAU868 was well tolerated and demonstrated significant BK antiviral activity in kidney transplant recipients with BK viremia. These data were delivered today as a late-breaking oral presentation by Daniel C. Brennan, M.D., medical director, Comprehensive Transplant Center, professor of medicine, The Johns Hopkins University School of Medicine, and study investigator, at the American Transplant Congress (ATC) 2022 in Boston, Massachusetts.

“BKV infections represent significant morbidity and mortality factors in kidney transplant recipients. Patients are typically given drugs to suppress their immune systems, which increases their risk of BKV nephropathy, which is strongly correlated with allograft loss and organ rejection. The current immunosuppressive protocols that we have in kidney transplantation can lead to reactivation of BKV. There is a need for a BKV treatment option that could address escalating BKV infections early without risking allograft rejection,” said Stanley C. Jordan, M.D., FASN, FAST, director of nephrology & transplant immunology, Cedars-Sinai Medical Center, professor of pediatrics and medicine at the David Geffen School of Medicine at University of California, Los Angeles, and study lead investigator. “These interim results from the Phase 2 clinical trial showed that MAU868 was well tolerated and demonstrated significant BK antiviral activity in kidney transplant recipients with BK viremia. These data support the further development of MAU868 as a therapy for BK viremia.”

“MAU868 is a first-in-class targeted therapy specifically designed to neutralize BKV. Data presented at ATC showed that MAU868 has a clinically meaningful virologic effect in kidney transplant patients with BK viremia,” said Celia Lin, M.D., chief medical officer at Vera Therapeutics. “These results demonstrate the transformative potential of MAU868, which may prevent devastating downstream consequences caused by BKV. We are working diligently on advancing our clinical program for MAU868 so that we can bring this important potential treatment option to kidney transplant patients who currently have no effective treatment options.”

Details of the oral late-breaking presentation are as follows:

Title:	A Randomized Study of MAU868 vs. Placebo to Treat BK Viremia in Kidney Transplant Recipients
Presenter:	Daniel C. Brennan, M.D.
Abstract Number:	7056
Presentation Number:	9004

This Phase 2, randomized, double-blind, placebo-controlled clinical trial is evaluating the safety and efficacy of MAU868 in patients who received a kidney transplant within one year of enrollment and, within 10 days of enrollment, had BK viremia. Patients received MAU868 or placebo intravenously (IV) every 28 days for 12 weeks, with 24 weeks follow-up. In this clinical trial, 20 patients received MAU868 and eight patients received placebo; all patients completed 12 weeks of treatment. This interim analysis reported results at 12 weeks for two cohorts: MAU868 1350 mg IV x4 doses, and MAU868 6750 mg IV followed by MAU868 1350 mg IV x3 doses. The primary endpoint was safety and tolerability; antiviral activity was assessed in secondary and post-hoc analyses.

Results showed that the antiviral effect was higher in the MAU868 group than the placebo group (see Table). Further, MAU868 was well tolerated, with a comparable frequency of adverse events and serious adverse events between groups.

Table: Antiviral Effect of MAU868 vs. Placebo at Week 12

	MAU868 (N=20)	**Placebo** (N=8)	**P-value**
Proportion of patients with a prespecified reduction of BK plasma viral load - n (%)			

- by ≥1 log	11 (55%)	1 (13%)	0.040
- to <lower limit of quantification (LLOQ)	4 (20%)	0	0.172
- of $<10^4$ DNA copies/mL	15 (75%)	3 (38%)	0.061
Log reduction in BK viremia - median (interquartile range [IQR]) DNA copies/mL	-1.14 (-1.88, -0.50)	0.37 (-0.72, 0.04)	0.051
Change in estimated glomerular filtration rate (eGFR) - median (IQR) mL/min/1.73 m^2	2.0 (-5.0, 4.0)	-6.0 (-8.5, -0.5)	0.217

About BK Virus (BKV)
BK Virus (BKV) is a polyoma virus that can be reactivated in settings of immunosuppression, such as in kidney transplant. It is a leading cause of kidney transplant loss and transplant-associated morbidity; there are currently no approved treatments for BKV.

About MAU868
MAU868 has the potential to neutralize infection by blocking BKV virions from binding to host cells. MAU868 is currently undergoing a randomized, double-blind, placebo-controlled Phase 2 clinical trial to assess the safety, pharmacokinetics, and efficacy for the treatment of BKV in kidney transplant patients. Vera holds an exclusive worldwide license for the development and commercialization of MAU868 in all indications acquired from Amplyx Pharmaceuticals, Inc., a wholly owned subsidiary of Pfizer Inc.

About Vera
Vera Therapeutics is a late-stage biotechnology company focused on developing treatments for serious immunological diseases. Vera's mission is to advance treatments that target the source of immunologic diseases in order to change the standard of care for patients. Vera's lead product candidate is atacicept, a fusion protein self-administered as a subcutaneous injection once weekly that blocks both B lymphocyte stimulator (BLyS) and a proliferation inducing ligand (APRIL), which stimulate B cells and plasma cells to produce autoantibodies contributing to certain autoimmune diseases, including IgA nephropathy (IgAN), also known as Berger's disease, and lupus nephritis. In addition, Vera is evaluating additional diseases where the reduction of autoantibodies by atacicept may prove medically useful. Vera is also developing MAU868, a monoclonal antibody designed to neutralize infection with BK Virus, a polyomavirus that can have devastating consequences in certain settings such as kidney transplant. For more information, please visit www.veratx.com.

Forward-looking Statements
Statements contained in this press release regarding matters, 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 forward-looking statements include statements regarding, among other things, the potential for MAU868 to be a first-in-class targeted therapy specifically designed to neutralize BKV and Vera's strategy and regulatory matters. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. Words such as "plans," "will," "may," "expects," "potential," and similar expressions are intended to identify forward-looking statements. These forward-looking statements are based upon Vera's current expectations and involve assumptions that may never materialize or may prove to be incorrect. Actual results could differ materially from those anticipated in such forward-looking statements as a result of various risks and uncertainties, which include, without limitation, risks related to the regulatory approval process, results of earlier clinical trials may not be obtained in later clinical trials, risks and uncertainties associated with Vera's business in general, the impact of the COVID-19 pandemic, and the other risks described in Vera's filings with the Securities and Exchange Commission. All forward-looking statements contained in this press release speak only as of the date on which they were made and are based on management's assumptions and estimates as of such date. Vera undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made, except as required by law.

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