Vera Therapeutics Announces Acquisition of Monoclonal Antibody From Pfizer to Treat BK Virus in Transplant Patients

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Ongoing Phase 2 clinical trial for MAU868 in kidney transplant patients; potential first-in-class

MAU868 Phase 2 data for kidney transplant to readout mid-2022

BK Virus is a leading cause of transplant loss and transplant-associated morbidity

BRISBANE, Calif., Dec. 17, 2021 (GLOBE NEWSWIRE) -- Vera Therapeutics, Inc. (Nasdaq: VERA), a clinical-stage biotechnology company focused on developing treatments for immunological diseases that improve patients' lives, announced today that it has acquired MAU868, a first-in-class monoclonal antibody to treat BK Virus (BKV) infections, and has entered into a credit facility with Oxford Finance LLC (Oxford) to provide borrowing capacity up to $50 million. MAU868, acquired from Amplyx Pharmaceuticals, Inc., a wholly owned subsidiary of Pfizer Inc., has the potential to neutralize infection by blocking BKV virions from binding to host cells.

"BKV is a leading cause of kidney transplant loss and transplant-associated morbidity, and there are currently no available antiviral treatments in the U.S. We are excited to acquire MAU868 from Pfizer and carry it forward in development," said Vera founder and CEO Marshall Fordyce, MD. "The acquisition of MAU868, a potentially transformative treatment for BKV, is consistent with our strategy to diversify our pipeline with new molecules that leverage our strengths and serve adjacent populations. We believe, based on currently available data, that MAU868 has the potential to significantly impact outcomes for kidney transplant patients and become the first effective therapy for BKV. We look forward to working with regulators to establish a new standard of care for kidney transplant patients."

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. MAU868 has been shown in an interim analysis of week 12 data from Cohort 1 and 2 of a Phase 2 study to be well tolerated and showed a greater proportion of subjects with decrease in BK plasma viral load versus placebo. Full Cohort 1 and 2 interim analysis results will be submitted for presentation at a conference in mid-2022.

Up to 90 percent of healthy adults are infected with BKV, but it remains latent in kidney and bladder tissues. Reactivation occurs in the setting of immune suppression, and causes clinical disease in the transplant setting. BKV is a significant cause of complications in these immunocompromised patients, including in kidney transplant and hematopoietic stem cell transplant (HSCT) recipients. In kidney transplant recipients, BKV is a leading cause of allograft loss and poor outcomes, while in HSCT recipients, the virus significantly increases the risk of severe hemorrhagic cystitis, which causes bladder damage. There are currently no approved treatments for BKV in the U.S.

MAU868 Asset Acquisition
In partial consideration for the asset acquisition, Vera made an upfront payment of $5.0 million. In addition to the upfront payment, Vera is also obligated to make certain milestone payments in an aggregate amount of up to $7.0 million based on certain regulatory milestones. Further, Vera is required to pay Amplyx low single-digit percentage royalties based on net sales on a country-by-country and product-by-product basis. The rights to MAU868 that Vera acquired from Amplyx are subject to a license agreement by and between Amplyx and Novartis International Pharmaceutical AG, pursuant to which Vera is obligated to make certain milestone payments in an aggregate amount of up to $69.0 million based on certain clinical development, regulatory and sales milestones. Further, the Company is required to pay Novartis mid-to-high single-digit percentage royalties based on net sales on a country-by-country and product-by-product basis.

Credit Facility
Vera also announced today that they entered into a credit facility with Oxford Finance. Under the terms of the loan agreement, Oxford will provide Vera with borrowing capacity of up to $50 million. The initial $5 million funded at closing, and an additional $45 million will be available in minimum draws of $5 million, at Vera's option through the end of 2022. The debt facility provides for at least 48-months of interest-only at close. There are no warrants or financial covenants associated with the credit facility. Armentum Partners served as the Company's financial advisor on the debt financing.

About Vera
Vera Therapeutics is a clinical-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. Vera is also developing MAU868, a monoclonal antibody that neutralizes 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 that are not historical facts 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 efficacy of our product candidates, research and clinical development plans, the scope, progress, and results of developing our product candidates, strategy, regulatory matters, including the timing and likelihood of success of obtaining drug approvals, market opportunity and our ability to complete certain milestones, the timing of the expected closing of the debt financing, and the expected use of the net proceeds therefrom. 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," "anticipates," "goal," "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 ability to realize the anticipated benefits of the acquisition, including the possibility that the expected benefits from the acquisition will not be realized or will not be realized within the expected time period, 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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