

Amplyx Doses First Patient in Phase 2 Clinical Trial of Anti-BKV Monoclonal Antibody in Renal Transplant Recipients

- MAU868 has the potential to be the first therapeutic to prevent and treat BKV-associated diseases in transplant patients



NEWS PROVIDED BY

Amplyx Pharmaceuticals →

Aug 17, 2020, 08:00 ET

SAN DIEGO, Aug. 17, 2020 /PRNewswire/ -- Amplyx Pharmaceuticals, a clinical-stage biopharmaceutical company developing innovative therapies for debilitating and life-threatening diseases in patients with compromised immune systems, today announced that the first patient has been dosed in its Phase 2 clinical trial evaluating the efficacy and safety of MAU868 for the treatment of BK viremia in kidney transplant recipients. MAU868 is a novel, human monoclonal antibody that potently neutralizes all four major genotypes of BK virus (BKV). BKV-associated nephropathy is a leading cause of kidney allograft loss.

"There are currently no treatments for BKV. Dosing the first patient represents a strong start to this important clinical trial and a key milestone in our development program taking us one step closer to bringing a first-in-class treatment to the vulnerable patients at risk for this devastating transplant complication," said Ciara Kennedy, PhD, president and chief executive officer. "Now, more than ever, it is important that we have therapies to treat our most immunocompromised patients."

Approximately 80-90% of adults worldwide have been exposed to BKV. While initial infection is usually asymptomatic or associated with mild flu-like illness, reactivation of BKV in immunocompromised patients can lead to serious, life threatening disease. In patients who have had kidney transplant, reactivation of BKV can lead to the loss of the transplanted kidney. In the absence of effective treatments available for BKV, the current standard of care relies on the reduction of immunosuppression; however, lowering the immunosuppression can also put the patient at risk for acute organ rejection.

"Over 650,000 Americans face end-stage renal disease; with diabetes, high blood pressure, and other causes of renal failure on the rise, this number is likely to increase. More than 100,000 Americans alone are waiting for a kidney transplant, there are simply not enough donor kidneys to go around," said Stanley Jordan, MD, medical director, kidney transplant program, Cedars-Sinai Medical Center. "The risk of BKV reactivation is a major concern following kidney transplantation. Effective treatments are desperately needed to preserve the life of transplanted kidneys which would mean fewer patients going back on dialysis or needing a second transplant. A therapy like MAU868 would be a game changer for the renal transplant community."

About the Phase 2 Trial

The Phase 2 clinical trial is a multicenter, randomized, double-blind, placebo-controlled study to assess the safety, pharmacokinetics, and efficacy of MAU868 for the treatment of BK viremia in kidney transplant recipients at centers in the US and Canada. The study's primary objectives are to assess the safety of MAU868 in this patient population and to evaluate the efficacy of MAU868 in reducing BKV plasma viral load. **ClinicalTrials.gov Identifier: NCT04294472**

About BK Virus

BK Virus (BKV) is one of 13 known polyomaviruses. Antibodies to BKV are found in approximately 80 to 90% of adults worldwide, indicating previous infection or exposure to the virus. Initial infection with BKV is usually asymptomatic or associated with a mild flu-like illness. After primary infection, BKV remains inactive, or latent, in the kidney and bladder. A weakened immune system may result in BKV reactivation and cause serious disease. In patients who have had kidney transplant, BKV can lead to the loss of the transplanted kidney. In the absence of effective treatment, reduction of immunosuppression is

recommended; however, lowering of the immunosuppression can lead to acute organ rejection. BKV reactivation in the bladder can also cause hemorrhagic cystitis. Severe cases require bladder irrigation, clot evacuation, blood transfusion, stenting and nephrostomy. There are currently no approved treatments for renal nephropathy or hemorrhagic cystitis caused by BKV.

About MAU868

MAU868 is a novel, human monoclonal antibody directed against the major viral capsid protein of BKV, VP1, which is essential for binding to and infection of cells. MAU868 neutralizes all four major genotypes of BKV at sub-nanomolar concentrations and has a high barrier to resistance *in vitro*. MAU868 also has neutralizing activity against the closely related JC virus, the cause of progressive multifocal leukoencephalopathy.

About Amplyx Pharmaceuticals

Amplyx Pharmaceuticals is developing innovative therapies for patients with compromised immune systems, including cancer and transplant patients, and the critically ill. The company's two lead products are fosmanogepix (APX001), a first-in-class antifungal, for the treatment of life-threatening fungal infections caused by pathogens such as *Candida*, *Aspergillus* and rare molds, and MAU868, a novel human monoclonal antibody that potently neutralizes the BK virus, which can cause significant morbidity and mortality in transplant patients. For more information, please visit www.amplyx.com

SOURCE Amplyx Pharmaceuticals

Related Links

<http://www.amplyx.com>