

Amplyx Pharmaceuticals Licenses Phase 2 Drug Candidate for BK Viral Disease in Transplant Patients

Company expands pipeline of innovative therapies for immunocompromised patients



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Amplyx Pharmaceuticals →

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SAN DIEGO, Sept. 16, 2019 /PRNewswire/ -- Amplyx Pharmaceuticals, a biotech company dedicated to developing innovative therapies for debilitating and life-threatening diseases in patients with compromised immune systems, announced today that it has executed an exclusive worldwide license agreement with Novartis under which Amplyx has acquired the rights to the Phase 2 anti-BK virus (BKV) monoclonal antibody, MAU868, for the treatment and prevention of BKV disease. Financial terms have not been disclosed.

MAU868 is a potent neutralizing monoclonal antibody with activity against BKV, which is present in 80 to 90 percent of the population. BKV reactivation can occur following kidney transplantation and may result in BKV nephropathy, a leading cause of renal allograft loss. BKV reactivation also occurs in patients who have received hematopoietic stem cell transplants (HSCT) and can lead to hemorrhagic cystitis, a painful and potentially life-threatening inflammatory condition of the bladder. BKV disease can have devastating and costly consequences in transplant patients. The company is planning two Phase 2 proof-of-concept clinical trials of MAU868 in BKV disease.

"MAU868 builds on Amplyx's significant experience from the fosmanogepix (APX001) program, currently in development for the treatment of life threatening invasive fungal infections, and expands the company pipeline of novel treatments for debilitating and life-threatening diseases in patients with compromised immune systems," said Ciara Kennedy, Ph.D., president and CEO of Amplyx. "We anticipate starting Phase 2 trials in the near future and, longer term, seeking approval for MAU868 as the first antiviral drug for BKV disease."

About BK Virus

BK virus is one of 13 known polyomaviruses. Antibodies to BKV are found in approximately 80 to 90 percent 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 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 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 new cells. MAU868 neutralizes all four 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 focused on 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) for the treatment of life-

threatening fungal infections caused by pathogens such as *Candida*, *Aspergillus* and rare molds; and MAU868, a 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.

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