

# Amplyx Pharmaceuticals Announces Positive Preliminary Data from Ongoing Fosmanogepix Phase 2 Study in Candidemia



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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 two independent review committees completed their planned safety and efficacy assessment of data from 50% of the planned study population enrolled in the Company's Phase 2 open-label clinical trial of fosmanogepix (APX001) for the treatment of candidemia.

The Data Review Committee (DRC) and Data Safety Monitoring Board (DSMB) have reviewed data from the first ten patients. The DRC adjudicated that fosmanogepix demonstrated a high level of treatment success at the end of study drug treatment. Treatment success is defined as clearance of *Candida* from the blood, patient is alive following treatment, and the patient received no other systemic antifungal therapies following initiation of study drug. Following review of the safety data, the DSMB recommended that the study continue according to the protocol. The Phase 2 study will continue to enroll patients, with a planned total of 20 patients by the end of the year, across sites in the United States, Europe and Israel.

"These initial results from the fosmanogepix Phase 2 candidemia study are the first efficacy data in patients and support the highly differentiated profile of fosmanogepix for the treatment of serious fungal infections, representing an important milestone for the development of fosmanogepix," said Ciara Kennedy, Ph.D., president and CEO of Amplyx.

Invasive fungal infections are a significant cause of morbidity and mortality in critically ill and immunocompromised patients. The rise of difficult-to-treat fungal infections, particularly those caused by multidrug-resistant strains, such as *Candida auris* and *Candida glabrata*, is a serious and growing public health threat. In addition, no new classes of antifungal drugs have been approved since 2001, and many of the existing antifungal agents are difficult to use, poorly tolerated or ineffective due to resistance to approved drug classes.

"Candidemia is a significant threat in patients who are critically ill or have compromised immune systems, with mortality among patients as high as 40%, even when patients receive standard-of-care antifungal therapy. The currently available antifungal agents are associated with significant side effects such as liver or kidney damage," said George Thompson, MD, professor of clinical medicine at the University of California, Davis, School of Medicine. "Clearly, there is a need for new medicines that are safe, better tolerated, are easier to administer without the risk of drug interactions and are available in both IV and oral formulations. Fosmanogepix has the potential to become an important therapy for treating patients with these life-threatening infections."

### **About Fosmanogepix**

Fosmanogepix is currently in Phase 2 clinical trials evaluating the efficacy and safety of both IV and oral formulations for the first-line treatment of patients with fungal infections. Manogepix (APX001A), the active moiety of fosmanogepix (APX001), inhibits the highly conserved fungal enzyme Gwt1, compromising growth of fungal pathogens. The novel mechanism of action of fosmanogepix translates into a highly versatile drug that demonstrates activity against drug-resistant strains and can be delivered in both oral and intravenous formulations. In multiple nonclinical studies, manogepix has shown broad-spectrum activity against common species of *Candida* and *Aspergillus*, including multi-drug resistant strains, such as *C. auris* and *C. glabrata*, as well as rare, hard-to-treat molds including *Fusarium*, *Scedosporium*, and fungi from the Mucorales order.

Invasive infections due to *Aspergillus*, *Fusarium*, *Scedosporium* and other rare molds are especially difficult to treat resulting in high mortality rates (50-80%), even when patients receive standard-of-care treatment. The frequency of fungi resistant to both the azole and echinocandin classes of drugs is increasing. Thus, there remains a significant unmet medical need for a new broad-spectrum antifungal to treat serious, invasive fungal infections and reduce the existing high morbidity and mortality.

### **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](http://www.amplyx.com).

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