

Amplyx Pharmaceuticals Advances Development of Novel Antifungal, Fosmanogepix

Completes Enrollment of Phase 2 Candida Trial

Treats First Patients in Phase 2 Trials in Aspergillus and Candida auris Infections



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SAN DIEGO, May 19, 2020 /PRNewswire/ -- Amplyx Pharmaceuticals, a biotech company developing innovative therapies for debilitating and life-threatening diseases in patients with compromised immune systems, announced today that it has advanced development of its lead program, fosmanogepix (APX001). Enrollment has been completed in a Phase 2 trial evaluating the safety and efficacy of fosmanogepix for the treatment of infections caused by *Candida*. Top-line data from the trial is expected by July; the results of an initial analysis of the first 10 patients enrolled showed a high level of treatment success. The first patients have also completed treatment in two additional Phase 2 clinical trials evaluating the safety and efficacy of fosmanogepix (APX001) for the treatment of invasive mold infections caused by *Aspergillus* and rare molds, as well as a study of invasive candidiasis caused by *Candida auris*, an emerging, life-threatening, drug-resistant fungal pathogen.

"There is an urgent need for effective new antifungal agents, especially those with activity against *Candida auris* and *Aspergillus*," said Thomas F. Patterson, M.D., chief, division of infectious diseases, UT Health San Antonio. "These infections are increasingly difficult to treat, and the rise in the rate of infections is alarming. The need for safe and effective therapies with new and different mechanisms of actions is critical, especially with the growing number of immunocompromised patients who are at increased risk for developing these life-threatening infections."

Amplix is developing fosmanogepix, a broad-spectrum, oral and intravenous antifungal representing a novel therapeutic class, with the potential to treat pathogens resistant to current available antifungal agents. In 2019, the U.S. Centers for Disease Control recognized drug-resistant *C. auris* as an urgent threat to global public health. Other drug-resistant *Candida* strains are recognized as serious threats, and the emergence of drug-resistant *Aspergillus* has been added to the watch list for global health threats, underscoring the need for innovation in the development of antifungals.

"Given the increasing threat of drug-resistant fungal pathogens, including certain strains that are resistant to all currently approved classes of antifungal drugs, there is a clear need to develop compounds that have new mechanisms of action," said Ciara Kennedy, Ph.D., president and chief executive officer of Amplix. "With its unique mechanism of action and activity against drug-resistant strains, fosmanogepix has the potential to address this important unmet need."

Candidemia is a major cause of morbidity and mortality in the healthcare setting. *Candida* species are ranked as the fourth main cause of bloodstream infections in hospitals, and the frequency of candidemia has increased in recent years. The prognosis following infection is generally poor, with a reported mortality rate for candidemia in the range of 30% to 60%. The ongoing *C. auris* study is a multi-center, open-label Phase 2 study to evaluate the safety and efficacy of both intravenous and oral fosmanogepix for the treatment of patients with candidemia, caused by *C. auris*, including patients with suspected or confirmed resistance to standard-of-care antifungal treatments.

Invasive aspergillosis is a severe, life-threatening fungal infection that typically affects immunocompromised patients, including those with acute leukemia, recipients of allogeneic hematopoietic cell transplant (HCT) or organ transplants, and those who are critically ill. The

reported mortality rate ranges from 30-95%. The current standard-of-care treatment options are associated with significant limitations, including renal or hepatic toxicities, drug-drug interactions and development of antimicrobial resistance. The ongoing *Aspergillus* study is a multi-center, open-label, Phase 2 study to evaluate the safety and efficacy of both intravenous and oral fosmanogepix for the treatment of patients with invasive mold infections caused by *Aspergillus* species and rare molds.

More information about the trials is available at www.clinicaltrials.gov, identifier NCT04148287 and NCT04240886.

About Fosmanogepix

Fosmanogepix, is a novel broad-spectrum antifungal agent being evaluated in multiple clinical trials in patients with life-threatening fungal infections. Enrollment was recently completed in a Phase 2 trial evaluating the safety and efficacy of the intravenous and oral formulations of fosmanogepix for the treatment of patients with *Candida* infections. In that study, fosmanogepix demonstrated a high level of treatment success in the first 10 patients treated. Additional Phase 2 studies of fosmanogepix are ongoing in patients with *Aspergillus* and other mold infections, as well as infections caused by multi-drug-resistant *Candida auris*, a life-threatening fungal infection recently characterized as an "urgent" threat by the Centers for Disease Control.

Fosmanogepix has a novel mechanism of action, and its active moiety 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 some fungi from the Mucorales order. Invasive fungal infections result in high mortality rates (30-80%), despite standard-of-care treatment. The frequency of fungi resistant to both the azole and echinocandin classes of drugs is increasing, and there is a significant unmet medical need for a new broad-spectrum antifungal agent.

Fosmanogepix has received Fast Track and Orphan Drug designations from the U.S. Food and Drug Administration for seven separate indications, and is designated as a Qualified Infectious Disease Product (QIDP) for the treatment of four indications.

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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