FDA Grants Fast Track Status to Amplyx Pharmaceuticals for IV and Oral Formulations of Fosmanogepix (APX001) for Seven Different Indications

Designation Underscores Urgent Need for New Antifungals Targeting Multidrug-Resistant Pathogens

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SAN DIEGO, Sept. 9, 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 the U.S. Food & Drug Administration (FDA) has granted Fast Track designations for both the intravenous (IV) and oral formulations of the company's lead antifungal candidate, fosmanogepix (APX001), for seven indications. These indications include treatment of invasive candidiasis, treatment of invasive aspergillosis, treatment of scedosporiosis, treatment of fusariosis, treatment of mucormycosis, treatment of cryptococcosis and treatment of coccidioidomycosis. Amplyx is investigating the safety and efficacy of fosmanogepix in its ongoing global Phase 2 clinical program.

Invasive fungal infections are a significant cause of morbidity and mortality in critically ill and immune-compromised patients. With the rise of increasingly difficult-to-treat fungal infections, particularly those caused by multidrug-resistant strains such as *Candida auris,* there 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 the rise of drug-resistant strains.

"The FDA Fast Track designation for fosmanogepix is an important step forward in addressing the need for new medicines to treat fungal infections," said Ciara Kennedy, Ph.D., president and CEO of Amplyx. "With fosmanogepix and its novel mechanism of action and robust clinical program, we are directly addressing the threat of invasive fungal infections by developing innovative therapies for immunocompromised patients who need them the most. We look forward to working closely with the FDA as we continue to advance fosmanogepix through clinical development."

Fast Track designation is awarded to expedite the study and regulatory review of drugs intended to treat serious or life-threatening conditions that demonstrate the potential to address unmet medical needs. The two formulations of fosmanogepix have previously been granted Qualified Infectious Disease Product (QIDP) designation for the four qualified fungal pathogens including *Candida* species, *Aspergillus* species, *Coccidioides* species and *Cryptococcus* species. QIDP designation also makes fosmanogepix eligible for priority review and an additional five years of U.S. market exclusivity, if approved. These incentives are part of the Generating Antibiotic Incentives Now Act (GAIN Act), which was enacted in July 2012 as part of the FDA Safety and Innovation Act (FDASIA) and was part of the fifth authorization of the Prescription Drug User Fee Act (PDUFA V). In addition to Fast Track and QIDP designations, fosmanogepix received orphan drug designation for the treatment of invasive candidiasis, invasive aspergillosis, cryptococcosis, coccidioidomycosis and rare mold infections caused by *Scedosporium* spp., *Fusarium* spp., and Mucorales fungi (including *Mucor* spp., and *Rhizopus* spp.). Orphan drug designation qualifies APX001 for seven years of market exclusivity in the U.S. upon FDA approval of a new drug application (NDA). Orphan drug and QIDP designation, combined with Fast Track designation, provide a total of twelve years of marketing exclusivity.

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 major 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* spp. and *Aspergillus* spp., including multi-drug resistant strains such as *Candida auris* and rare, hard-to-treat molds including *Fusarium* spp., *Scedosporium* spp., and fungi from the Mucorales order.

Invasive infections due to *Aspergillus, Fusarium, Scedosporium* and fungi from the Mucorales order 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 lead product is fosmanogepix (APX001) for the treatment of life-threatening fungal infections caused by pathogens such as *Candida*, *Aspergillus* and rare molds. For more information, please visit www.amplyx.com.

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