

# Amplyx Pharmaceuticals Receives Fourth "Qualified Infectious Disease Product" (QIDP) Designation from the FDA for APX001

QIDP Designation Granted for Treatment of Cryptococcosis Provides Priority Review, Fast-Track Status and Five Additional Years of Market Exclusivity



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**Amplyx Pharmaceuticals** →

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SAN DIEGO, March 19, 2018 /PRNewswire/ -- Amplyx Pharmaceuticals, a company developing first-in-class products for life-threatening infections, including deadly fungal pathogens, today announced that the US Food and Drug Administration (FDA) has granted a fourth Qualified Infectious Disease Product (QIDP) designation to APX001, the company's lead antifungal product candidate.

The QIDP designation, a provision under the U.S. Generating Antibiotic Incentives Now (GAIN) Act, was approved by Congress in 2012 to offer incentives to companies to bring to market new treatments for deadly infections. These incentives provide APX001 with eligibility for priority FDA review and fast-track status, and an additional five years of market exclusivity under the Hatch-Waxman Act.

Amplyx had previously received QIDP designation as well as orphan drug designation from the FDA for APX001 for the treatment of invasive candidiasis, invasive aspergillosis, and coccidioidomycosis. This new QIDP status expands the eligible population to include the treatment of cryptococcosis.

"Amplyx has now received QIDP designation for all of the qualified fungal pathogens covered by the program, which serves to highlight the broad spectrum of activity of APX001," said Ciara Kennedy, PhD, Chief Executive Officer of Amplyx. "The associated government incentives will provide a pathway to make APX001 available as quickly as possible to patients who urgently need new treatments, and provide APX001 with market exclusivity for up to 12 years in the United States."

### **About APX001**

APX001 is the prodrug of APX001A, which is a first-in-class small molecule drug candidate that inhibits the highly conserved fungal enzyme Gwt1, compromising growth of major fungal pathogens, including *Candida* and *Aspergillus*. 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. As with multidrug-resistant bacteria, the frequency of fungi resistant to both the azole and candin 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.

The novel mechanism of action of APX001 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, APX001A has shown broad-spectrum activity against common species of *Candida* spp., and *Aspergillus* spp., including multi-drug resistant strains including *Candida auris* and rare, hard-to-treat molds including *Fusarium* spp., *Scedosporium* spp., and fungi from the Mucorales order.

### **About Amplyx Pharmaceuticals**

Amplyx Pharmaceuticals is developing first-in-class products for life-threatening infections, with a near-term focus on deadly fungal pathogens in vulnerable, immune compromised

patients. Amplyx's drug discovery and development efforts have been supported by significant venture investment and more than \$10 million in grants from the National Institutes of Health. For more information, please visit [www.amplyx.com](http://www.amplyx.com).

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