

## SCYNEXIS Receives Qualified Infectious Disease Product (QIDP) Designation from the FDA for Antifungal Agent SCY-078 for Oral Use

RESEARCH TRIANGLE PARK, N.C.--(BUSINESS WIRE)-- Drug discovery and development company SCYNEXIS, Inc., today announced that the Food and Drug Administration (FDA) designated SCY-078 as a Qualified Infectious Disease Product (QIDP) for oral use for the indications of invasive *Candidiasis*, including *Candidemia*, and invasive *Aspergillosis*. The QIDP designation, provided under the 2012 U.S. Generating Antibiotic Incentives Now (GAIN) Act, allows SCYNEXIS to have priority review, eligibility for fast-track status, and an additional five years of market exclusivity in the U.S. for SCY-078.

SCY-078, formerly MK-3118, SCYNEXIS's lead product, is entering Phase 2. SCY-078 has shown activity against the two main pathogens responsible for the majority of invasive fungal infections (IFI), *Candida* and *Aspergillus* species, and is an oral and parenteral glucan synthase inhibitor developed for the treatment of IFI.

"Receiving the QIDP designation from the FDA gives us even greater confidence as we advance SCY-078 towards Phase 2 clinical trials and eventually to the marketplace," said Dr. Yves Ribeill, SCYNEXIS president and chief executive officer. "Glucan synthase inhibitors have been very effective in treating invasive fungal infections in a hospital setting, but there is currently no oral formulation."

### About Invasive Fungal Infections

Invasive fungal infections (IFI) are serious, often life-threatening infections caused by a variety of fungal species. The most common invasive fungal infections stem from *Candidiasis* and *Aspergillosis*, responsible for approximately 85 percent of all invasive fungal infections in the U.S. and Europe. The incidence of invasive fungal infections has increased significantly over the past two decades, as the populations of patients at risk have continued to rise. Morbidity and mortality remain high despite the currently available antifungal agents. Because there are limited treatment options, and they are used widely, there has been an increase in the number of infections due to drug-resistant strains.

### About SCY-078

SCY-078 (formerly MK-3118) is an oral glucan synthase inhibitor being developed for the treatment of invasive fungal infections. SCY-078 is a semi-synthetic derivative of the natural product enfumafungin—a structurally distinct class of glucan synthase inhibitors. Glucan synthase inhibitors have been very effective in treating invasive fungal infections in a hospital setting but are currently only available in intravenous formulations. Multiple Phase 1

studies have been completed on this novel compound, and data were presented at the 49<sup>th</sup> and 50<sup>th</sup> Interscience Conference on Antimicrobial Agents and Chemotherapy (ICAAC) and published in multiple journals including the May 2012 issue of *Bioorganic & Medicinal Chemistry Letters* and the November 2012 issue of the *Journal of Antimicrobial Chemotherapy*.

## **About SCYNEXIS**

SCYNEXIS is a pharmaceutical company committed to the discovery, development and commercialization of novel anti-infectives to address significant unmet therapeutic needs. We are developing our lead product candidate, SCY-078, as a novel oral and intravenous (IV) drug for the treatment of serious and life-threatening invasive fungal infections in humans. In addition, we have clinical and preclinical programs based on the use of cyclophilin inhibitors to treat viral diseases, as well as contract research and development services in primarily in the field of animal health. [www.scynexis.com](http://www.scynexis.com)

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