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# SCYNEXIS Applauds the Biomedical Advanced Research and Development Authority (BARDA) for Its New Priority Focus on Investment in Development of Antifungal Treatments to Fight Infections Caused by Drug-Resistant Fungal Threats

- BARDA is seeking to support the development of broad-spectrum, oral/IV antifungal drug candidates with novel mechanisms of action that target *Candida* species, including *Candida auris,* and *Aspergillus* species.
- Ibrexafungerp, a first-in-class, broad-spectrum oral/IV antifungal meets all the priorities outlined by BARDA in its new Broad Agency Announcement (BAA) released this week, and has shown activity against multiple drug-resistant pathogens, including *C. auris, C. albicans*, *C. glabrata*, *C. parapsilosis* and *C. tropicalis*, as well as *Aspergillus fumigatus*, *Histoplasma* spp. and *Mucorales*.

JERSEY CITY, N.J., Nov. 17, 2022 (GLOBE NEWSWIRE) -- SCYNEXIS, Inc. (NASDAQ: SCYX), a biotechnology company pioneering innovative medicines to overcome and prevent difficult-to-treat and drug-resistant infections, today applauded action taken this week by the Biomedical Advanced Research and Development Authority (BARDA) to add to the areas of interest in its new Broad Agency Announcement (BAA) the development of antifungal Medical Countermeasures (MCM) to treat infections caused by drug-resistant fungal threats. For the first time, BARDA announced this week it is seeking partnerships to develop broad-spectrum next-generation antifungal drugs to treat high-priority fungal infections.

“It is extremely exciting to see BARDA announce increased emphasis on fighting dangerous fungal pathogens,” said Marco Taglietti, M.D., President and Chief Executive Officer of SCYNEXIS. “Ibrexafungerp, with its promising activity against multiple drug resistant and often-deadly fungal infections, has enormous potential to benefit patients with severe fungal disease and limited treatment options. As a leader in the antifungal area with multiple ongoing Phase 3 studies, SCYNEXIS is well positioned to answer BARDA’s call to action, and we are pleased with our continued clinical progress as we remain committed to bringing our innovative, potent antifungal to market as a potential option for patients with difficult-to-treat fungal infections.”

The announcement regarding the increased focus on antifungal treatment development was made during BARDA Industry Day (BID) held on November 15 and 16, 2022, an annual conference regarding ongoing collective efforts to support continued innovation and advancement in MCM development and preparedness against chemical, biological, radiological and nuclear (CBRN) threats, pandemic influenza and emerging infectious

diseases. According to the BARDA BAA, priorities include drug candidates that represent a first-in-class antifungal with a novel mechanism of action or have an improved formulation or alternate delivery regimens (e.g., oral and intravenous).

This call to action follows on the heels of the publication in October of the World Health Organization (WHO) published its first-ever report highlighting a list of fungal "priority pathogens" that represent the greatest menacing threat to public health. The WHO dangerous pathogens list includes well known pathogens such as *Candida auris* (*C. auris*) and other *Candida* species, such as *C. albicans*, *C. glabrata*, *C. parapsilosis* and *C. tropicalis*, as well as *Aspergillus fumigatus*, *Histoplasma* spp. and *Mucorales*.

“The deadly and drug-resistant pathogens on the WHO list are organisms against which ibrexafungerp shows great activity, even in strains highly resistant to other antifungals,” said David Angulo, M.D., Chief Medical Officer at SCYNEXIS. “The data from our Phase 3 FURI and CARES studies provide evidence of the clinical activity of ibrexafungerp against severe, difficult-to-treat fungal infections refractory to currently available treatments. The BARDA news this week and the WHO’s call for action is further validation of our corporate strategy to focus on life-threatening invasive fungal infections. At SCYNEXIS we are proud to be on the front lines with ibrexafungerp to fight this never-ending warfare against antimicrobial resistant pathogens.”

**About Ibrexafungerp**

Ibrexafungerp [pronounced eye-BREX-ah-FUN-jerp] is an antifungal agent and the first representative of a novel class of structurally-distinct glucan synthase inhibitors, triterpenoids. This agent combines the well-established activity of glucan synthase inhibitors with the potential flexibility of having oral and intravenous (IV) formulations. Ibrexafungerp is in late-stage investigation and development for multiple indications, including life-threatening fungal infections caused primarily by *Candida* (including *C. auris*) and *Aspergillus* species in hospitalized patients. It has demonstrated broad-spectrum antifungal activity, *in vitro* and *in vivo*, against multidrug-resistant pathogens, including azole- and echinocandin-resistant strains. The FDA granted Qualified Infectious Disease Product (QIDP) and Fast Track designations for the oral and IV formulations of ibrexafungerp for the indications of invasive candidiasis (IC), including candidemia, and invasive aspergillosis (IA) and has granted Orphan Drug Designation for the IC and IA indications. The European Medicines Agency (EMA) has granted ibrexafungerp Orphan Medicinal Product designation for the indication of IC. Ibrexafungerp is formerly known as SCY-078.

**About SCYNEXIS**

SCYNEXIS, Inc. (NASDAQ: SCYX) is a biotechnology company pioneering innovative medicines to help millions of patients worldwide overcome and prevent difficult-to-treat infections that are becoming increasingly drug-resistant. SCYNEXIS scientists are developing the company’s lead asset, ibrexafungerp (formerly known as SCY-078), as a broad-spectrum, systemic antifungal for multiple fungal indications in both the community and hospital settings. SCYNEXIS has initiated the launch of its first commercial product in the U.S., BREXAFEMME® (ibrexafungerp tablets). The U.S. Food and Drug Administration (FDA) approved BREXAFEMME on June 1, 2021. SCYNEXIS filed a supplemental New Drug Application (sNDA) to expand BREXAFEMME’s labelling to include the prevention of recurrent vulvovaginal candidiasis, and the FDA assigned a target PDUFA action date of

November 30, 2022, for this additional indication. In addition, late-stage clinical investigation of oral ibrexafungerp for the treatment of life-threatening invasive fungal infections in hospitalized patients is ongoing. For more information, visit www.scynexis.com.

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