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SCYNEXIS and Hansoh Pharma Announce NMPA Acceptance of the New Drug Application for Ibrexafungerp in China

JERSEY CITY, N.J., July 20, 2023 (GLOBE NEWSWIRE) -- SCYNEXIS, Inc. (NASDAQ: SCYX), a biotechnology company pioneering innovative medicines to overcome and prevent difficult-to-treat and drug-resistant infections, today announced that China's National Medical Products Administration (NMPA) has accepted for review a New Drug Application (NDA) for oral ibrexafungerp tablets for the treatment of adult and post-menarchal pediatric females with vulvovaginal candidiasis (VVC) in the Chinese mainland. The application was submitted by partner Hansoh Pharmaceutical Group Company Limited (3692.HK), one of the leading biopharmaceutical companies in China, and is based on positive results from Phase 3 studies in which ibrexafungerp successfully achieved statistically significant superiority over placebo for the primary and key secondary study endpoints.

In February 2021, SCYNEXIS entered into an agreement for the development and commercialization rights for oral ibrexafungerp in the greater China region with Hansoh Pharma. Under the terms of the agreement, Hansoh is responsible for the development, regulatory approval and commercialization of ibrexafungerp in Greater China. Ibrexafungerp, once approved, is expected to become a new, first in class anti-fungal treatment for Chinese patients with vulvovaginal candidiasis (VVC).

"We are delighted by the progress of our partner and the opportunity to make our novel antifungal agent available to patients worldwide," said David Angulo, M.D., President and Chief Executive Officer of SCYNEXIS. "We are excited to be contributing to the global fight in the treatment of fungal infections."

Ms. Sun Yuan, Executive Director of the Board of Hansoh Pharma, added, "The successful NDA filing of Ibrexafungerp in China marks a significant step in our efforts to combat antifungal resistance, a pressing global health threat. We appreciate the exceptional work carried out by our team and strong support from our partner throughout the regular filing process and the initial assessment conducted by the NMPA. The acceptance of the NDA brings us one more step closer to making this novel and differentiated antifungal available to patients in Greater China."

About Ibrexafungerp

Ibrexafungerp is an antifungal agent and the first representative of a novel class of structurally-distinct glucan synthase inhibitors, triterpenoids. This agent provides, for the first time, the opportunity for oral antifungal treatment with the well-established activity of glucan synthase inhibitors. 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 Hansoh Pharma

Hansoh Pharma（03692.HK) is a leading innovation-driven pharmaceutical company in Greater China. It focuses on major disease treatment areas including oncology, anti-infectives, CNS diseases and metabolic diseases as well as autoimmune diseases, and is dedicated to improving human health through continuous innovation. As of now, the company has marketed seven innovative drugs, and has more than 30 innovative drug programs in different clinical stages with over 40 clinical trials in progress, forming a competitive pipeline. The company was listed on the Hong Kong Stock Exchange in June 2019. For more information, please visit www.hspharm.com.

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 is developing its proprietary class of enfumafungin-derived antifungal compounds ("fungerps") as broad-spectrum, systemic antifungal agents for multiple fungal indications. The U.S. Food and Drug Administration (FDA) approved the first representative of this antifungal class, BREXAFEMME® (ibrexafungerp tablets), in June 2021 for its first indication in vulvovaginal candidiasis (VVC), followed by a second indication in November 2022 for reduction in the incidence of recurrent VVC. Late-stage clinical investigation of ibrexafungerp for the treatment of life-threatening invasive fungal infections is ongoing. Additional assets in the novel "fungerp" class of antifungals are currently in pre-clinical and discovery phase, including the compound SCY-247. For more information, visit www.scynexis.com.

CONTACT:

Scynexis
Investor Relations
Irina Koffler
LifeSci Advisors
Tel: (646) 970-4681
ikoffler@lifesciadvisors.com

Hansoh Pharma
Sophia Dong, Investor Relations
IR@hspharm.com

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