

November 14, 2019



# **SCYNEXIS Commends the CDC for the Recognition of *Candida auris* as a New "Urgent Threat" in its Updated Report on Antibiotic Resistance Threats in the United States**

**SCYNEXIS is developing ibrexafungerp as a novel treatment for *Candida auris* and other difficult-to-treat fungal infections**

***Candida auris*, a frequently multidrug-resistant pathogen, highlighted as new "Urgent Threat", the highest level of concern**

**CDC's "Urgent Threat" designation underscores the pressing need for immediate U.S. public health action, including resources and funding, to support advancement of novel effective agents against *Candida auris***

JERSEY CITY, N.J., Nov. 14, 2019 /PRNewswire/ -- SCYNEXIS, Inc. (NASDAQ : SCYX), a biotechnology company delivering innovative therapies for difficult-to-treat and often life-threatening infections, today commended the Centers for Disease Control and Prevention (CDC) for the inclusion of *Candida auris*, a frequently multi-drug resistant pathogen, to the "Urgent Threat" list in its second report on *Antibiotic Resistance Threats in the United States, 2019*. The report aims to raise awareness of deadly pathogens and highlight the need to combat the growing public health threat of antimicrobial resistance.

"As a drug developer on the frontline in the battle against antimicrobial resistance, we recognize the growing threat resistant infections pose to our society," said Marco Taglietti, M.D., President and Chief Executive Officer of SCYNEXIS. "Drug resistance is a major public health issue that does not discriminate between bacteria and fungi, yet, to date, very limited public resources have been deployed to fight resistant fungi. With *Candida auris* now classified as an 'Urgent Threat' by the CDC, we are hopeful that new public, non-dilutive funding options will be available to companies like SCYNEXIS to accelerate the development of novel agents to fight this and other deadly fungal infections."

Dr. Taglietti continued: "When the CDC first raised the *C. auris* alarm in 2016, we rapidly initiated a robust program to determine whether our investigational agent, ibrexafungerp, could provide physicians with a new weapon against this emerging threat. Ibrexafungerp showed excellent activity against *C. auris* across multiple *in vitro* and *in vivo* studies, leading to the initiation of our Phase 3, open-label, CARES study in 2018. We believe this is the most advanced clinical trial against *C. auris* and, as reported at [ECCMID 2019](#), has already

resulted in successful outcomes in patients with *C. auris* infections."

## **About the CDC's Antibiotic Resistance Threats in the United States, 2019 Report**

The [CDC's first comprehensive analysis](#) of the top 18 antibiotic-resistant threats in the U.S. in 2013, marked the first warning by a government agency of the threat to public health posed by antibiotic resistance. This report stimulated U.S. and European government funding agencies, including BARDA, NIH, NIAID, Wellcome Trust and others, to provide funding for the development of anti-infectives focused on treating "Urgent Threat" pathogens, including *Clostridium difficile*, Carbapenem-resistant *Enterobacteriaceae* (CRE) and drug-resistant *Neisseria gonorrhoeae*.

In [the 2019 Antibiotic Resistance Threats report](#), the CDC states that each year in the U.S., there are more than 2.8 million antibiotic-resistant infections and more than 35,000 people die as a result. The report prioritizes bacteria and fungi into one of four categories based on level of concern: Urgent, Serious, Concerning, and Watch List, with urgent being the highest threat level. This second report, for the first time, includes three fungal pathogens in the Threat List including, *Candida auris*, under the "Urgent Threat", Drug-resistant *Candida* (formerly Fluconazole-resistant *Candida*) a "Serious Threat" and Azole-resistant *Aspergillus fumigatus* classified under "Watch List", a new category for 2019.

## **About *Candida auris***

*Candida auris* or *C. auris*, a fungal strain first reported in 2009, has been linked to invasive fungal infections in more than 30 countries to date, including the U.S., with [over 2,000 patients](#) in the U.S. infected or colonized by *Candida auris* since 2016. On April 6, 2019, the [New York Times highlighted the rising threat posed by this drug-resistant pathogen in two separate articles](#). *Candida auris* is not like any fungus seen to date globally, as it is highly transmissible and can spread from patient to patient and surface to patient. It has led to outbreaks in hospitals across the world as it is difficult to eliminate once it has infiltrated a hospital. In some countries *Candida auris* has become the second most identified *Candida* isolate in patients with candidemia. The CDC estimates that infections with *C. auris* are associated with a mortality rate of up to 60% and that some strains of this species of *Candida* have proven to be resistant to all three major classes of antifungal drugs, rendering treatment difficult. This type of broad resistance to approved antifungal agents has not been observed in other species of *Candida*. For more information, please see the [CDC website](#) on *Candida auris*.

## **About the CARES Study**

The CARES study is a multicenter, open-label, non-comparator, single-arm study to evaluate the safety and efficacy of oral ibrexafungerp in patients >18 years of age with a documented candidiasis infection, including candidemia, caused by *Candida auris*.

Enrolled patients receive an initial loading dose of 750mg BID (twice a day) of oral ibrexafungerp during the first two days of treatment and subsequent oral doses of 750mg QD (once a day) for up to 90 days. Patients are evaluated several times during treatment, with treatment efficacy assessed at the end of ibrexafungerp therapy. Subjects are then followed for another six weeks.

The open-label designs of the CARES studies allow for evaluation of the data on an interim basis to further inform subsequent regulatory steps of the development program. SCYNEXIS believes that compelling data from the CARES studies could allow ibrexafungerp to become eligible for the regulatory Limited Population Pathway for Antibacterial and Antifungal Drugs (LPAD), potentially resulting in an NDA submission based on streamlined development. The LPAD was established under the 21st Century Cures Act of 2016, and FDA draft guidance issued in June 2018 suggests smaller, shorter or fewer clinical trials may be sufficient to support approval to treat a serious or life-threatening infection in a limited population with unmet needs.

More information about the CARES study can be found at <https://clinicaltrials.gov/ct2/show/NCT03363841>.

### **About Ibrexafungerp**

Ibrexafungerp [pronounced eye-BREX-ah-FUN-jerp] is an investigational 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 currently in development for the treatment of fungal infections caused primarily by *Candida* (including *C. auris*) and *Aspergillus* species. It has demonstrated broad spectrum antifungal activity, *in vitro* and *in vivo*, against multidrug-resistant pathogens, including azole- and echinocandin-resistant strains. The FDA has granted Qualified Infectious Disease Product (QIDP) and Fast Track designations for the formulations of ibrexafungerp for the indications of invasive candidiasis (IC) (including candidemia), invasive aspergillosis (IA) and VVC (including prevention of recurrent VVC) and has granted Orphan Drug Designation for the IC and IA indications. Ibrexafungerp is formerly known as SCY-078.

### **About SCYNEXIS**

SCYNEXIS, Inc. (NASDAQ: SCYX) is a biotechnology company committed to positively impacting the lives of patients suffering from difficult-to-treat and often life-threatening infections by developing innovative therapies. The [SCYNEXIS team](#) has extensive experience in the life sciences industry, having discovered and developed more than 30 innovative medicines over a broad range of therapeutic areas. SCYNEXIS's lead product candidate, ibrexafungerp (formerly known as SCY-078), is a novel IV/oral antifungal agent in Phase 3 clinical and preclinical development for the treatment of multiple serious and life-threatening invasive fungal infections caused by *Candida*, *Aspergillus* and *Pneumocystis* species. For more information, visit [www.scynexis.com](http://www.scynexis.com).

### **Forward Looking Statement**

Statements contained in this press release regarding expected future events or results are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. These risks and uncertainties include, but are not limited to, risks inherent in SCYNEXIS's ability to successfully develop and obtain FDA approval for ibrexafungerp. These and other risks are described more fully in SCYNEXIS's filings with the Securities and Exchange Commission, including without limitation, its most recent Annual Report on Form 10-K under the caption "Risk Factors" and other documents subsequently filed with or furnished to

the Securities and Exchange Commission. All forward-looking statements contained in this press release speak only as of the date on which they were made. SCYNEXIS undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made.

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