

October 2, 2019



SCYNEXIS to Present Data at IDWeek 2019 and the 9th Congress on Trends in Medical Mycology (TIMM-9) Highlighting Scientific and Clinical Evidence of Ibrexafungerp's Activity Against Resistant Fungal Pathogens, Including *Candida auris*

New in vitro study provides additional data on the potent activity of ibrexafungerp against multidrug-resistant pathogen, *Candida auris*

Patient case study demonstrates ibrexafungerp's ability to successfully treat intra-abdominal abscesses resulting from fungal infections following standard of care's failure (FURI trial)

Ibrexafungerp to be highlighted during "Antifungal Pipeline" session at TIMM-9

JERSEY CITY, N.J., Oct. 2, 2019 /PRNewswire/ -- SCYNEXIS, Inc. (NASDAQ: SCYX), a biotechnology company delivering innovative therapies for difficult-to-treat and often life-threatening infections, today announced that data, which further demonstrates the potential of ibrexafungerp as a treatment for invasive fungal infections, will be presented at IDWeek 2019, occurring October 2-6, 2019 in Washington DC, and TIMM-9, occurring October 11-14, 2019 in Nice, France. Ibrexafungerp (formerly SCY-078), the first representative of a novel triterpenoid antifungal family being developed for oral and intravenous (IV) usage, is in clinical development for the treatment of multiple serious fungal infections, including many that have shown resistance to existing therapies.

"When the Centers for Disease Control and Prevention (CDC) first alerted the public in 2016 of the threat *Candida auris* posed as a dangerous and emerging global pathogen, we immediately began evaluating the activity of ibrexafungerp against *Candida auris* through multiple *in vitro*, *in vivo* and clinical studies," said Dr. David Angulo, Chief Medical Officer of SCYNEXIS. "To our knowledge, ibrexafungerp is the first new experimental antifungal to be tested in patients with *Candida auris* infections, and the data so far indicates ibrexafungerp's high activity against this deadly pathogen. We continue to advance this important new therapy through our ongoing clinical studies and look forward to sharing those results in our effort to address these difficult-to-treat infections."

Details for the upcoming presentations are as follows:

IDWeek 2019

Title: [Activity of Ibrexafungerp \(formerly SCY-078\) Against *Candida auris*: In Vitro, In Vivo and Clinical Case Studies of Candidemia](#)

Presenter: Stephen Barat, PhD

Date and Time: Thursday, October 3, 2019, 12:15 pm – 1:30 pm ET

Poster Presentation #: 672

Session: Novel Antimicrobials and Approaches Against Resistant Bugs

Location: Walter E. Washington Convention Center, Washington DC

This poster will highlight a large body of evidence demonstrating the activity and effectiveness of ibrexafungerp against Candida auris. In vitro studies tested ibrexafungerp against >100 clinical isolates of C. auris and evaluated the effects of ibrexafungerp against C. auris biofilms. In vivo activity against C. auris was evaluated using a disseminated murine model and a cutaneous infection guinea pig model. In humans, an ongoing open-label trial of oral ibrexafungerp for treatment of patients with infections caused by C. auris (the CARES study) is ongoing in the U.S. and India.

9th Trends in Medical Mycology (TIMM 2019)

Oral Presentation

Title: [Ibrexafungerp \(formerly SCY-078\)](#)

Presenter: David Angulo, MD

Date and Time: Saturday, October 12, 2019, 5:05 pm – 5:30 pm GMT

Oral Presentation #: 11.3

Session: Symposium 11, The Anti-fungal Pipeline

Location: Nice-Acropolis Convention Center, Nice, France

This oral presentation will focus on antifungal agents currently being developed. Ibrexafungerp is one of three products presented during this session. The presentation will highlight oral ibrexafungerp's studies that demonstrate its broad-spectrum of activity against *Candida*, *Aspergillus* and *Pneumocystis*, along with its activity against resistant organisms and development pathway of oral ibrexafungerp for treatment of hospital-treated fungal infections in patients with resistant and refractory infections, including *Candida auris*.

Poster Presentations

Title: [*Candida auris* is Highly In Vitro Susceptible to Ibrexafungerp \(Formerly SCY-078\) in EUCAST Antifungal Susceptibility Testing](#)

Presenter: Maiken Cavlin Arendrup, MD, PhD

Date and Time: Sunday, October 13, 2019, 11:30 am – 12:30 pm GMT

Poster Presentation #: P414

Location: Nice-Acropolis Convention Center, Nice, France

Candida auris is a multidrug-resistant yeast rapidly emerging as a significant cause of nosocomial infections. This poster will present data on an *in vitro* study testing the activity of ibrexafungerp against 122 clinical *C. auris* isolates (from India (n=120) and Oman (n=2)). The *in vitro* activity of ibrexafungerp (IBX) against *C. auris* was uniform with MICs displaying

a Gaussian distribution spanning 0.06-2 mg/L suggesting an equal efficacy across the 122 isolates. In contrast, MIC distributions for anidulafungin, micafungin, isavuconazole, voriconazole, itraconazole and posaconazole were wide (spanning 10-13 dilutions) suggesting differential activity against the isolates. Ibrexafungerp, a novel oral glucan synthase inhibitor, shows promising *in vitro* activity against *C. auris*, suggesting it may be a welcomed therapeutic against this emerging threat with few treatment options.

Title: [Successful Treatment of a Patient with Retroperitoneal Abscess caused by *Candida krusei* with the Investigational Agent, Ibrexafungerp \(formerly SCY-078\): A Case Report from the FURI study](#)

Presenter: George R. Thompson III, MD

Date and Time: Sunday, October 13, 2019, 11:30 am – 12:30 pm GMT

Poster Presentation #: P402

Location: Nice-Acropolis Convention Center, Nice, France

This poster presentation will highlight a single case of a patient with an intra-abdominal fungal infection treated with oral ibrexafungerp from the FURI study. The case presents a 71-year old male patient with ischemic stroke, pulmonary edema, and tracheostomy, treated for a retroperitoneal abscess, a complication of a perforated duodenal ulcer. *Candida krusei* was isolated in peri-duodenal drain cultures and the patient was initiated on micafungin therapy for 21 days but remained culture positive. Micafungin therapy was terminated, the patient was enrolled in the FURI study and ibrexafungerp was initiated for a total of 21 days of therapy. Clinical improvement was observed during therapy. At the End-of-Treatment visit, the clinical signs and symptoms of fungal disease were considered by the investigator to be resolved. No drug-related adverse events were reported.

Title: [Activity of Ibrexafungerp \(formerly SCY-078\) Against *Candida auris*: In Vitro, In Vivo and Clinical Case Studies of Candidemia](#)

Presenter: David Angulo, MD

Date and Time: Saturday, October 12, 2019, 11:30 am – 12:30 pm GMT

Poster Presentation #: P201

Location: Nice-Acropolis Convention Center, Nice, France

This poster will highlight the current *in vitro*, *in vivo* and two clinical cases for ibrexafungerp against *Candida auris*. *In vitro* and *in vivo* studies demonstrated that ibrexafungerp is active against *C. auris*, including multidrug-resistant (MDR) strains. The MIC mode for ibrexafungerp was 1ug/ml and the MIC₅₀ and MIC₉₀ were 0.5 and 1 ug/ml, respectively. Many echinocandin-resistant *C. auris* isolates have shown susceptibility to ibrexafungerp. Further, ibrexafungerp has been shown to reduce biofilm thickness. In animal models of *C. auris* infection, treatment with ibrexafungerp resulted in improved survival and reduced fungal burden in both the murine model of disseminated infection and the guinea pig model of cutaneous infection as compared to untreated controls. In humans, two patients with difficult to treat *C. auris* candidemias were enrolled in the CARES study and responded positively to oral ibrexafungerp with eradication of the infection.

The IDWeek 2019 and TIMM-9 presentations will be available on the SCYNEXIS website accordingly following each event.

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 the FURI and CARES Studies

Both studies are multicenter, open label, non-comparator, single arm studies to evaluate the safety and efficacy of oral ibrexafungerp in patients >18 years of age with:

- FURI study: a documented invasive and/or severe mucocutaneous fungal disease that has been intolerant or refractory (rIFI) to standard of care (SoC) antifungal treatment.
- CARES study: a documented candidiasis infection, including candidemia, caused by *Candida auris*.

In both studies, patients are also considered for enrollment if they have an eligible fungal disease and, in the judgement of the investigator, cannot receive approved oral antifungal options (e.g., susceptibility of the organism or risk for drug-drug interactions) and continued IV antifungal therapy is not desirable or feasible due to clinical or logistical circumstances. 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 FURI and 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 FURI and/or 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 studies can be found at:

- FURI study: <https://clinicaltrials.gov/ct2/show/NCT03059992>.
- CARES study: <https://clinicaltrials.gov/ct2/show/NCT03363841>.

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.

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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