

May 6, 2020



## SCYNEXIS Announces Six Abstracts Published by 30th ECCMID Highlighting the Potential Clinical Utility of Ibrexafungerp

- *Oral ibrexafungerp continues to show potential to address a broad range of indications ranging from vaginal yeast infections to life-threatening refractory invasive fungal infections*
- *Findings indicate oral ibrexafungerp could potentially decrease length of hospital stays by reducing dependence on IV-administered antifungals*

JERSEY CITY, N.J., May 06, 2020 (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 the publication of six abstracts in the 30<sup>th</sup> European Congress of Clinical Microbiology and Infectious Diseases (ECCMID) abstract book, [now available online](#).

“We are pleased to have six abstracts accepted and presented in the 30<sup>th</sup> ECCMID abstract book. Cumulatively, the body of work presented in these abstracts provides evidence to support ibrexafungerp’s potential clinical utility, from vaginal yeast infections to life-threatening refractory invasive fungal infections, including resistant organisms, like *Candida auris*,” said Marco Taglietti, M.D., Chief Executive Officer of SCYNEXIS. “We appreciate ECCMID’s efforts to support scientific progress by publishing these abstracts in the absence of the conference, especially at a time when there is heightened awareness of infectious diseases and their devastating impact on global public health. The current COVID-19 pandemic reinforces the need to continually develop new anti-infectives and prepare for the next emerging threat.”

Abstract details:

**Title:** Efficacy and Safety of Oral Ibrexafungerp in 41 Patients with Refractory Fungal Diseases, Interim Analysis of a Phase 3 Open-label Study (FURI)  
**Abstract #:** 9710  
**Author:** Barbara D. Alexander, MD, Duke University

**Highlights:** An interim analysis of 41 patients from the Phase 3 clinical study evaluating ibrexafungerp for the treatment of patients with refractory candidiasis or patients who were intolerant to the standard of care (FURI Study) found that 83% of the patients achieved a clinical benefit (including 56% with complete or partial response and 27% with stable disease), compared to 15% with disease progression. One patient was categorized as indeterminate. Ibrexafungerp was well-tolerated with the most common treatment-related adverse events being of gastrointestinal origin.

**Link:** Please scroll down to abstract #9710 on page 4490 of [Abstract Book Part 5](#)

**Title:** Clinical Experience of Oral Ibrexafungerp for Treatment of Four Patients with  
**Abstract #:** Invasive Candidiasis from the FURI Study  
**Author:** 988

**Highlights:** Juergen Pratts, MD, Medical University, Graz, Austria  
A case report of four patients from the Phase 3 FURI study treated at Medical University Hospital, Graz, Austria, evaluating ibrexafungerp for the treatment of patients with refractory candidiasis or patients who were intolerant to the standard of care. The four patients were diagnosed with the different *Candida* infections, including, femoro-tibial osteomyelitis, candidemia, intraabdominal abscess and oropharyngeal candidiasis. At the end of treatment, two patients had a complete response, one patient had a partial response and one patient had a stable response. Results suggest that the use of ibrexafungerp could be effective against invasive candidiasis and could significantly decrease in-hospital stays by reducing dependence on IV-administered antifungals.

**Link:** Please scroll down to abstract #988 on page 524 of [Abstract Book Part 1](#)

**Title:** Ibrexafungerp Demonstrates Potent and Consistent *In Vitro* Activity Against >400  
**Abstract #:** Global *Candida auris* Isolates, Including Isolates with Elevated MIC's to  
**Author:** Echinocandins

3646  
David Angulo, MD, SCYNEXIS, Inc.

**Highlights:** A compilation of four independent *in vitro* studies testing the activity of ibrexafungerp against a total 445 *Candida auris* isolates. The ibrexafungerp MIC<sub>90</sub> value against the 445 clinical isolates was 1 mg/mL; the modal and MIC<sub>50</sub> values were 0.5 mg/mL each. Of the 445 isolates, 32 of the *C. auris* strains had elevated MIC's to echinocandins. Only 1 of the 32 isolates had elevated MIC's to ibrexafungerp (> 2 tube dilution above mode). The result highlights ibrexafungerp's potential to combat the growing global health threat posed by *Candida auris*.

**Link:** Please scroll down to abstract #3646 on page 1728 of [Abstract Book Part 2](#)

**Title:** Prevention of *Pneumocystis* Pneumonia by Ibrexafungerp in a Murine Prophylaxis  
**Abstract #:** Model.

**Author:** 1879  
David Angulo, MD, SCYNEXIS, Inc.

**Highlights:** A preclinical study demonstrated that a 30 mg/kg B.I.D. dose of ibrexafungerp prevented *Pneumocystis* Pneumonia (PCP) in a murine model, suggesting that it warrants further testing for preventing PCP in immunocompromised patients.

**Link:** Please scroll down to abstract #1879 on page 898 of [Abstract Book Part 1](#)

**Title:** *In Vitro* Activity of Ibrexafungerp in pH 7.0 and pH 4.5 Testing Environments Against  
**Abstract #:** 187 Fluconazole-susceptible and -resistant *Candida* Species from Vulvovaginal  
**Author:** Candidiasis Patients.

3218  
Jack Sobel, MD, Wayne State University

**Highlights:** Ibrexafungerp exhibited significant *in vitro* activity against fluconazole-resistant and fluconazole-sensitive vaginal *Candida* isolates at normal and low pH environments and, unlike, fluconazole, ibrexafungerp retained its activity at lower pH (4.5). These results suggest that ibrexafungerp may be an effective antifungal agent in a lower pH environment such as that found in the vagina of patients with vulvovaginal candidiasis.

**Link:** Please scroll down to abstract #3218 on page 1535 of [Abstract Book Part 2](#)

**Title:** CANDIMAD study: a prospective, -multicenter, laboratory-based survey of  
**Abstract #:** antifungal resistance in *Candida* spp. causing invasive candidiasis in Madrid

**Author:** 1651  
Judith Diaz-Garcia, PharmD, Hospital General Universitario Gregorio Marañón, Universidad Complutense de Madrid, Madrid, Spain

- Highlights:** An active surveillance study evaluating 312 clinical isolates from 292 patients from 15 hospitals in Madrid, Spain. Ibrexafungerp showed consistent high activity against all strains of *Candida* and, in particular, ibrexafungerp was more active against *C. parapsilosis* than the echinocandins, including micafungin and anidulafungin.
- Link:** Please scroll down to abstract #1651 on page 800 of [Abstract Book Park 1](#)

The abstracts are currently available on ECCMID's website [here](#).

### **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, the 'fungerps'. This agent combines the well-established activity of glucan synthase inhibitors with the potential flexibility of having oral and 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 vulvovaginal candidiasis (VVC) and has granted Orphan Drug Designation for the IC and IA indications. Ibrexafungerp is formerly known as SCY-078.

### **About the FURI Study**

The FURI 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 invasive and/or severe mucocutaneous fungal disease that has been intolerant or refractory (rIFI) to standard of care fungal treatment. 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 ibrexafungerp for up to 180 days at a dosing regimen that will depend on fungal disease. Patients are evaluated several times during treatment, with efficacy assessed at the end of ibrexafungerp therapy. Subjects are then followed for another six weeks. The study is planned to be conducted at approximately 40 sites globally and enrollment is expected to continue until ibrexafungerp's commercial availability. The Company expects to enroll approximately 200 subjects.

### **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. Our lead candidate, ibrexafungerp (formerly known as SCY-078), is a broad-spectrum, IV/oral antifungal agent representing a novel therapeutic class, in late stage development for multiple indications, ranging from vaginal yeast infections to life-threatening fungal infections in hospitalized patients. The SCYNEXIS team has deep expertise in anti-infective drug development and marketing, which can be leveraged to advance ibrexafungerp from clinical development to commercialization. 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; the expected costs of studies and when they might begin or be concluded; and SCYNEXIS's reliance on third parties to conduct SCYNEXIS's clinical studies. 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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