Fig. 3

Figure 3: Isolation of Staphylococcus at Baseline and During, and After Dalbayancin Treatment (Evaluable Population) Baseline Dalbavancin 60 Days After End of IV Dalbayancin Osteomyelitis Specimen collected in (%) 35 (44 9) 14 (17.9) 13 (16.7) 29 (82.9) 8 (57.1) 7 (53.8) Isolates grown from the specimen? Staphylococcus 20 (69.0) 6 (75.0) 2 (28.6) 11/18 tested (61.1) 0 /4 tested (0.0) 1/1 tested (100.0) Resistant to oxacillin Osteomyelitis of the Foot (n=51) 9 (17 6) Specimen collected in (%) 24 (47 1) 10 (19.6) Any isolates grown from the 21 (87.5) 6 (60.0) 5 (55.6) specimen? Staphylococcus 14 (66.7) 5 (83.3) 1 (20.0) 1 (100.0) Resistant to ovacillin 8 /13 tested (61.5) 0/3 tested (0.0) Joint Infection (n=32) Any specimen collected, n (%) 3 (9.4) 2 (6.3) Any isolates grown from the 15 (78.9) 2 (66.7) 2 (100.0) specimen? 15 (100.0) 2 (100.0) 2 (100.0) Staphylococcus Resistant to oxacillin 5/14 tested (35.7) 0/1 tested (50.0) 1/2 tested (50.0)

**Conclusion.** In this real-world study in patients with Staphylococcal osteomyelitis and joint infection, DAL resulted in high rates of clinical and microbiological success.

Disclosures. Jennifer McGregor, RPh, AbbVie (Employee) Anathakrishnan Ramani, MD, FACP, AAHIVS, CIC, Allergan (prior to its acquisition by AbbVie) (Speaker's Bureau) John Lock, PharmD, BCPS, AQ-ID, AbbVie (Employee) Pedro Gonzalez, MD, MT, AbbVie (Employee)

1248. Efficacy and Safety of Oral Ibrexafungerp in 41 Patients with Refractory Fungal Diseases, Interim Analysis of a Phase 3 Open-label Study (FURI) Barbara D. Alexander, MD, MHS<sup>1</sup>; Oliver Cornely, Prof.<sup>2</sup>; Peter Pappas, MD<sup>3</sup>; Rachel Miller, MD<sup>1</sup>; Jose A. Vazquez, MD, FIDSA<sup>4</sup>; Luis Ostrosky-Zeichner, MD5; Andrej Spec, MD6; Riina Rautemaa-Richardson, DDS, PhD, FRCPath7; Robert Krause,  $\mathrm{MD}^8$ ; George R. Thompson III,  $\mathrm{MD}^9$ ; Caryn Morse,  $\mathrm{MD}^{10}$ ; John W. Sanders, III,  $\mathrm{MD}^{11}$ ; David Andes,  $\mathrm{MD}^{12}$ ; David Andes,  $\mathrm{MD}^{12}$ ; George Lyon, MD<sup>13</sup>; Francisco M. Marty, MD<sup>14</sup>; Emily Silverman, BS<sup>15</sup>; Marisa H. Miceli, MD, FIDSA<sup>16</sup>; Thomas F. Patterson, MD<sup>17</sup>; Martin Hoenigl, MD<sup>18</sup>; Nkechi Azie, MD<sup>19</sup> David A. Angulo, MD<sup>19</sup>; <sup>1</sup>Duke University, Durham, NC; <sup>2</sup>University of Cologne, Faculty of Medicine and University Hospital Cologne, Cologne, Nordrhein-Westfalen, Germany; 3University of Alabama at Birmingham, Birmingham, Alabama; <sup>4</sup>Medical College of Georgia at Augusta University, Augusta, Georgia; <sup>5</sup>University of Texas Health Science Center, Houston, Houston, Texas; <sup>6</sup>Washington University, St. Louis, St. Louis, Missouri; <sup>7</sup>University of Manchester, Manchester, England, United Kingdom; <sup>8</sup>Medical University, Graz, Graz, Steiermark, Austria; <sup>9</sup>UC-Davis, Sacramento, California; <sup>10</sup>Wake Forest Baptist Hospital, Winston-Salem, North Carolina; <sup>11</sup>Wake Forest School of Medicine, Winston-Salem, NC; <sup>12</sup>University of Wisconsin, Madison, Wisconsin; 13 Emory Health, Atlanta, Georgia; 14 Brigham and Women's Hospital, Boston, Massachusetts; 15 Dana-Farber Cancer Institute, Boston, Massachusetts; 16University of Michigan, Ann Arbor, Michigan; 17University of Texas Health San Antonio, San Antonio, TX; 18 University of California, San Diego, San Diego, CA; 19SCYNEXIS, Inc., Jersey City, New Jersey

## Session: P-58. Novel Agents

Background. Candida infections resistant to currently available antifungals are an emerging global threat. Ibrexafungerp is an investigational broad-spectrum glucan synthase inhibitor antifungal with activity against Candida and Aspergillus species, including azole- and echinocandin-resistant strains. A Phase 3 open-label, single-arm study of oral ibrexafungerp (FURI) (Clinicaltrials.gov NCT03059992) is ongoing for the treatment of patients (≥18 years) with fungal diseases who are intolerant of or refractory to standard antifungal therapies.

Methods. An independent Data Review Committee (DRC) provided an assessment of treatment response for 41 patients. Patients were enrolled in 22 centers from 6 countries. Patients were eligible for enrollment if they had proven or probable, invasive or severe mucocutaneous candidiasis and documented evidence of failure of, intolerance to, or toxicity related to a currently approved standard-of-care antifungal treatment or could not receive approved oral antifungal options (e.g., susceptibility of the organism) and a continued IV antifungal therapy was undesirable or unfeasible.

Results. The 41 patients assessed had the following infection types: intra-abdominal abscesses, oropharyngeal candidiasis, esophageal candidiasis, candidemia, and others. The DRC adjudicated 23 patients (56%) as achieving complete or partial response, 11 patients (27%) maintaining stable disease, 6 patients (15%) with progression of disease and one case was considered as indeterminate. The efficacy of oral ibrexafungerp by pathogen is shown in Table 1. Ibrexafungerp was well-tolerated with the most common treatment-related adverse events being of gastrointestinal origin. No deaths due to progression of fungal disease were reported.

Table 1: Ibrexafungerp Outcomes by Pathogen

Complete or Partial Response	Stable disease	Progression of Disease
9	5	3
5	2	
2	3	
3		
2		2
1		
	1	
		1
	Partial Response  9 5 2 3 2 1	Partial Response  9

Conclusion: Preliminary analysis of these 41 cases indicate that oral ibrexafungerp provides a favorable therapeutic response in the majority of patients with difficult to treat Candida spp. infections, including those caused by non-albicans Candida species

Disclosures. Barbara D. Alexander, MD, MHS, SCYNEXIS, Inc. (Employee, Scientific Research Study Investigator, Research Grant or Support) Oliver Cornely, Prof., Actelion (Grant/Research Support)Actelion (Other Financial or Material Support, Personal fees)Al Jazeera Pharmaceuticals (Consultant)Allecra Therapeutics (Other Financial or Material Support, Personal fees)Amplyx (Other Financial or Material Support, Personal fees)Amplyx (Grant/Research Support)Astellas (Grant/Research Support) Astellas (Other Financial or Material Support, Personal fees) Basilea (Other Financial or Material Support, Personal fees)Basilea (Grant/Research Support)Biosys UK Limited (Other Financial or Material Support, Personal fees)Cidara (Other Financial or Material Support, Personal fees)Cidara (Grant/Research Support)Da Volterra (Grant/Research Support)Da Volterra (Other Financial or Material Support, Personal fees)Entasis (Other Financial or Material Support, Personal fees)F2G (Other Financial or Material Support)F2G (Grant/Research Support)Gilead (Grant/Research Support) Gilead (Other Financial or Material Support, Personal fees) Grupo Biotoscana (Other Financial or Material Support, Personal fees)Janssen Pharmaceuticals (Grant/ Research Support) Matinas (Other Financial or Material Support, Personal fees) Medicines Company (Grant/Research Support) MedPace (Grant/Research Support) MedPace (Other Financial or Material Support, Personal fees)Melinta Therapeutics (Grant/ Research Support)Menarini Ricerche (Other Financial or Material Support, Personal fees)Merck/MSD (Other Financial or Material Support, Personal fees)Merck/MSD (Grant/Research Support)Mylan Pharmaceuticals (Consultant)Nabriva Therapeutics (Other Financial or Material Support, Personal fees)Octapharma (Other Financial or Material Support, Personal fees) Paratek Pharmaceuticals (Other Financial or Material Support, Personal fees)Pfizer (Other Financial or Material Support, Personal fees)Pfizer (Grant/Research Support)PSI (Other Financial or Material Support, Personal fees)Rempex (Other Financial or Material Support, Personal fees)Roche Diagnostics (Other Financial or Material Support, Personal fees)Scynexis (Other Financial or Material Support, Personal fees)Scynexis (Grant/Research Support)Seres Therapeutics (Other Financial or Material Support, Personal fees) Tetraphase (Other Financial or Material Support, Personal fees) Peter Pappas, MD, SCYNEXIS, Inc. (Consultant, Advisor or Review Panel member, Research Grant or Support) Rachel Miller, MD, SCYNEXIS, Inc. (Scientific Research Study Investigator) Luis Ostrosky-Zeichner, MD, Amplyx (Scientific Research Study Investigator) Astellas (Consultant, Scientific Research Study Investigator, Other Financial or Material Support, Non-branded educational speaking)Biotoscana (Consultant, Other Financial or Material Support, Non-branded educational speaking)Cidara (Consultant, Scientific Research Study Investigator)F2G (Consultant)Gilead (Consultant)Mayne (Consultant)Octapharma (Consultant)Pfizer (Other Financial or Material Support, Non-branded educational speaking)Scynexis (Consultant, Grant/Research Support, Scientific Research Study Investigator)Stendhal (Consultant)Viracor (Consultant) Andrei Spec, MD, SCYNEXIS, Inc. (Scientific Research Study Investigator, Advisor or Review Panel member) Riina Rautemaa-Richardson, DDS, PhD, FRCPath, SCYNEXIS, Inc. (Scientific Research Study Investigator) Robert Krause, MD, SCYNEXIS, Inc. (Scientific Research Study Investigator) Caryn Morse, MD, SCYNEXIS, Inc. (Scientific Research Study Investigator) John W. Sanders, III, MD, SCYNEXIS, Inc. (Scientific Research Study Investigator) David Andes, MD, SCYNEXIS, Inc. (Scientific Research Study Investigator, Advisor or Review Panel member) George Lyon, MD, SCYNEXIS, Inc. (Scientific Research Study Investigator) Francisco M. Marty, MD, Allovir (Consultant)Amplyx (Consultant)Ansun (Scientific Research Study Investigator)Avir (Consultant)Cidara (Scientific Research Study Investigator)F2G (Consultant, Scientific Research Study Investigator) Kyorin (Consultant) Merck (Consultant, Grant/Research Support, Scientific Research Study Investigator)New England Journal of Medicine (Other Financial or Material Support, Honorarium for Video)Regeneron (Consultant, Scientific Research Study Investigator)ReViral (Consultant)Scynexis (Scientific Research Study Investigator)Symbio (Consultant)Takeda (Scientific Research Study Investigator)United Medical (Consultant)WHISCON (Scientific Research Study Investigator) Marisa H. Miceli, MD, FIDSA, SCYNEXIS, Inc. (Advisor or Review Panel member) Thomas F. Patterson, MD, SCYNEXIS, Inc. (Advisor or Review Panel member) Martin Hoenigl, MD, SCYNEXIS, Inc. (Grant/Research Support, Scientific Research Study Investigator, Advisor or Review Panel member) Nkechi Azie, MD, SCYNEXIS, Inc. (Employee, Shareholder) David A. Angulo, MD, SCYNEXIS, Inc. (Employee, Shareholder)

1249. Genetic Evidence That Gepotidacin Shows Well-balanced Dual Targeting against DNA Gyrase And Topoisomerase IV in Neisseria gonorrhoeae Pan Chan, PhD¹; Karen Ingraham, MS¹; Sharon Min, MS¹; Nicole Scangarella-Oman, MS²; Steve Rittenhouse, PhD¹; Jianzhong Huang, PhD¹; ¹GlaxoSmithKline,