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BACKGROUND

- Rezafungin, a novel long-acting intravenous echinocandin, was approved in the US in 2023 for adult patients with candidemia or invasive candidiasis, with safety established for up to 4 weekly doses. It was approved in the EU in 2023 for adult patients with invasive candidiasis.<sup>1,2,3,4</sup>
- Once weekly dosing regimens offer an advantage in outpatient settings, eliminating the requirement of central venous catheters and daily medication administration.
- This study describes early real-world experience with rezafungin.

METHODS

- Retrospective, cohort study conducted in US Infectious Disease physician office infusion centres of patients receiving ≥ 1 dose of rezafungin.
- Data collection included demographics, medical history, treatment details, microbiology, and adverse events.
- Outcomes were assessed as clinical success if patients had complete or partial resolution of infection without need for other anti-fungal agents. Non-success was defined as persistent or recurrent infection at the end of treatment or required discontinuation of rezafungin. Patients were non-evaluable if clinical response was indeterminate.

RESULTS

Patient Characteristics

Characteristic	Results (N = 35)
Age, median (IQR) years	65 (53-72)
Female, n (%)	26 (74.3)
BMI, median (IQR)	25.6 (22-29.7)
Location prior to treatment, n (%)	
Community	20 (57)
Hospital	15 (43)
Charlson comorbidity index, median (IQR)	4 (2-6)
Comorbidities, n (%)	
Cardiovascular disease	16 (46)
Immunocompromised <sup>1</sup>	13 (37)
Diabetes	9 (26)
Malignancy	6 (17)
Chronic renal disease	4 (11)
Patients receiving 400mg rezafungin loading dose, n (%)	35 (100)
Doses of rezafungin received, median (IQR)	2 (1-4)

- 43% were hospitalised prior to rezafungin treatment, with the remainder (57%) initiating therapy in the outpatient setting.
- The cohort had a high rate of comorbidities, and more than one-third of patients were immunocompromised.
- Median number of doses were 2. Eight received 4 doses and 3 received 5 doses. One BJI patient remains on therapy with 32 doses administered to date.
- 35 patients received 40 treatment episodes of rezafungin. Four patients received re-treatment with additional doses, all with subsequent treatment success.

Prior Antifungal Therapies

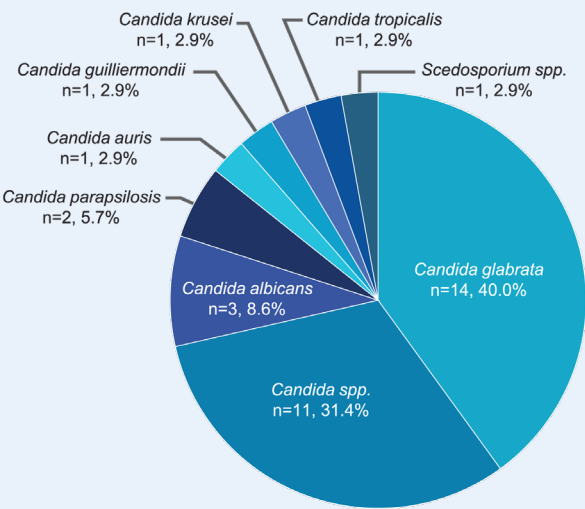
Prior Antifungal Therapies <sup>2</sup>	Results (N = 35)
Oral azole (1 agent)	10 (28.6)
Oral azole (2 agents)	2 (5.7)
Oral azole (4 agents)	1 (2.9)
IV micafungin	12 (34.3)
Oral azole (1 agent) then IV micafungin	4 (11.4)
Oral azole (1 agent) then IV micafungin + IV fluconazole	1 (2.9)
Oral azole (2 agents) then IV micafungin	2 (5.7)

Safety

4 non-serious adverse reactions occurred in 3 patients, with none resulting in medication discontinuation

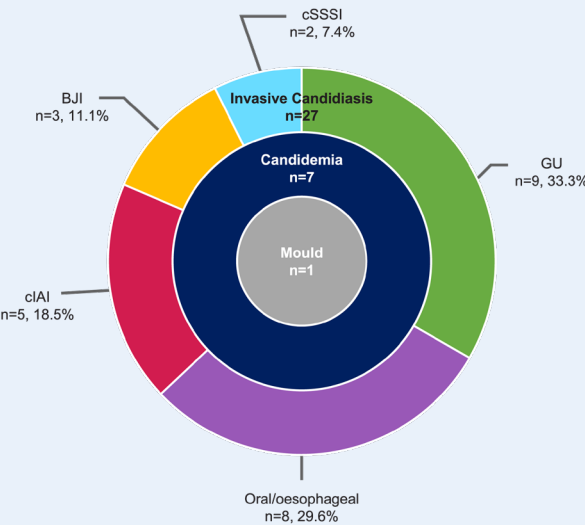
Adverse events included: headache (n=1), myalgia (n=1), nausea/vomiting (n=1), dizziness (n=1)

Pathogens



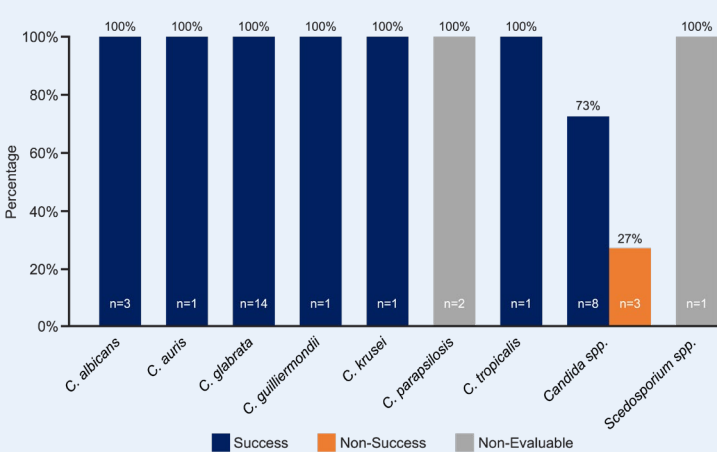
- Non-albicans *Candida* species accounted for the majority of pathogens (n=20, 57%).
- C. glabrata*, with the highest incidence of azole resistance, was the most frequently isolated pathogen.<sup>5,6</sup> Published literature indicates that the non-albicans spp. identified in our cohort also have reported resistance to azoles.<sup>5,6</sup>
- Scedosporium* spp., a mould isolate was identified in one patient who failed all other prior therapies.

Diagnostic Groups



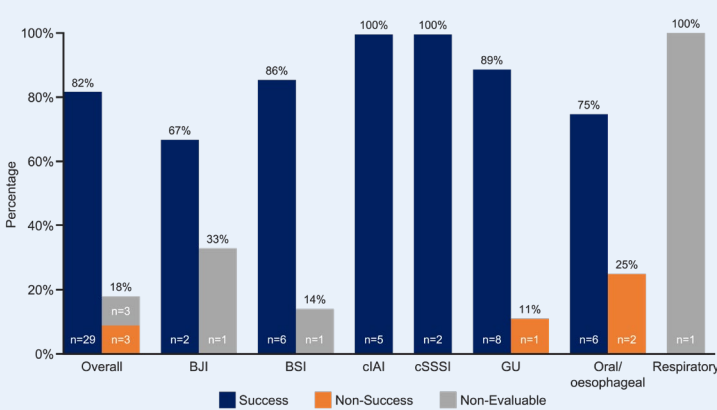
- Candidemia pathogens were *C. glabrata* (n=5), *C. guilliermondii* (n=1) and *C. parapsilosis* (n=1).

Clinical Outcomes by Pathogen



- Treatment success was achieved for all *C. albicans*, *C. auris*, *C. glabrata*, *C. guilliermondii*, *C. krusei*, and *C. tropicalis* isolates.
- This cohort included 14 patients with *C. glabrata* who all achieved treatment success.
- The treatment non-success occurred with 3 *Candida* spp. isolates. Two non-evaluable patients had *C. parapsilosis*, of which one remains on therapy and one expired unrelated to rezafungin. One with reported *Scedosporium* spp. isolate had an undetermined outcome.

Clinical Outcomes by Diagnosis



- 88% of patients with invasive *Candida* infections and candidemia had successful treatment outcomes with rezafungin.
- Treatment non-success occurred in 3 patients with persistent/recurrent infection, 2 with oral/oesophageal disease and one with GU disease. One with oral/oesophageal disease with non-success was re-treated with 4 additional doses, resulting in a successful outcome.

Key Findings

- Rezafungin was a safe and effective treatment in a comorbid, heavily pre-treated population with difficult-to-treat *Candida* pathogens.
- High success rates for rezafungin were observed with invasive *Candida* infections and Candidemia.
- Rezafungin was successful in eradication of disease in numerous *Candida* pathogens, including *C. glabrata* and other non-albicans isolates frequently resistant to azoles.
- This real-world data provides support for the successful outpatient use of weekly rezafungin therapy in patients with various *Candida* fungal infections.

References

1. Rezzayo (rezafungin) [package insert]. Lincolnshire, IL: Melinta Therapeutics, LLC; 2023.  
2. Rezzayo (INN-rezafungin) [product information]. Frankfurt, Germany: Mundipharma GmbH; 2023.  
3. Thompson GR, et al. Lancet. 2023; 401:49-59.  
4. Thompson GR, et al. Clin Infect Dis. 2021; 6:e3647-e3655. Erratum in: Clin Infect Dis. 2021; 73:561-562.  
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6. Pristov KE, et al. Clin Microbiol Infect. 2019; 25:792-798.

Abbreviations and Footnotes

Abbreviations: IQR, interquartile range; BMI, body mass index; BJI, bone and joint infection; cIAI, complicated intra-abdominal infection; CKD, chronic kidney disease; cSSSI, complicated skin and skin structure infection; GU, genitourinary infection; HIV, human immunodeficiency virus.

Footnotes: <sup>1</sup>Immunocompromised was defined as: immune deficiency (cancer, HIV, genetic disorder, autoimmune disease, organ transplant, CKD), neutropenia (<500 cells/mL) or use of immunosuppressive agents. Reasons included: immunosuppressive agents (n=5), cancer (n=3), organ transplant (n=3), CKD (n=2) <sup>2</sup>Oral azoles included: fluconazole (n=18), voriconazole (n=3), itraconazole (n=3), isavuconazonium (n=1), ketoconazole (n=1), posaconazole (n=1). No patients received 3 oral azoles and 3 had no reported prior use of anti-fungals. Six patients received oral polyenes in addition to azole therapy.