Patient Profile: Olivia

Immunocompromised, on daily echinocandin therapy inpatient, otherwise dischargeable



BACKGROUND AND PRESENTATION

Patient Demographics and History

- 22-year old female
- BMT Transplant, Leukemia (AML) patient

Current Medications

- Venetoclax-based regimen
- Tacrolimus
- Micafungin

Case Details

- Prior azole prophylaxis but developed breakthrough invasive fungal infection
- Blood sample was positive for C. glabrata and patient diagnosed with candidemia
- Initiated micafungin, port removed
- 3 days later, blood culture was negative
- Requires 2 weeks of antifungal therapy and line holiday

Progress Notes

- Concerned about compromising BMT engraftment, tacrolimus interaction, and appropriate dose of venetoclax
- Patient interested in discussing options given their limited transportation (lives 2 hours from hospital)
- Dischargeable except for echinocandin therapy

This hypothetical patient profile is meant to be illustrative and is not intended to offer medical advice.

Determination of appropriate treatment is at the discretion of the healthcare provider.

*INDICATION AND USAGE

REZZAYO® (rezafungin for injection) is an echinocandin antifungal indicated in patients 18 years of age or older who have limited or no alternative options for the treatment of candidemia and invasive candidiasis. Approval of this indication is based on limited clinical safety and efficacy data.

Limitations of Use

REZZAYO® has not been studied in patients with endocarditis, osteomyelitis, and meningitis due to *Candida*.

Please see accompanying Prescribing Information for REZZAYO® (rezafungin for injection).



Why choose REZZAYO® (rezafungin for injection)?

Proven echinocandin efficacy now in a *once-weekly* formulation^{1,2}

Once-weekly rezafungin was non-inferior to caspofungin in the ReSTORE study, a multicenter, double-blind, double-dummy, randomized phase 3 trial. Adults with candidemia or invasive candidiasis received either IV rezafungin once a week* or IV caspofungin** for no more than 4 weeks. Rezafungin was non-inferior to caspofungin[†] for the primary endpoints of day-14 global cure[‡] and 30-day all-cause mortality with a 20% non-inferiority margin assessed in the MITT population[§].



No clinically relevant drug-drug interactions with common oncology and immunosuppressive drugs

Two clinical studies demonstrated no clinically relevant drug-drug interactions between REZZAYO® and drugs likely to be administered concomitantly, including¹:

Immunosuppressant	Cardiac, cholesterol, diabetes	Oncology	Other
cyclosporine	digoxin	ibrutinib	caffeine
mycophenolate mofetil	metformin	venetoclax	efavirenz
tacrolimus	pitavastatin		midazolam
	repaglinide		
	rosuvastatin		



No dose adjustments for special populations

Same dosing for patient populations based on age, sex, race, weight, with renal impairment, or undergoing hemodialvsis.¹

*400 mg in week 1, followed by 200 mg weekly, for a total of two to four doses. ** 70 mg loading dose on day 1, followed by 50 mg daily. † 59% of patients in the rezafungin group and 61% of patients in the caspofungin group had a global cure at day 14 (weighted treatment difference -1·1% [95% CI -14·9 to 12·7]. 24% of patients in the rezafungin group and 21% of patients in the caspofungin group died or had an unknown survival status at day 30 (treatment difference 2·4% [95% CI -9·7 to 14·4]. ‡ Global cure consisted of clinical cure, radiological cure, and mycological eradication. § All patients who received one or more doses of study drug and had documented *Candida* infection.

IMPORTANT SAFETY INFORMATION

Contraindications

• REZZAYO® is contraindicated in patients with known hypersensitivity to rezafungin or other echinocandins.

Warnings and Precautions

- Infusion-related Reactions: REZZAYO® may cause infusion-related reactions, including flushing, sensation of warmth, urticaria, nausea, or chest tightness. If these reactions occur, slow or pause the infusion.
- 2 Please see additional Important Safety Information throughout and accompanying Prescribing Information for REZZAYO® (rezafungin for injection).

Envision a new treatment path

REZZAYO® offers an alternative option for continuity of echinocandin treatment in the outpatient setting

Patient with invasive candidiasis Malready on echinocandin therapy Otherwise dischargeable Needs to complete candidemia or invasive candidiasis treatment Discharge on REZZAYO® Hospital inpatient (at discharge) Hospital outpatient Free-standing infusion center Home infusion Physician's office

Invasive candidiasis management, simplified



No requirement for a PICC or

clinically significant

drug-drug interactions



No impact on QTc interval



Alternative Option:

May provide greater transparency into adherence with 7 days of therapy in every dose

Offers patients
who cannot take oral
medications a onceweekly option



Fungicidal activity against the most common and emerging *Candida* species



With **once-weekly REZZAYO**®, patients

don't need to

remain hospitalized

to complete their

echinocandin

therapy

IMPORTANT SAFETY INFORMATION (continued)

Warnings and Precautions (continued)

- Photosensitivity: REZZAYO® may cause photosensitivity. Advise patients to use protection from sun exposure and other sources of UV radiation.
- Hepatic Adverse Reactions: Abnormalities in liver tests have been seen in clinical trial patients treated with REZZAYO®. Monitor
 patients who develop abnormal liver tests and evaluate patients for their risk/benefit of continuing REZZAYO® therapy.

Please see additional Important Safety Information throughout and accompanying Prescribing Information for REZZAYO® (rezafungin for injection).



A Once-Weekly Echinocandin

for Adult Patients with Candidemia and Invasive Candidiasis*

WHY CHOOSE **REZZAYO®?**

REZZAYO® is administered once weekly for one hour by IV infusion.

Initial 400 mg loading dose, followed by a 200 mg dose once weekly thereafter. The safety of REZZAYO® has not been established beyond 4 weekly doses.

Onceweekly **REZZAYO®**



Daily IV echinocandin





Week 2

Day 11

No PICC required

Day 8: 200 mg weekly dose







Day 9





Day 12



Day 13



Daily PICC maintenance to prevent infection

A once-weekly IV infusion of REZZAYO®:



Could allow for earlier discharge of patients on echinocandins who are otherwise dischargeable

- ✓ No requirement for a PICC or central line
- ✓ No known clinically significant drug-drug interactions
- ✓ No dose adjustments for special populations
- ✓ May help address logistical challenges associated with daily infusions
- ✓ May provide greater transparency into adherence with 7 days of therapy in every dose

1. REZZAYO®. Prescribing information. Melinta Therapeutics, LLC; 2023. 2. Thompson GR 3rd, Soriano A, Cornely OA, et al. Rezafungin versus caspofungin for treatment of candidaemia and invasive candidiasis (ReSTORE); a multicentre, double-blind, double-dummy, randomised phase 3 trial, Lancet, 2023;401(10370);49-59, doi:10.1016/S0140-6736(22)02324-8

IMPORTANT SAFETY INFORMATION (continued) Adverse Reactions

Most common adverse reactions (incidence ≥ 5%) are hypokalemia, pyrexia, diarrhea, anemia, vomiting, nausea, hypomagnesemia, abdominal pain, constipation, and hypophosphatemia.

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