

Rezafungin: New Echinocandin, New Opportunities?

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Disclosures

- Nothing to disclose regarding financial or personal relationships with commercial entities relevant to this presentation.
- The content of this presentation will include discussion of unapproved or investigational uses of products

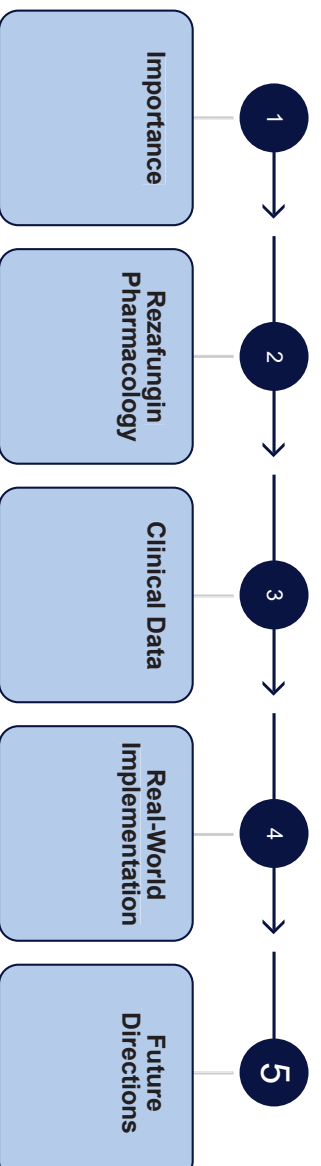


Objectives

- Describe the mechanism of action, spectrum of activity and pharmacologic properties of Rezafungin
- Compare and contrast rezafungin to other antifungal agents, with respect to antifungal activity, pharmacokinetic properties, dosing, and cost
- Evaluate current and emerging evidence supporting efficacy of rezafungin in the management of invasive fungal infections
- Discuss the current place in therapy of rezafungin based upon available literature, operational considerations, and patient factors

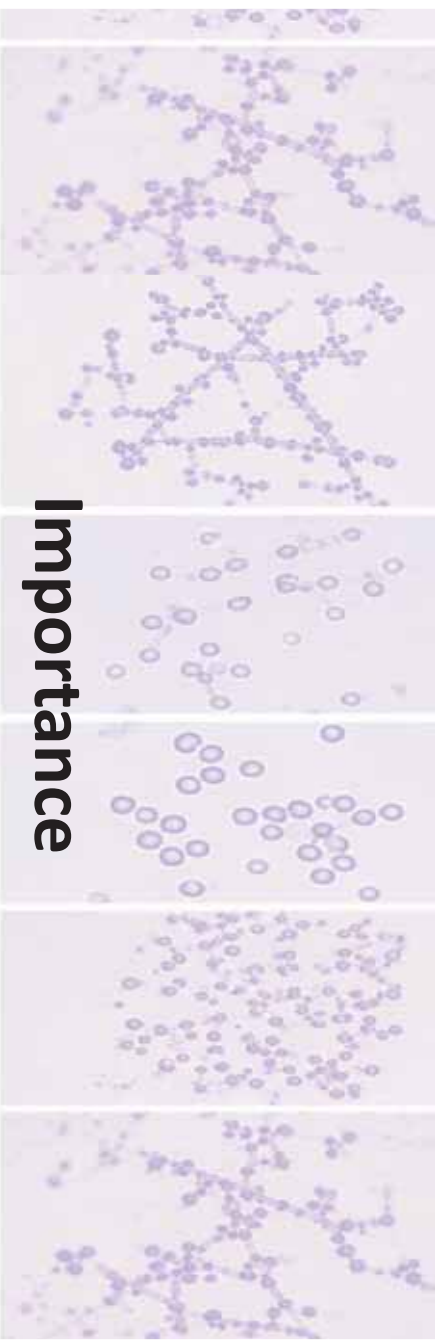


Agenda

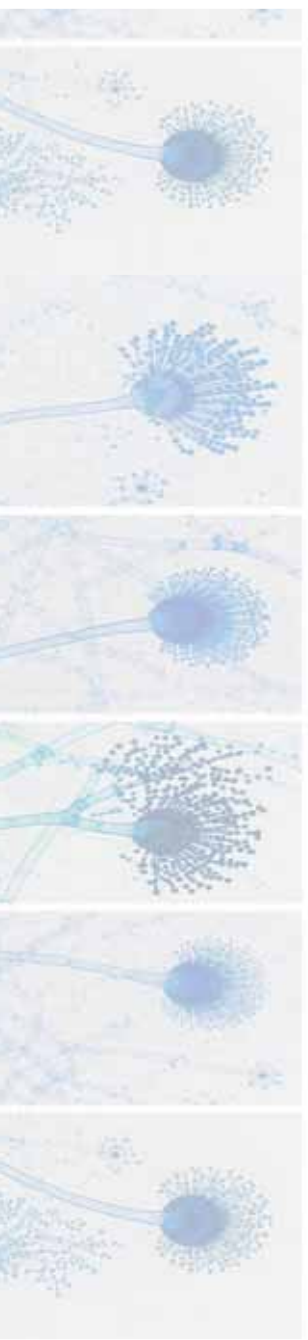


Abbreviations

- ABLC – amphotericin B lipid complex
- ADE – adverse drug event
- Amb – amphotericin B
- AND – anidulafungin
- C – candidemia
- CAS – caspofungin
- CNS – central nervous system
- CYP450 – cytochrome P450
- DOT – days of therapy
- FLC – fluconazole
- HSCT – hematopoietic stem cell transplant
- HIV – human immunodeficiency virus
- IC – invasive candidiasis
- IFI – invasive fungal infection
- ISA – isaconazole
- IRES – intrinsic reduced echinocandin susceptibility
- L-AMB – liposomal amphotericin B
- MFG – micafungin
- mITT – modified intention-to-treat
- PAFE – post-antifungal effect
- PK – pharmacokinetics
- POS – posaconazole
- RCT – randomized controlled trial
- RZF – rezafungin
- SOT – solid organ transplant
- TEAE – treatment-emergent adverse events
- VOR – voriconazole



Importance



Global Burden: Fungal Infections



Table 3. WHO fungal priority pathogens list

Critical group	High group	Medium group
Cryptococcus neoformans	Histoplasma capsulatum	Scedosporium spp.
Candida auris	Eumycetozoa causative agents	Leishmania protozoa
Aspergillus fumigatus	Mucorales	Coccidioides spp.
Candida albicans	Fusarium spp.	Pneumocystis jirovecii
	Candida tropicalis	Cryptococcus gattii
	Candida parapsilosis	Pneumocystis carinii
		Pneocystis spp.

<https://www.who.int/publications/i/item/9789240060241>



National Burden

Candidemia 30-day Mortality Trends in the United States 2015-2024 (N=29,454)

Figure 1. Thirty-day candidemia mortality rate by year

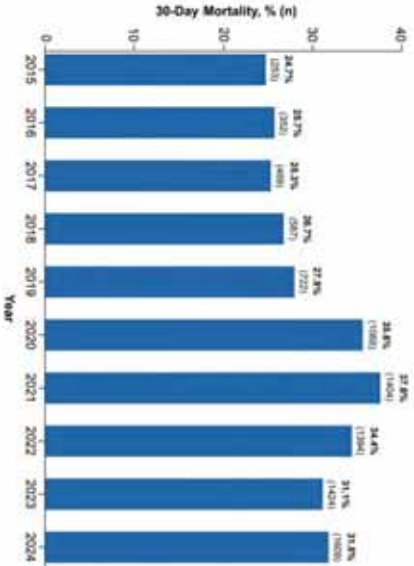
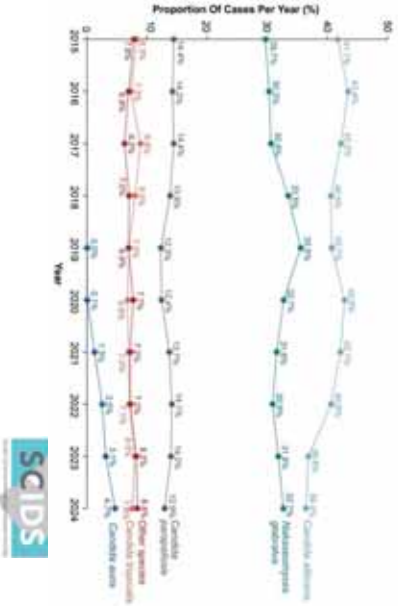


Figure 2. Proportion of Candida species among candidemia cases



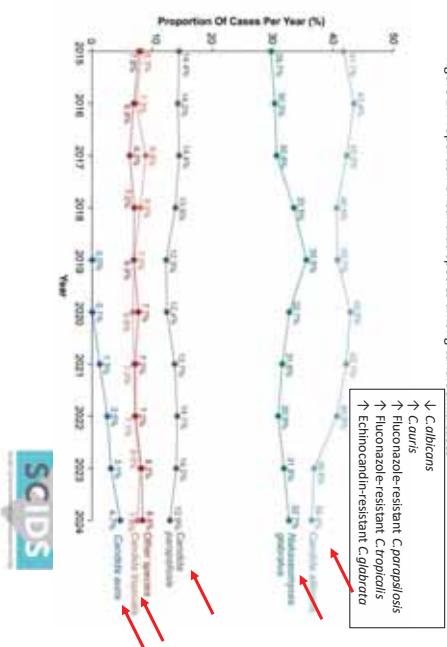
National Burden

Candidemia 30-day Mortality Trends in the United States 2015-2024 (N=29,454)

Figure 1. Thirty-day candidemia mortality rate by year



Figure 2. Proportion of Candida species among candidemia cases



Pérez M et al. Clin Infect Dis. Published online May 11, 2026.

Objectives of the Antifungal Pipeline

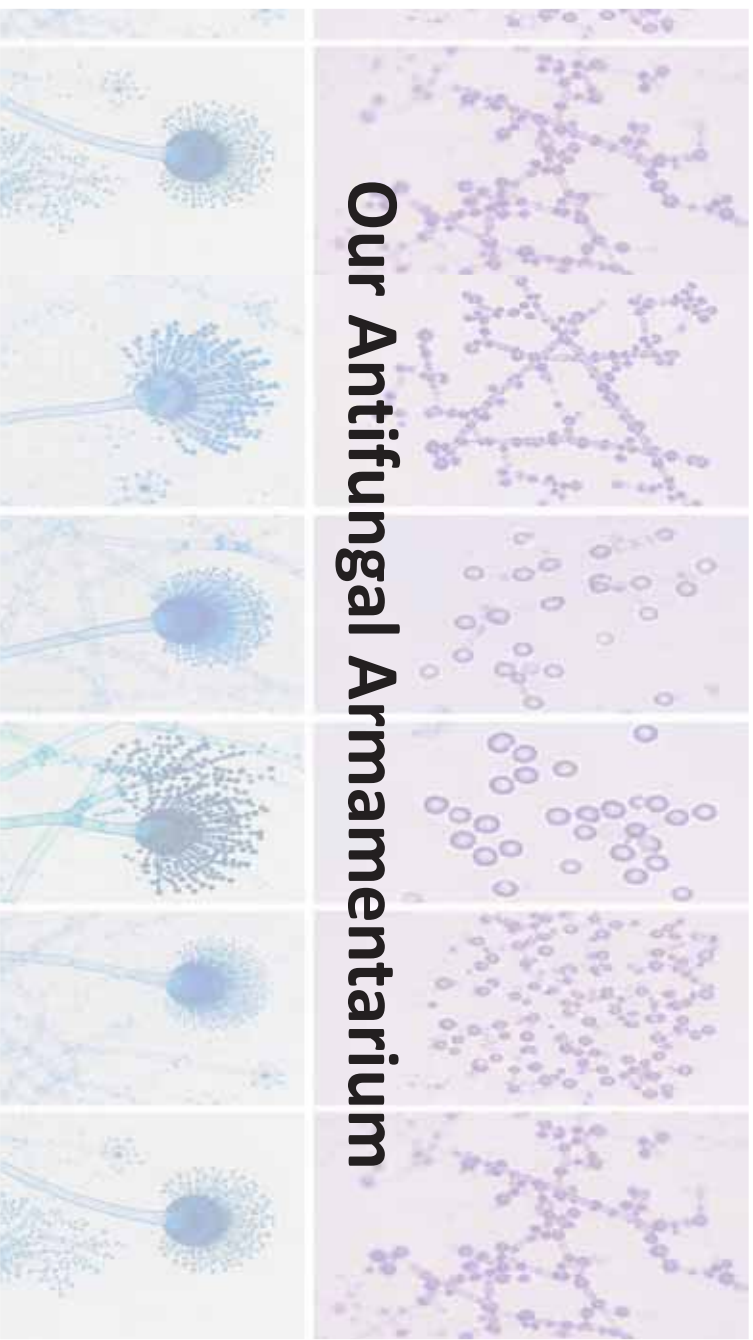
Optimize

- ☐ Antifungal spectrum
- ☐ Pharmacometrics
- ☐ Safety/tolerability
- ☐ Candidacy
- ☐ Compliance

Reduce

- ☐ Mortality
- ☐ Treatment duration
- ☐ Selection of new resistance
- ☐ Patient and caregiver burden

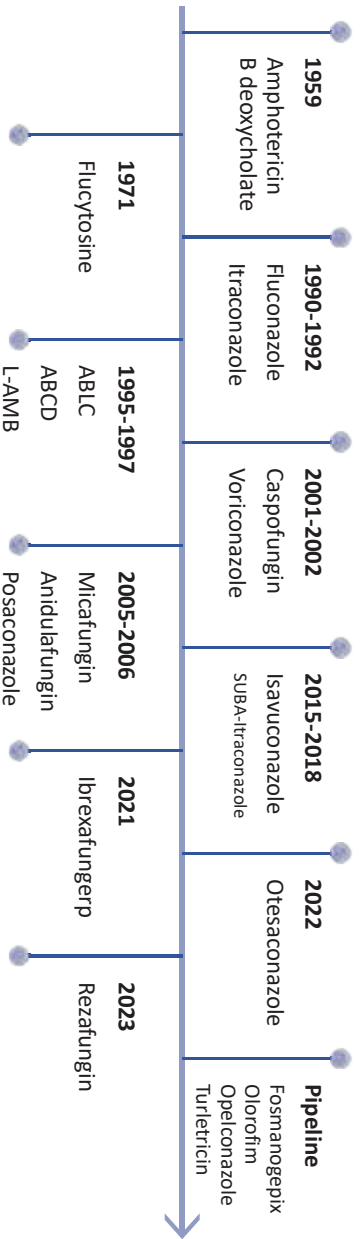




Our Antifungal Armamentarium

Importance of the Antifungal Pipeline

Our Antifungal Armamentarium



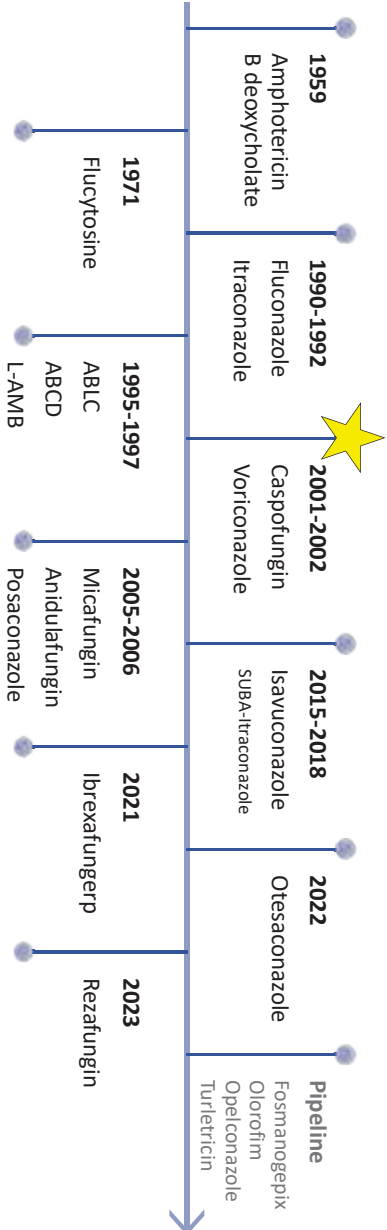
*Timeline in order of FDA approval date

<https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm>



Importance of the Antifungal Pipeline

Our Antifungal Armamentarium



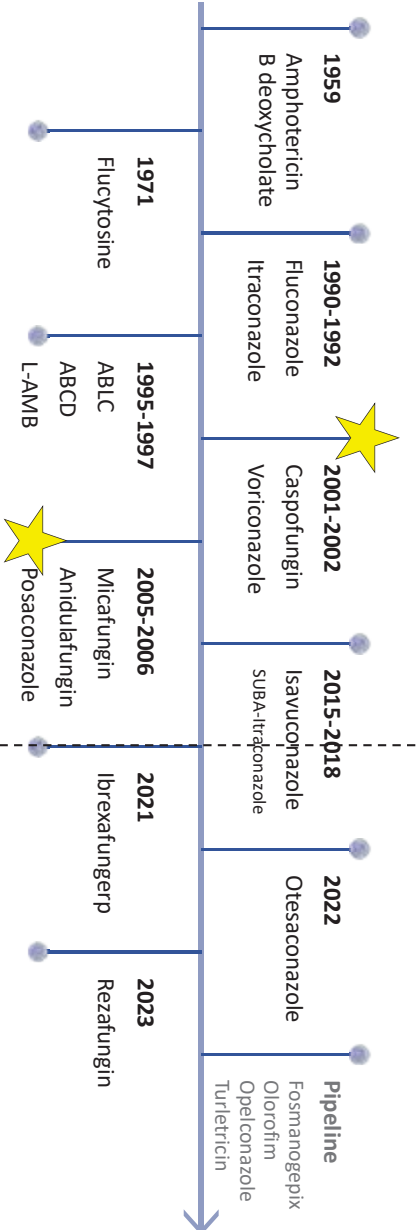
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Importance of the Antifungal Pipeline

Our Antifungal Armamentarium

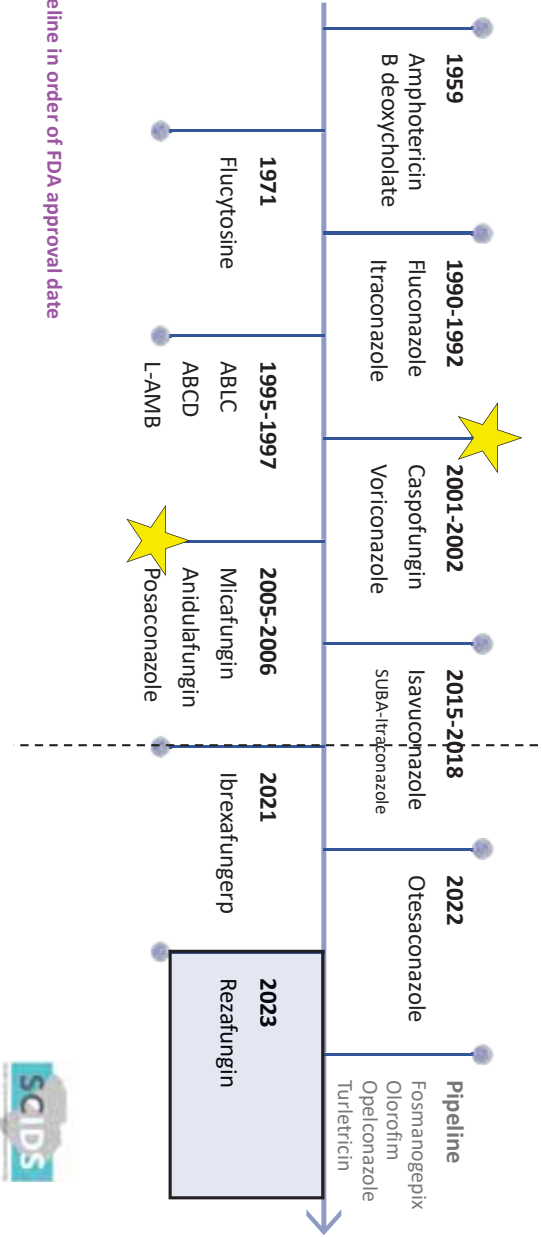


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Our Antifungal Armamentarium

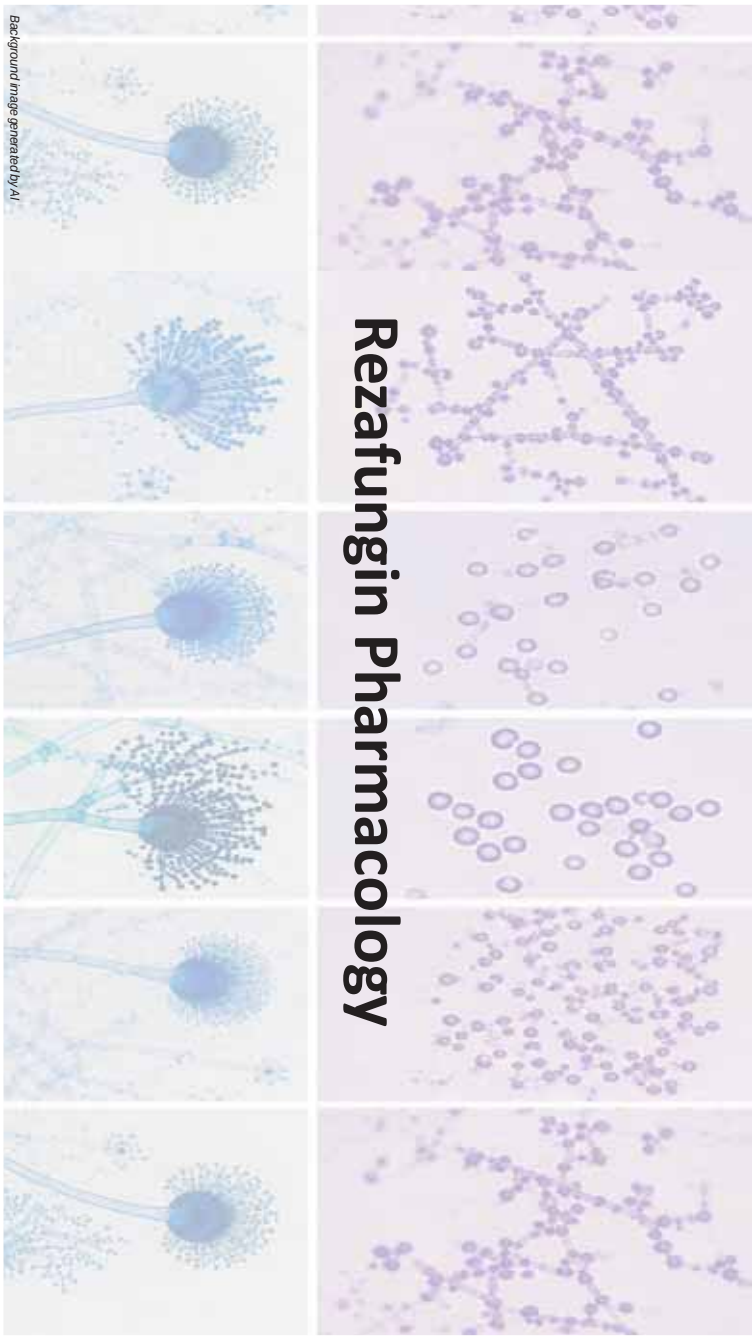


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<https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm>



Rezafungin Pharmacology



Background image generated by AI

Rezafungin

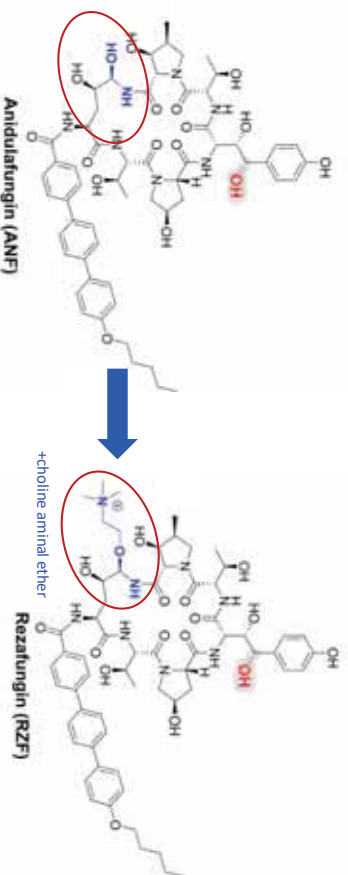
- Next generation echinocandin
 - Non-competitive 1,3,β-D-glucan synthase inhibitor
- Structural analog of anidulafungin



REZZAVO® (rezafungin for injection). Package insert. Melinta Therapeutics LLC; 2023

Rezafungin

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 - Non-competitive 1,3,β-D-glucan synthase inhibitor
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REZZAVO® (rezafungin for injection). Package insert. Melinta Therapeutics LLC; 2023
Logvinuk D et al. J Am Chem Soc. 2022;144(13):5965-5975.

Rezafungin

- Next generation echinocandin
 - Non-competitive 1,3,β-D-glucan synthase inhibitor
- Structural analog of anidulafungin

	Rezafungin
Dose, mg (LD/MD)	400 / 200 weekly
T _{1/2} (hours)	~152
C _{max} _{ss}	19.2 ± 5.9
AUC _{ss}	827 ± 252
Vd (L)	67-95



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 - Non-competitive 1,3,β-D-glucan synthase inhibitor
- Structural analog of anidulafungin

	Rezafungin	Anidulafungin	Caspofungin	Micafungin
Dose, mg (LD/MD)	400 / 200 weekly	200 / 100 daily	70 / 50-150 daily	100-150 daily
T _{1/2} (hours)	~152	27-55	13-15	13-17
C _{max} _{ss}	19.2 ± 5.9	7-23	9-11	10-16
AUC _{ss}	827 ± 252	110-142	87-120	97-167
Vd (L)	67-95	30-50	9.7	25-75



REZZAVO® (rezafungin). Package insert. Melinta Therapeutics LLC; 2023.
Micafungin. Package insert. Teva Pharmaceuticals USA, Inc; 2005.
Caspofungin acetate. Package insert. Fresenius SE & Co; 2001.
EXALIS® (anidulafungin). Package insert. Pfizer Inc; 2006.
Quindós G et al., Rev Iberoam Micol. Published online February 5, 2026.

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Caspofungin acetate. Package insert. Fresenius SE & Co. 2001.
ERAXIS™ (anidulafungin). Package insert. Pfizer Inc. 2006.
Quindos G et al., Rev Iberoam Micol. Published online February 5, 2026.



Rezafungin

- Next generation echinocandin
 - Non-competitive 1,3,β-D-glucan synthase inhibitor
- Structural analog of anidulafungin

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Quindos G et al., Rev Iberoam Micol. Published online February 5, 2026.



Rezafungin

- Next generation echinocandin
 - Non-covalent
 - Structural
- “Front loaded plasma exposure”

Rezafungin		Miconazole	
Dose, mg (LD/M ²)		0-150 daily	100-150 daily
T _{1/2} (hours)		13-15	13-17
C _{max} ss	19.2 ± 5.9	7-23	10-16
AUC ₀₋₂₄ ss	827 ± 252	110-142	97-167
Vd (L)	67-95	30-50	25-75

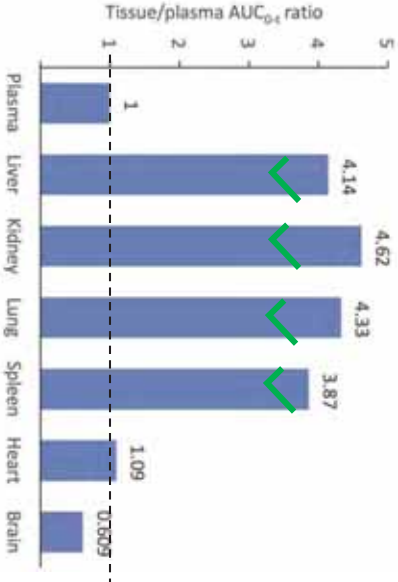
REZAFUNGIN Rezafungin Package insert, Medava Therapeutics LLC 2023.
Miconazole Miconazole Package insert, Bristol-Myers Squibb 2023.
Caspofungin Caspofungin Package insert, Pfizer Inc 2006.
Echinocandin Echinocandin Package insert, Farnam 2000.
Gardasyl Gardasyl (Rezafungin) Package insert, Pfizer Inc 2006.
Gardasyl 2 Gardasyl 2 (Rezafungin) Package insert, Pfizer Inc 2006.



Tissue Penetration

Rat Model

Tissue/Plasma AUC₀₋₂₄ Following 5mg/kg RZF



Org V et al, Antimicrob Agents Chemother. 2022;66(1):e0139021.
Andes D et al J Antimicrob Chemother. 2025;80(1):18-28.

Cynomolgus monkey

Tissue [¹⁴C-labelled rezafungin] vs. Time Post-Dose

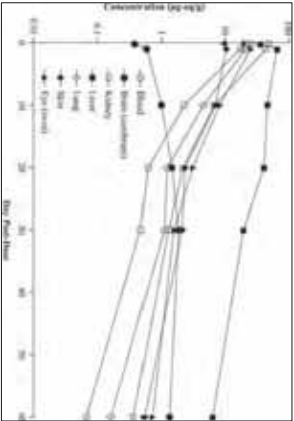


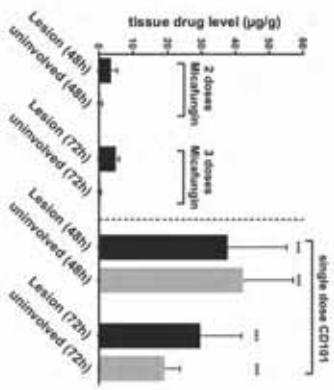
TABLE 2 Comparative tissue:plasma AUC exposure ratios for CD101 and marketed echinocandins

Tissue:plasma AUC ratio*		CD101		CASP		MICA		AND	
Tissue		CD101		CASP		MICA		AND	
Liver	4.14		10.2		7.8		12.4		
Kidney	4.62		5.5		3.2		10.7		
Lung	4.33		1.2		3.6		10.4		

*Values for caspofungin (CASP), miconazole (MICA), and anidulafungin (AND) are from reference 13.

Tissue Penetration

Murine Model – Intra-abdominal Abscess
(*C.albicans* SC4315)

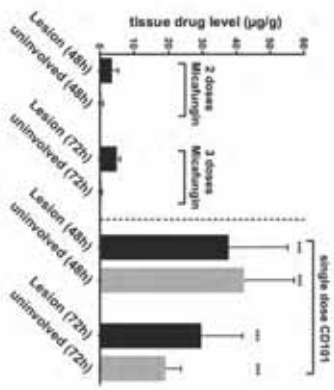


↑ Intra-abdominal abscess penetration with RZF vs. Micafungin

Zhao Y et al. *Antimicrob Agents Chemother*. 2017;61(10):e01009-17.
Miesel L et al. *Antimicrob Agents Chemother*. 2021;55(3):e01992-20.

Tissue Penetration

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Zhao Y et al. *Antimicrob Agents Chemother*. 2017;61(10):e01009-17.
Miesel L et al. *Antimicrob Agents Chemother*. 2021;55(3):e01992-20.

Tissue	RZF Tissue Penetration
Soft tissue abscess	↑
Liver	
Lungs	
Kidneys	
Heart	
Urine	
Brain	
Eye	
Bone	ND

Drug-Drug Interactions

Flanagan et al., (2023)

Phase 1 open-label crossover studies, RZF vs. CYP450 and/or transporter proteins, immunosuppressants

TABLE 3 Summary of the pharmacokinetic outcomes for each of the probe/test drugs coadministered with rezafungin, compared with administration alone, and potential dosing implications^a

Drug	Possible mechanism(s)	Observation ^b		Suggested action
		C _{max}	AUC	
Tacrolimus	CYP3A4, P-gp	++	↑ ~14%	No change in dose
Regorafenib	CYP2C8, OATP	++	↑ ~16% (D-xx)	No change in dose
Metformin	OCT, MATE1	++	++	No change in dose
Posaconazole	BCRP, OATP	↑ ~12%	↑ ~12%	No change in dose
Pravastatin	OATP	++	++	No change in dose
Caffeine	CYP1A2	++	++	No change in dose
Elevanterz	CYP2B6	++	++	No change in dose
Midazolam	CYP3A4	++	++	No change in dose
Digoxin	P-gp	++	++	No change in dose
Cyclosporine	CYP3A4, P-gp	++	++	No change in dose
Ibuprofen	CYP3A4, P-gp, BCRP	↑ ~17%	++	No change in dose
Mycophenolate mofetil ^c	Other ^d	↑ ~19%	↑ ~10%	No change in dose
Venetoclax	CYP3A4, P-gp	++	++	No change in dose

^aThe magnitude of the change indicates the ratio of the geometric mean PK parameter for the test (with rezafungin) relative to the reference (drug alone).

^bChange affecting absorption or enthepagic inclusion.

^cMycophenolate acid was the analyte measured.

^dObservations: AUC₀₋₁₂ was under the concentration-time curve (from time zero to the time point of the last quantifiable sample) and the AUC₀₋₂₄ extrapolated to time infinity, unless otherwise noted; C_{max} maximum concentration; ++, no change (the ratio of the PK parameter value varied by up to ~10%, and the 90% CI was within 80 to 125%); ↑, increase in exposure; ↓, decrease in exposure.



Flanagan S et al. Microbiol Spectr. 2023;11(3):e0133923.

Rezafungin Pharmacology

Drug-Drug Interactions

Antifungal		Clinically Significant Drug-Drug Interactions	
Rezafungin	None		
Anidulafungin	None		
Micafungin	Very weak CYP3A4 inhibitor (↑ cyclosporine, sirolimus, nifedipine) – no adj req		
Caspofungin	OATP inducers e.g., rifampin (↓CAS), OATP substrates e.g., cyclosporine (↑CAS) CYP3A5 non-expressors (↓Tacrolimus)		
Amphotericin B	Nephrotoxic drugs, Potassium-depleting agents (corticosteroids, digoxin)		
Fluconazole	CYP3A4/5, CYP2C9, CYP2C19, QTC-prolonging agents		
Voriconazole	CYP3A4/5, CYP2C9, CYP2C19, Pgp, QTC-prolonging agents		

Clinical Significance



Drug-Drug Interactions

Antifungal

Rezafungin

Clinically Significant Drug-Drug Interactions

None

Clinical Significance

Key Takeaway:

- Low clinically significant DDI potential with commonly prescribed comedications
- Comparable to other echinocandins
- Favorable to azoles/amphotericin B

VoriconazoleCYP3A4/5, CYP2C9, CYP2C19, Pgp, QIC-prolonging agents

Flanagan S et al. Microbiol Spectr. 2023;11(3):e013923.
Flanagan S et al. Clin Pharmacol Drug Dev. 2020;9(4):565-565.
Zhang Y et al. J. Clin. Pharm. 2020;55(2):159-162.

Azeiza J et al. Rev Esp Quimioter. 2023;35(3):256-258.
Gargano M, Anderson J. Antimicrob Agents Technol. 2010.

Spectrum of Activity

Candida spp. (including C. auris)			
Aspergillus spp. (not nidulans)			
Pneumocystis jirovecii			
In-vivo (human/animal)	In-vivo (animal)	In-vitro only	No activity
Candida albicans Candida glabrata Candida parapsilosis Candida tropicalis *Candida krusei *Candida dubliniensis *Candida lusitanae *Candida guilliermondii ^ΔCandida auris ^YAspergillus fumigatus ^Ypneumocystis spp.	^ΔCandida auris ^YAspergillus spp. ^Ypneumocystis spp.	Aspergillus flavus Aspergillus niger Aspergillus terreus Cryptic Aspergillus spp.	Aspergillus nidulans Scedosporium spp. Lomentospora spp. Trichosporon spp. Cryptococcus spp. Histoplasma spp. Mucorales

REZZANO® (rezafungin for injection). Package insert. Melinta Therapeutics LLC; 2023
Garcia-Effron G et al. J Fungi (Basel). 2020;6(4):262.

^{*}small sample size
^Δcase reports only
^Yunpublished human data

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Spectrum of Activity

Activity of Rezafungin and Comparators Against Invasive Candidiasis Isolates Globally - SENTRY Antimicrobial Surveillance Program (2019-2020), N=1427

Candida spp. (n)	MIC50 / MIC90 (mg/L)					
	RZF	AND	CAS	MCF	FLC	VRC
C.albicans (651)	0.03 / 0.06	0.03 / 0.06	0.015 / 0.03	0.015 / 0.03	0.12 / 0.25	0.004 / 0.015
C.tropicalis (166)	0.03 / 0.06	0.03 / 0.06	0.03 / 0.03	0.03 / 0.06	0.25 / 1	0.03 / 0.06
C.glabrata (289)	0.06 / 0.06	0.06 / 0.12	0.03 / 0.06	0.015 / 0.03	4 / 16	0.06 / 0.5
C.parapsilosis (239)	1 / 2	2 / 4	0.25 / 0.5	1 / 1	0.5 / 8	0.008 / 0.12
C.krusei (40)	0.03 / 0.03	0.06 / 0.06	0.06 / 0.12	0.06 / 0.12	32 / 32	0.25 / 0.25
C.dubliniensis (42)	0.06 / 0.12	0.06 / 0.12	0.03 / 0.06	0.015 / 0.03	0.12 / 0.25	0.004 / 0.008

*C.parapsilosis, C.guilliermondii exhibit IRES phenotype due to intrinsic FKS1 polymorphisms



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<i>Candida</i> spp. (n)	MIC50 / MIC90 (mg/L)					
	RZF	AND	CAS	MCF	FLC	VRC
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<i>C.tropicalis</i> (166)	0.03 / 0.06	0.03 / 0.06	0.03 / 0.03	0.03 / 0.06	0.25 / 1	0.03 / 0.06
<i>C.glabrata</i> (289)	0.06 / 0.06	0.06 / 0.12	0.03 / 0.06	0.015 / 0.03	4 / 16	0.06 / 0.5
<i>C.parapsilosis</i> (239)	1 / 2	2 / 4	0.25 / 0.5	1 / 1	0.5 / 8	0.008 / 0.12
<i>C.krusei</i> (40)	0.03 / 0.03	0.06 / 0.06	0.06 / 0.12	0.06 / 0.12	32 / 32	0.25 / 0.25
<i>C.dubliniensis</i> (42)	0.06 / 0.12	0.06 / 0.12	0.03 / 0.06	0.015 / 0.03	0.12 / 0.25	0.004 / 0.008

**C.parapsilosis*, *C.guilliermondii* exhibit IRES phenotype due to intrinsic FKS1 polymorphisms

Canvallihaes C et al. J Clin Microbiol. 2022;60(4):e0244921.



Candida auris

Organism group (n)	RZF MIC range, MIC _{50/90} mg/L (%S)	CSF MIC range, MIC _{50/90} mg/L (%NR)	AND MIC range, MIC _{50/90} mg/L (%NR)	MCF MIC range, MIC _{50/90} mg/L (%NR)
All US <i>C. auris</i> (79)	0.03 - >4, 0.5/1 (86.1)	0.03 - >4, 0.12/1 (91.1)	0.06 - >4, 0.5/1 (96.2)	0.06 - >4, 0.25/0.5 (96.2)
FLC-R <i>C. auris</i> (77)	0.03 - >4, 0.5/1 (85.7)	0.03 - >4, 0.12/1 (90.9)	0.06 - >4, 0.5/1 (96.1)	0.06 - >4, 0.25/0.5 (96.1)
Amb-R and FLC-R <i>C. auris</i> (35)	0.03 - 2, 0.25/1 (88.6)	0.03 - >4, 0.12/0.5 (91.4)	0.06 - 2, 0.5/0.5 (100.0)	0.06 - 1, 0.25/0.5 (100.0)

n, number; SCF, rezafungin; MIC, minimum inhibitory concentration; %S, susceptible; CSF, susceptible; %NR, non-resistant; AND, anidulafungin; MCF, micafungin; FLC, fluconazole; Amb, amphotericin B; VRC, voriconazole



Candida auris

Organism group (n)	RZF MIC range, MIC _{50/90} mg/L (%S)	CSF MIC range, MIC _{50/90} mg/L (%NR)	AND MIC range, MIC _{50/90} mg/L (%NR)	MCF MIC range, MIC _{50/90} mg/L (%NR)
All US <i>C. auris</i> (79)	0.03 – >4, 0.5/1 (86.1)	0.03 – >4, 0.12/1 (91.1)	0.06 – >4, 0.5/1 (96.2)	0.06 – >4, 0.25/0.5 (96.2)
FLC-R <i>C. auris</i> (77)	0.03 – >4, 0.5/1 (85.7)	0.03 – >4, 0.12/1 (90.9)	0.06 – >4, 0.5/1 (96.1)	0.06 – >4, 0.25/0.5 (96.1)
Amb-R and FLC-R <i>C. auris</i> (35)	0.03 – 2, 0.25/1 (88.6)	0.03 – >4, 0.12/0.5 (91.4)	0.06 – 2, 0.5/0.5 (100.0)	0.06 – 1, 0.25/0.5 (100.0)

n, number; SCS, susceptible; MIC, minimum inhibitory concentration; CSF, cerebrospinal; AND, non-resistant; MCF, fluconazole; Amb, amphotericin B; FLC, voriconazole

C. auris	CLSI M27		EUCAST		CDC
	S	S	R	ECOFF	
	AND	-	≤0.25	>0.25	≥4
	MCF	-	≤0.25	>0.25	≥4
	CAS	-	-	-	≥2
RZF	≤0.5	-	-	0.125	-



Winkler M et al. [poster] Presented at: IDWeek 2015; October 19–22, 2015; Atlanta, GA, Poster 1156.
CLSI M27M45-Ed2.0:2015 Performance Standards for Antifungal Susceptibility Testing of Yeasts
EUCAST - Overview of antifungal ECOFFs and clinical breakpoints for yeasts, molds and dematiomycetes; Version 6.0. Published June 26, 2015.

Spectrum Report Card

Table 3. WHO fungal priority pathogens list

Critical group	High group	Medium group
<i>Cryptococcus neoformans</i>	☒ <i>Histoplasma capsulatum</i> (<i>Candida glabrata</i>)	<i>Sporothrix schenckii</i> spp.
☒ <i>Candida albicans</i>	<i>Histoplasma capsulatum</i> spp.	<i>Leishmania</i> spp.
☒ <i>Aspergillus fumigatus</i>	<i>Eurotium</i> spp.	<i>Coccidioides</i> spp.
☒ <i>Candida lusitana</i>	<i>Mucor</i> spp.	☒ <i>Fusarium</i> spp.
☒ <i>Candida lusitana</i>	<i>Candida lusitana</i>	<i>Cryptococcus gattii</i>
☒ <i>Candida lusitana</i>	<i>Candida lusitana</i>	<i>Trichosporon</i> spp.
☒ <i>Candida lusitana</i>	<i>Candida lusitana</i>	<i>Pneumocystis jirovecii</i>
☒ <i>Candida lusitana</i>	<i>Candida lusitana</i>	<i>Pneumocystis jirovecii</i>
☒ <i>Candida lusitana</i>	<i>Candida lusitana</i>	<i>Pneumocystis jirovecii</i>

Candida spp.
(including *C. auris*)

Aspergillus spp.
(not *nidulans*)

Pneumocystis jirovecii



Rezafungin

Next generation, **long-acting** echinocandin

- ✓ Once weekly IV administration (no PLCC required)
- ✓ Front-loaded plasma exposure
- ✓ Comparable, potentially enhanced tissue penetration
- ✓ No significant drug-drug or drug-disease interactions
- ✓ Comparable spectrum of activity



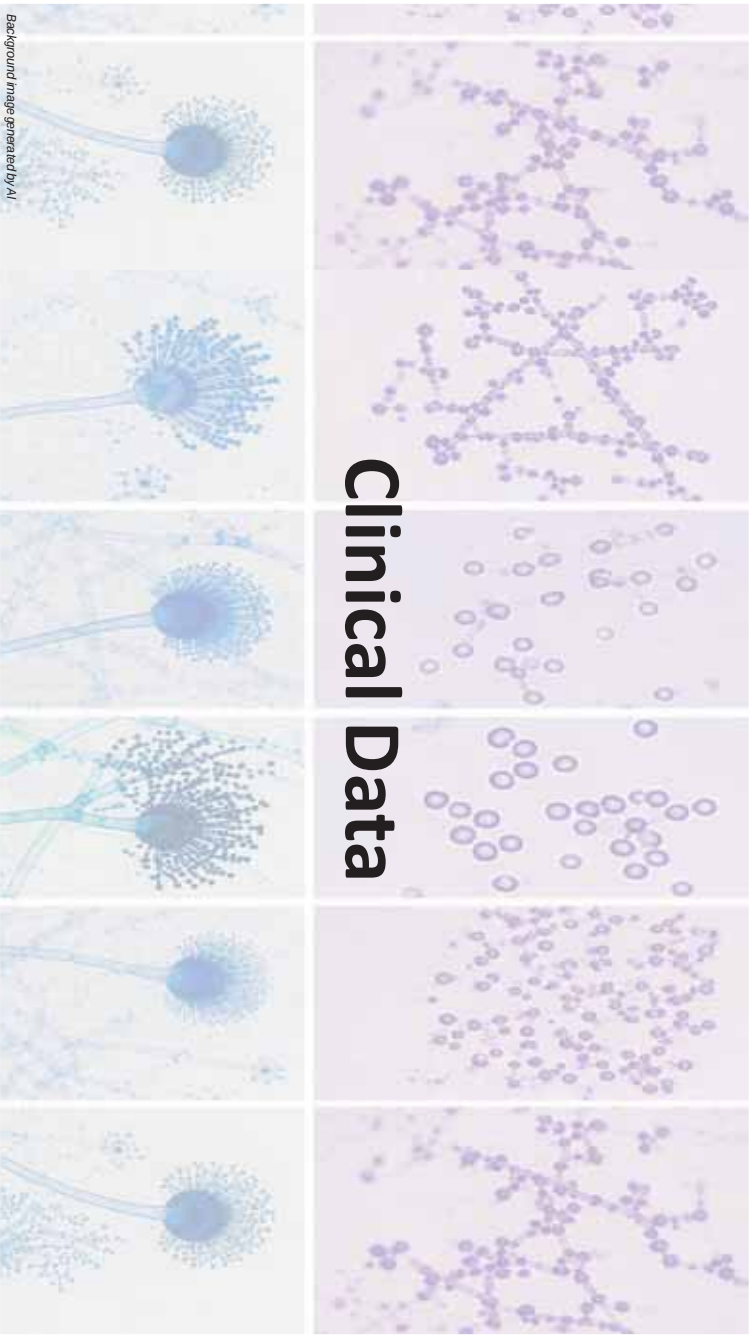
Rezafungin

Next generation, **long-acting** echinocandin

- ✓ Once weekly IV administration (no PLCC required)
- ✓ Front-loaded plasma exposure
- ✓ Comparable, potentially enhanced tissue penetration
- ✓ No significant drug-drug or drug-disease interactions
- ✓ Comparable spectrum of activity

Sounds pretty nice, right?





Rezafungin Clinical Data

FDA-Approved Indication

INDICATIONS AND USAGE

REZZAYO 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 for REZZAYO. (1, 12.4, 14)



2016 IDSA Guidelines



I. What is the Treatment for Candidemia in Nonneutropenic Patients?

Recommendations

1. An echinocandin (caspofungin: loading dose 70 mg, then 50 mg daily; micafungin: 100 mg daily; anidulafungin: loading dose 200 mg, then 100 mg daily) is recommended as initial therapy (*strong recommendation; high-quality evidence*).
2. Fluconazole, intravenous or oral, 800-mg (12 mg/kg) loading dose, then 400 mg (6 mg/kg) daily is an acceptable alternative to an echinocandin as initial therapy in selected patients, including those who are not critically ill and who are considered unlikely to have a fluconazole-resistant *Candida* species (*strong recommendation; high-quality evidence*).

III. What is the Treatment for Candidemia in Neutropenic Patients?

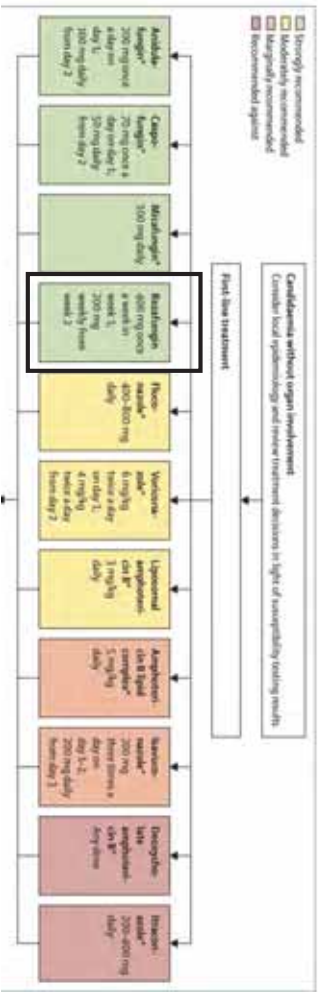
Recommendations

14. An echinocandin (caspofungin: loading dose 70 mg, then 50 mg daily; micafungin: 100 mg daily; anidulafungin: loading dose 200 mg, then 100 mg daily) is recommended as initial therapy (*strong recommendation; moderate-quality evidence*).
4. Transition from an echinocandin to fluconazole (usually within 5–7 days) is recommended for patients who are clinically stable, have isolates that are susceptible to fluconazole (eg *C. albicans*), and have negative repeat blood cultures following initiation of antifungal therapy (*strong recommendation; moderate-quality evidence*).

Pappas P et al. Clin Infect Dis. 2016;62(4):e1-e50.



2025 ECMM/ISHAM/ASM Guidelines



- Echinocandins, including the new drug rezafungin, are the recommended first-line treatment for candidaemia and all forms of invasive candidiasis except for CNS and ocular infections due to their broad activity and safety profile.

Comey O et al. Lancet Infect Dis. 2025;25(5):e280-e293.



Pivotal Studies

STRIVE (Phase 2)


MAJOR ARTICLE


Invited

Rezafungin Versus Caspofungin in a Phase 2, Randomized, Double-blind Study for the Treatment of Candidemia and Invasive Candidiasis: The STRIVE Trial

George A. Thompson, MD, Alan Burman, MD, John P. Donnelly, MD, et al. *Clinical Infectious Diseases* 2021;73(11):e3647-e3655

RESTORE (Phase 3)

Rezafungin versus caspofungin for treatment of candidaemia and invasive candidiasis (ReSTORE): a multicentre, double-blind, double-dummy, randomised phase 3 trial

George A. Thompson, MD, Alan Burman, MD, John P. Donnelly, MD, et al. *Lancet* 2021;397(10281):1028-1038

Pooled RESTORE/STRIVE

Efficacy and safety of rezafungin and caspofungin in candidaemia and invasive candidiasis: pooled data from two prospective randomised controlled trials

George A. Thompson, MD, Alan Burman, MD, John P. Donnelly, MD, et al. *Lancet* 2021;397(10281):1028-1038


MAJOR ARTICLE


Invited

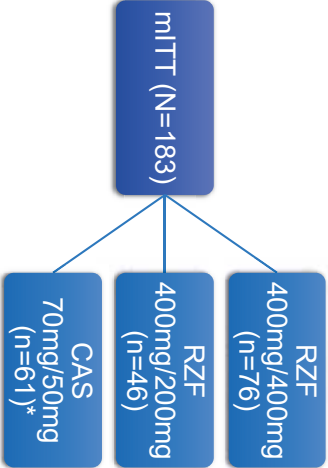
Rezafungin Versus Caspofungin for the Treatment of Candidemia and Invasive Candidiasis: Results from the Double-blind, Randomized, Phase 3 ReSTORE Trial Including the China Extension Study

George A. Thompson, MD, Alan Burman, MD, John P. Donnelly, MD, et al. *Clinical Infectious Diseases* 2021;73(11):e3647-e3655

Thompson G et al., Clin Infect Dis. 2021;73(11):e3647-e3655.

STRIVE

- Phase-2, multicenter, randomized, **dose-finding** study
- Adults with candidemia (79%) and/or invasive candidiasis (21%)
 - Excluded: osteoarticular, endovascular, ocular or CNS source; ANC ≤500/μL



*35.3% CAS switched to oral fluconazole after 9 (2-18) days

Candida spp.	n
C.albicans	91 (49.7)
C.glabrata	37 (20.2)
C.parapsilosis	28 (15.3)
C.tropicalis	22 (12.0)
C.krusei	5 (2.7)
C.dublinensis	5 (2.7)
Other	8 (4.4)



Thompson G et al., Clin Infect Dis. 2021;73(11):e3647-e3655.

STRIVE

Phase-2, dose-finding study (mITT, N=183)

Clinical + Mycological Response Day 5 / Day 14	RZF 400/400 (n=76)	RZF 400/200 (n=46)	CAS (n=61)
	55.3% / 60.5%	73.9% / 76.1%	62.3% / 67.2%
30-day all-cause mortality	RZF 400/400 (n=76)	RZF 400/200 (n=46)	CAS (n=61)
	15.8%	4.4%	13.1%
Time to blood culture clearance	RZF Pooled (n=103)	Post-hoc Log Rank p=0.0016	
	19.5 hr	CAS (n=53)	22.8hr

***No serious adverse events in either group**
(RZF vs. CAS): hypokalemia (16.4% vs. 13.2%); diarrhea (13.4 vs 14.7); vomiting (10.4% vs 7.4%)

Thompson G et al., Clin Infect Dis. 2021;73(11):e3647-e3655.

STRIVE

Rezafungin was safe and effective in the treatment of candidemia and/or invasive candidiasis

Phase 3: Rezafungin 400mg loading dose, followed by 200mg once weekly



RESTORE

Phase 3, randomized (1:1), double-blind, non-inferiority trial, 20% NI margin

International: 15 countries, 66 tertiary care centers (Oct 2018 – Aug 2021)

*21 systemic symptom (fever, hypothermia, hypotension, tachycardia, tachypnea) and mycological evidence of C +/- IC from blood or sterile site

Thompson G et al. Lancet. 2023;401(10370):49-59.



RESTORE

Phase 3, randomized (1:1), double-blind, non-inferiority trial, 20% NI margin

International: 15 countries, 66 tertiary care centers (Oct 2018 – Aug 2021)

Population

- **Inclusion:** Adults with candidemia +/- IC*
- **Exclusion:** osteoarticular, endovascular, ocular, CNS, urinary source; chronic disseminated candidiasis; non-removable indwelling device; severe hepatic impairment

*21 systemic symptom (fever, hypothermia, hypotension, tachycardia, tachypnea) and mycological evidence of C +/- IC from blood or sterile site

Thompson G et al. Lancet. 2023;401(10370):49-59.



RESTORE

Phase 3, randomized (1:1), double-blind, non-inferiority trial, 20% NI margin

International: 15 countries, 66 tertiary care centers (Oct 2018 – Aug 2021)

Population	• Inclusion: Adults with candidemia +/- IC* • Exclusion: osteoarticular, endovascular, ocular, CNS, urinary source; chronic disseminated candidiasis; non-removable indwelling device; severe hepatic impairment
Intervention	• RZF 400/200mg weekly vs. CAS 70/50mg daily x 14-28 days • Optional PO (placebo vs. fluconazole) after day 3 if met criteria

*≥1 systemic symptom (fever, hypothermia, hypotension, tachycardia, tachypnea) and mycological evidence of C +/- IC from blood or sterile site

Thompson G et al. Lancet. 2023;401(10370):49-59.



RESTORE

Phase 3, randomized (1:1), double-blind, non-inferiority trial, 20% NI margin

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Clinical Infectious Diseases

IOSA GUIDELINE

Oral Stepdown Criteria

- Fluconazole-susceptible *Candida* isolate
- Baseline symptoms of candidiasis resolved
- Blood culture negative for *Candida* spp.

*≥1 systemic symptom (fever, hypothermia, hypotension, tachycardia, tachypnea) and mycological evidence of C +/- IC from blood or sterile site

Thompson G et al. Lancet. 2023;401(10370):49-59.



RESTORE

Phase 3, randomized (1:1), double-blind, non-inferiority trial, 20% NI margin

International: 15 countries, 66 tertiary care centers (Oct 2018 – Aug 2021)

Population	• Inclusion: Adults with candidemia +/- IC* • Exclusion: osteoarticular, endovascular, ocular, CNS, urinary source; chronic disseminated candidiasis; non-removable indwelling device; severe hepatic impairment
Intervention	• RZF 400/200mg weekly vs. CAS 70/50mg daily x 14-28 days • Optional PO (placebo vs. fluconazole) <u>after day 3</u>, if met criteria
Primary Outcomes	• 14-day global cure (clinical + mycological + radiographic) (EMA) • 30-day all-cause mortality (FDA)

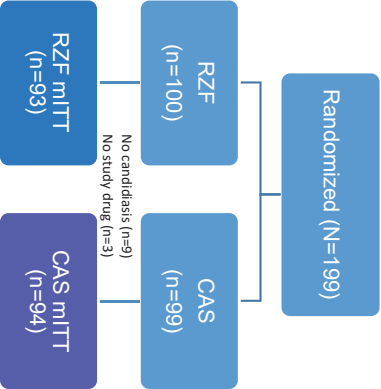
*≥1 systemic symptom (fever, hypothermia, hypotension, tachycardia, tachypnea) and mycological evidence of C +/- IC from blood or sterile site

Thompson G et al. Lancet. 2023;401(10370):49-59.



RESTORE

Enrollment & Population



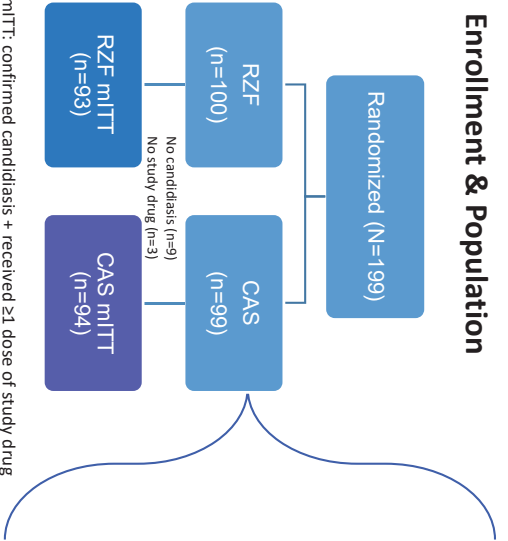
mITT: confirmed candidiasis + received ≥1 dose of study drug

Thompson G et al. Lancet. 2023;401(10370):49-59.



RESTORE

Enrollment & Population



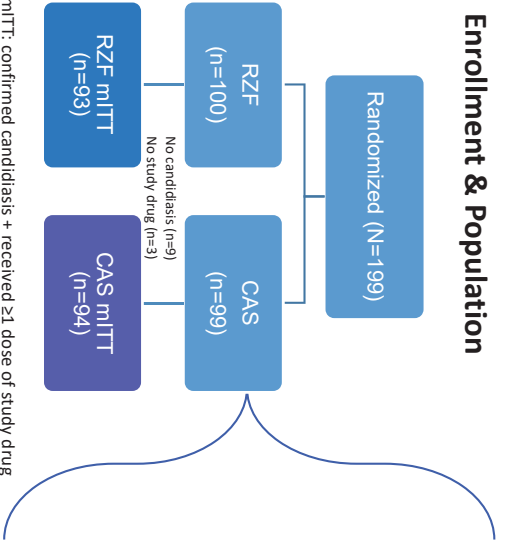
Demographics	RZF (n=93)	CAS (n=94)
Mean age	59.5	62.0
Mean BMI, kg/m²	25.4 (7)	24.5 (7)
Candidemia only*	70 (70)	68 (69)
Invasive candidiasis	30 (30)	31 (31)
Mean APACHE II <20	84 (84)	81 (83)
ANC ≥500/μL	91 (91)	93 (94)

all data n(%), mean (SD), median (IQR); *CVC present: 80% RZF vs 75% CAS

Thompson G et al. Lancet. 2023;401(10370):49-59.

RESTORE

Enrollment & Population



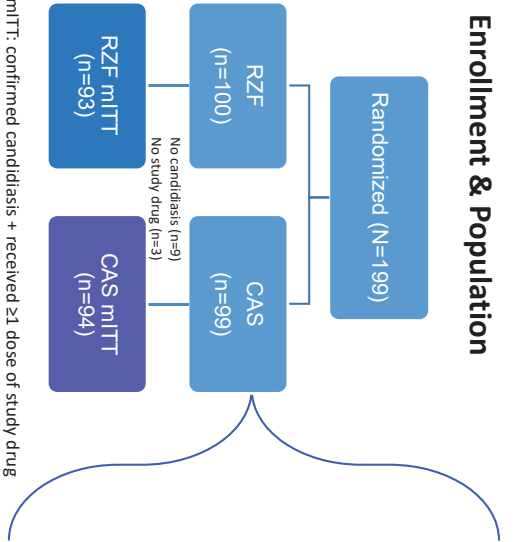
Demographics	RZF (n=93)	CAS (n=94)
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Candidemia only*	70 (70)	68 (69)
Invasive candidiasis	30 (30)	31 (31)
Mean APACHE II <20	84 (84)	81 (83)
ANC ≥500/μL	91 (91)	93 (94)
Treatment Characteristics	RZF (n=93)	CAS (n=94)
Median DOT (days)	14 (7-14)	14 (13-15)
Switched to oral PO switch on day 4-6	25 (25) 16 (64)	35 (36) 18 (51)
IV DOT 15-28 days (%)	17 (17)	27 (28)

all data n(%), mean (SD), median (IQR); *CVC present: 80% RZF vs 75% CAS

Thompson G et al. Lancet. 2023;401(10370):49-59.

RESTORE

Enrollment & Population



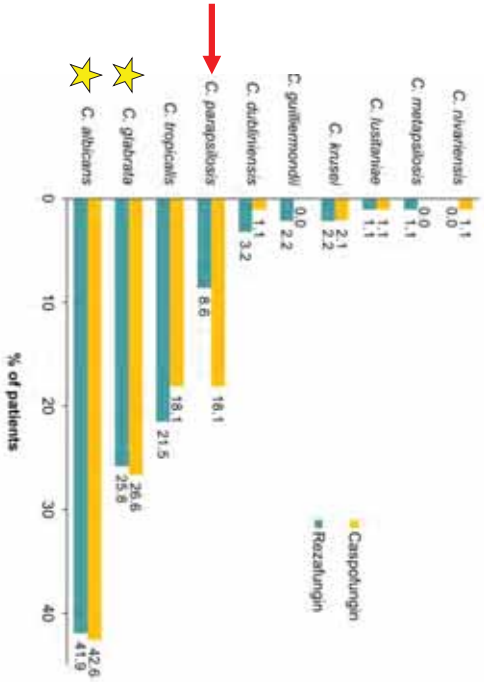
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all data n(%), mean (SD), median (IQR). *CVC present: 80% RZF vs 75% CAS

Thompson G et al. Lancet. 2023;401(10370):49-59.

RESTORE

Candida spp. Distribution



Majority WT isolates

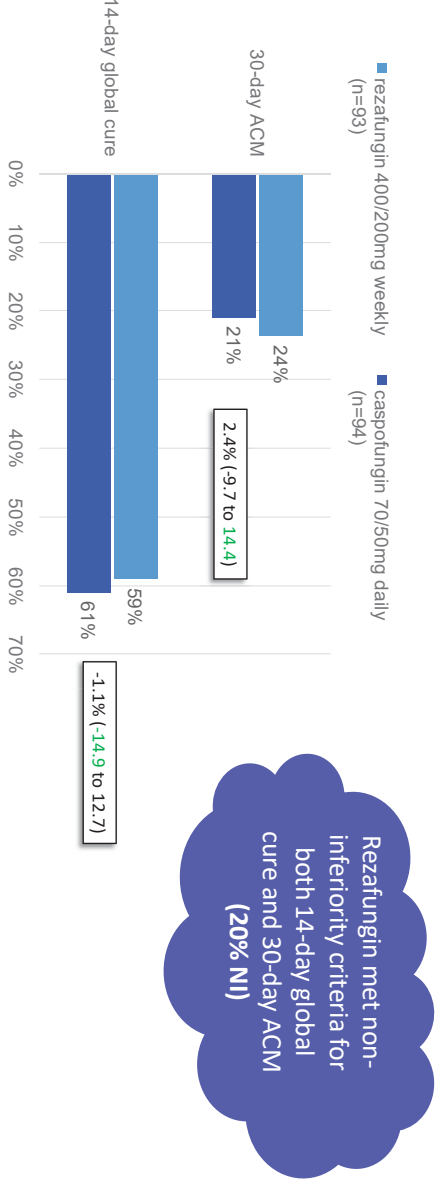
Fluconazole-R (n=17, 9%)
0% (0/78) C. albicans
8.2% (4/49) C. glabrata
19.4% (7/36) C. tropicalis
25.0% (6/24) C. parapsilosis
Echinocandin-R (n=2, 1%, RZF group)
n=1 RZF-R C. dubliniensis
n=1 CAS-I, RZF-S C. glabrata (FKS2 HS1 mutant)

Locke JB et al., Antimicrob Agents Chemother. 2024;68(5):e0158423.
Thompson G et al. Lancet. 2023;401(10370):49-59.



RESTORE

Primary Outcomes



Thompson G et al. Lancet. 2023;401(10370):49-59.

Rezafungin Clinical Data

RESTORE

Culture Clearance Outcomes

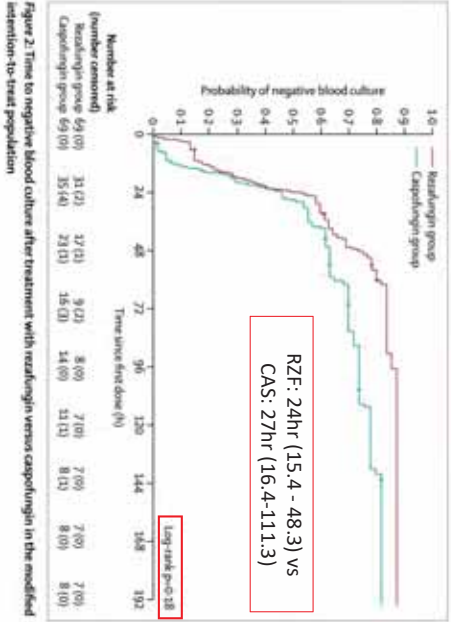
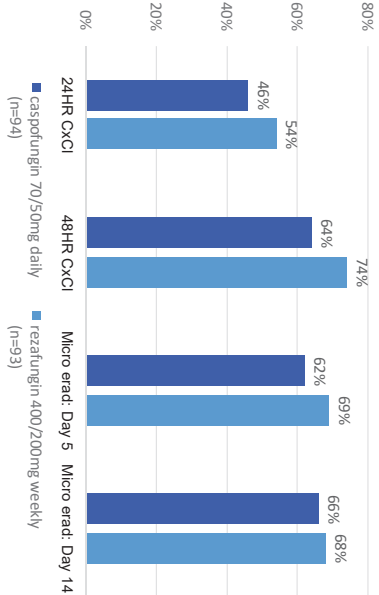


Figure 2. Time to negative blood culture after treatment with rezafungin versus caspofungin in the modified intention-to-treat population



Thompson G et al. Lancet. 2023;401(10370):49-59.
Quindós G et al., Rev Iberoa Micol. Published online February 5, 2026.

RESTORE/STRIVE

Pooled Safety

	RZF (n=151)	CAS (n=166)	p-Value
≥1 TEAE	138 (91)	138 (83)	0.03
≥1 study drug-related TEAE	22 (15)	18 (11)	0.39
≥1 serious study drug-related AE	3 (2) ^a	5 (3) ^a	0.73
TEAEs occurring ≥10%			
Diarrhea	17 (11)	17 (10)	0.86
Hypokalemia	22 (15)	17 (10)	0.30
Pyrexia	18 (12)	11 (7)	0.12
Anemia	15 (10)	13 (8)	0.56
All occurred on placebo (IV saline or PO placebo)			
^a transaminitis, anaphylactic shock			

- Special interest AEs + Pearls
- **Infusion reactions**
 - Consider ↓ infusion rate if occurs
 - May resolve spontaneously
 - Anaphylaxis mimic, not anaphylaxis
 - **Low risk at recommended rate:**
Infuse RZF over 1 hour (~250 mL/hr)
 - **Photosensitivity**
 - Sunscreen recommended

REZZAVO® (rezafungin for injection). Package insert. Melinta Therapeutics LLC; 2023
Thompson G et al. Lancet. 2023;401(10370):49-59.
Thompson G et al., Lancet Infect Dis. 2024;24(3):319-328.

RESTORE/STRIVE

Pooled Safety

	RZF (n=151)	CAS (n=166)	p-Value
≥1 TEAE			
≥1 study drug-related			
≥1 serious study dr			
TEAEs occurring ≥1			
Diarrhea			
Hypokalemia			
Pyrexia			
Anemia			
All occurred on place			
^a transaminitis, anaphylactic shock			

Take Home: Rezafungin was well tolerated and presented no serious safety concerns.

Counseling Pearls

- Photosensitivity possible, sunscreen recommended.
- Minimize infusion reactions at **250mL/hr over 1 hour**
- Consider reducing rate if occurs

REZZAVO® (rezafungin for injection). Package insert. Melinta Therapeutics LLC; 2023
Thompson G et al. Lancet. 2023;401(10370):49-59.
Thompson G et al., Lancet Infect Dis. 2024;24(3):319-328.

Author Conclusions

Rezafungin demonstrated similar safety and efficacy to caspofungin +/- oral fluconazole in the treatment of adults with candidemia +/- IC

Clinical implications of early clearance outcomes warrant further research

Real-world data from expanded access program may provide insight for use in excluded populations

Thompson G et al. Lancet. 2023;401(10370):49-59.

Key Limitations

Large non-inferiority margin (20%)

- E.g., MCF landmark trial NI 15% vs CAS

Potentially underpowered – low mortality vs. epidemiologic rate

- 20% vs. 30-40%

Limited generalizability to populations more likely to experience

↓ antifungal tolerability and compliance

- Long-term (>4 doses, osteoarticular/endovascular), APACHE II>20, ANC<500

Thompson G et al. Lancet. 2023;401(10370):49-59.
Pappas P et al. Clin Infect Dis. 2007;45(7):883-893.

My Conclusions

- Rezafungin is safe, effective and advantageous in the right patient
- Course completion or outpatient option for eligible patients to shorten LOS, avoid PICC, minimize clinic visits, caregiver burden, improve QOL

Strongest evidence base (upfront use)

- ☐ Hemodynamically stable, non-neutropenic
- ☐ Uncomplicated candidemia only and/or IC
 - ☐ No concern for metastatic foci
 - ☐ Non-osteoarticular, endovascular, urinary, CNS source
- ☐ *C. albicans*, *C. glabrata* > *C. tropicalis* > *C. parapsilosis* > *C. krusei*
- ☐ Confirmed rezafungin susceptibility
- ☐ Treatment duration is definable

My Conclusions

- Rezafungin is safe, effective and advantageous in the right patient
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Is there data for other indications?

How do we identify the right patient?

My Conclusions

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Is there data for other indications?

How do we identify the right patient?

Rezafungin Clinical Data

Study	Age/Sex/ Co/M	Indication	Pathogens	Antifungal Course	Rezafungin Dose/DOT	Rationale for RZF	Outcome
Chirio et al. (2023)	75/M	Prosthetic joint infection	<i>C.glabrata</i> • AND 100mg x 5 weeks • CAS-impregnated spacer + AND 200mg x 1 wk → RZF		400/400mg/16 weeks	Long-term OPAT Consolidation therapy	Clinical cure : no breakthrough to date; spacer removed at 16 weeks; cx negative and RZF stopped; No ADE
Vicente et al. (2024)	68/M	Spondylodiscitis	<i>C.parapsilosis</i> (fluc-R) • AND → VOR + L-AMB (stopped d/r ADE) → RZF		400/200mg/26 weeks	Long-term OPAT Azole/ampho B to x Azole resistance	Clinical cure : worsening imaging week 11 but clinically stable; resolution + radiographic improvement at 26 wks RZF
Reinhold et al. (2025)	67/M	Sternal osteomyelitis	<i>C.glabrata</i> • CAS x 19d • → RZF		NR / 36 weeks	Long-term OPAT Biofilm activity (retained source)	Clinical cure : Complete mycologic response at day 365; delayed wound healing; No ADE
Reinhold et al. (2025)	55/F	Sternal wound infection, mediastinitis, PV AV IE	<i>C.parapsilosis</i> (fluc-R) • AND x 15 days • → RZF		NR / 30 weeks (ongoing)	Long-term OPAT Biofilm activity (conservative mgmt) Azole resistance	Clinical cure : Alive at 270 days; partial response D380; follow up PET-CT planned; No ADE
Keck et al. (2025)	NR	Prosthetic joint infection (Hip)	<i>C.parapsilosis</i> • RZF upfront		400/200mg/12 weeks	Long-term OPAT Azole DDI (sotalol, warfarin)	Clinical cure : improved functional status week 6; no recurrence to-date; No ADE
Jenkins et al. (2025)	70/M	Recurrent vertebral osteomyelitis	<i>C.auris</i> • Ep 1: MCF x 7 wks (MIC 0.06) • Ep 2: MCF x 7d → MCF + L-AMB (LMCF MIC 0.12) x 6 weeks –toxicity → RZF		400/200mg/24 weeks	Long-term OPAT Ampho B Toxicity	Clinical cure : asymptomatic w/o recurrence at 172 days follow-up; ADE: intermittent migraines

Vicente G et al. Microorganisms. 2024 Apr 30;12(5):903.
Reinhold J et al. Mycoses. 2025 Sep;68(9):970-14.
Chirio M et al. Case report. Infect Dis (ECMD). 2023; #93388.
Keck J et al. Infect Dis Ther. 2025 Apr;14(4):888-895.
Jenkins L et al. ASM Case Rep. 2025 Oct 7;3(6):e00114-23.

Osteoarticular Candidiasis

Study	Age/Sex/ Co/M	Indication	Pathogens	Antifungal Course	Rezafungin Dose/DOT	Rationale for RZF	Outcome
Chiurio et al. (2023)	75/M	Prosthetic joint infection	<i>C.glabrata</i> • CAS+impregnated spacer + AND 200mg x 1 wk → RZF	AND 100mg x 5 weeks	400/400mg/16 weeks	Long-term OPAT Consolidation therapy	Clinical cure: no breakthrough to date; spacer removed at 16 weeks; CX negative and RZF stopped; No ADE
Vicente et al. (2024)	68/M	Spondylodiscitis	<i>C.parapsilosis</i> (fluc-R) • AND → VOR + L-AMB (stopped d/t ADE) → RZF	AND x 15 days	400/200mg/26 weeks	Long-term OPAT Azole/ampho B tox <i>Azole resistance</i>	Clinical cure: worsening imaging week 11 but clinically stable; resolution + radiographic improvement at 26 wks RZF
Reinhold et al. (2025)	67/M	Sternal osteomyelitis	<i>C.glabrata</i> • CAS x 19d → RZF	AND x 15 days	NR / 36 weeks	Long-term OPAT (retained source)	Clinical cure: Complete mycologic response at day 365; delayed wound healing; No ADE
Reinhold et al. (2025)	55/F	Sternal wound infection, mediastinitis, PV AV IE	<i>C.parapsilosis</i> (fluc-R) • AND x 15 days → RZF	AND x 15 days	NR / 30 weeks (ongoing)	Long-term OPAT Biofilm activity (conservative mgmt) <i>Azole resistance</i>	Clinical cure: Alive at 270 days, partial response D180, follow up PET-CT planned; No ADE
Keck et al. (2025)	NR	Prosthetic joint infection (Hip)	<i>C.parapsilosis</i> • RZF upfront	AND x 15 days	400/200mg/12 weeks	Long-term OPAT Azole DDI (sotolol, warfarin)	Clinical cure: improved functional status week 6, no recurrence to-date; No ADE
Jenkins et al. (2025)	70/M	Recurrent vertebral osteomyelitis	<i>C.auris</i> • Ep 1: MCF x 7 wks (MIC 0.06) • Ep 2: MCF x 7d → MCF + L-AMB (LMCF MIC 0.12) x 6 weeks → toxicity → RZF	AND → VOR + L-AMB (stopped d/t ADE) → RZF	400/200mg/24 weeks	Long-term OPAT Ampho B toxicity	Clinical cure: asymptomatic w/o recurrence at 172 days follow-up; ADE: intermittent migraines

Vicente G et al., Microorganisms, 2024 Apr 30;12(5):903.
Reinhold I et al. Mycoses, 2025 Sep;68(9):e70114.
Chiurio M et al., Case report, Infect Dis: ECCMID, 2023; #P3388.

Keck J et al. Infect Dis Ther, 2025 Apr;1(4):889-895.
Jenkins L et al. ASM Case Rep, 2025 Oct 7;3(6):e00114-25.

Osteoarticular Candidiasis

Study	Age/Sex/ Co/M	Indication	Pathogens	Antifungal Course	Rezafungin Dose/DOT	Rationale for RZF	Outcome
Chiurio et al. (2023)	75/M	Prosthetic joint infection	<i>C.glabrata</i> • AND 100mg x 5 weeks • CAS+impregnated spacer + AND 200mg x 1 wk → RZF	AND 100mg x 5 weeks	400/400mg/16 weeks	Long-term OPAT Consolidation therapy	Clinical cure: no breakthrough to date; spacer removed at 16 weeks; CX negative and RZF stopped; No ADE
Vicente et al. (2024)	68/M	Spondylodiscitis	<i>C.parapsilosis</i> (fluc-R) • AND → VOR + L-AMB (stopped d/t ADE) → RZF	AND x 15 days	400/200mg/26 weeks	Long-term OPAT Azole/ampho B tox <i>Azole resistance</i>	Clinical cure: worsening imaging week 11 but clinically stable; resolution + radiographic improvement at 26 wks RZF
Reinhold et al. (2025)	67/M	Sternal osteomyelitis	<i>C.glabrata</i> • CAS x 19d → RZF	AND x 15 days	NR / 36 weeks	Long-term OPAT (retained source)	Clinical cure: Complete mycologic response at day 365; delayed wound healing; No ADE
Reinhold et al. (2025)	55/F	Sternal wound infection, mediastinitis, PV AV IE	<i>C.parapsilosis</i> (fluc-R) • AND x 15 days → RZF	AND x 15 days	NR / 30 weeks (ongoing)	Long-term OPAT Biofilm activity (conservative mgmt) <i>Azole resistance</i>	Clinical cure: Alive at 270 days, partial response D180, follow up PET-CT planned; No ADE
Keck et al. (2025)	NR	Prosthetic joint infection (Hip)	<i>C.parapsilosis</i> • RZF upfront	AND x 15 days	400/200mg/12 weeks	Long-term OPAT Azole DDI (sotolol, warfarin)	Clinical cure: improved functional status week 6, no recurrence to-date; No ADE
Jenkins et al. (2025)	70/M	Recurrent vertebral osteomyelitis	<i>C.auris</i> • Ep 1: MCF x 7 wks (MIC 0.06) • Ep 2: MCF x 7d → MCF + L-AMB (LMCF MIC 0.12) x 6 weeks → toxicity → RZF	AND → VOR + L-AMB (stopped d/t ADE) → RZF	400/200mg/24 weeks	Long-term OPAT Ampho B toxicity	Clinical cure: asymptomatic w/o recurrence at 172 days follow-up; ADE: intermittent migraines

Vicente G et al., Microorganisms, 2024 Apr 30;12(5):903.
Reinhold I et al. Mycoses, 2025 Sep;68(9):e70114.
Chiurio M et al., Case report, Infect Dis: ECCMID, 2023; #P3388.

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Endovascular Candidiasis

Study	Age/Sex/ Co/M	Indication	Pathogens	Antifungal Course	Rezafungin Dose/DOT	Rationale for RZF	Outcome
Trapani et al., (2023)	64/M	Native MV endocarditis	<i>C.parapsilosis</i>	• Ep 1: L-AMB • Ep 2: CAS -> FLC (d/c/d/t GI symptoms) → RZF x 8 months	NR / 32 weeks	Long-term OPAT (consolidation) Azole toxicity	Clinical cure
Vieconne et al (2024)	26/M	TEVAR endocarditis	<i>C.tropicalis</i>	• CAS + FLC + L-AMB • RZF + ISA - d/c/d/d/t hepatotoxicity → RZF	NR / 18 weeks	Long-term OPAT Azole resistance (all except ISA) Azole toxicity	Clinical cure w/o relapse to-date; ongoing
Benitez-Cano et al. (2025)	64/M	Azole-resistant vascular graft infection, non-surgical candidate	<i>C.parapsilosis</i>	• AND+ISA x 2 months; • RZF x 35 days until dispo • RZF x 3.5 months	NR / 16 weeks	Long-term OPAT (consolidation)	Clinical cure - PET-CT confirmed resolution after completion of course; No ADE
Trapani et al. (2025)	66/M	PV endocarditis c/b endophthalmitis	<i>C.parapsilosis</i>	• FLC + CAS + L-AMB • RZF + FLC x 12 months • FLC monotherapy	NR / 52 weeks	Long-term OPAT (consolidation)	Clinical cure - no recurrence reported to-date
Chandramohan et al. (2025)	50/F	Recurrent pulmonic valve PVE	<i>C.glabrata</i>	• Ep 1 (fBS): MCF x 14d • Ep 2 (PVE): MCF bwks f/b po VOR supp (non-op) • Ep 3 (PVE): MCF x 21d + surgery → RZF	400/200 / 24 weeks	Long-term OPAT (consolidation)	Clinical cure ; No recurrence at 6 months after stopping No ADE
Reinhold et al. (2025)	77/M	Abdominal aortic graft infection	<i>C.collicans</i> C.krusei	• AND x 45 days • → RZF	NR / 10 weeks	Long-term OPAT (consolidation) Azole resistance	Clinical cure ; complete response at day 180 Mild cutaneous photosensitivity

Trapani F et al., case series [abstract]. In: ECMMID, April 15-18, 2023, #O1225.
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Reinhold et al. (2025)	77/M	Abdominal aortic graft infection	<i>C.albicans</i> C.krusei	- AND x 45 days → RZF	NR / 10 weeks	Long-term OPAT (consolidation) Azole resistance	Clinical cure ; complete response at day 180 Mild cutaneous photosensitivity

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Reinhold et al. (2025)	77/M	Abdominal aortic graft infection	<i>C.albicans</i> C.krusei	- AND x 45 days → RZF	NR / 10 weeks	Long-term OPAT (consolidation) Azole resistance	Clinical cure ; complete response at day 180 Mild cutaneous photosensitivity

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Other: Extended Treatment Durations

Study	Age/Sex/ Co/M	Indication	Pathogens	Antifungal Course	Rezafungin Dose/DOT	Rationale for RZF	Outcome
Pechacek et al. (2022)	60/F Liver Transplant	Refractory IA candidiasis w abscess	<i>C.krusei</i>	- Micalfungen – worsened, source control failure - RZF <i>q/d</i>, peritoneal PK	400/200mg / 12 weeks	Salvage Intraperitoneal PK	Complete resolution (improved by week 7) No ADE
Stack et al. (2025)	57/M	LVAD driveline infection	<i>C.auris</i>	- MCF /AmB >POS - Indefinite MCF 100mg daily → RZF	400/200mg / 16 weeks	Long-term OPAT Patient requested to avoid daily IV / PICC Azole DDI (warfarin, sildenafil)	Breakthrough fungemia after 4 months No ADE
Keck et al (2025)	NR	Refractory mucosal and VVC	<i>C.albicans</i>	- Ep 1: POS/cbortl troche - Ep 1: POS/NY S85 f/b AND x 14 days - Ep 3: POS → teraconazole, progression → RZF	400/200mg / 6 weeks	Salvage	Clinical resolution by week 4 no recurrence 3-months No ADE
Löttsch et al. (2025)	71/M Lung Transplant	Post-transplant candidemia 2/2 wound infection, on long-term ravulizumab for CMV- induced TMA/HUS	<i>C.dubliniensis</i>	- CAS x 18 days – cxd achieved - RZF x 4wks - Recurrent SSTI, RZF + PO FLC x 5 months, ongoing	400/200mg / 24 weeks	Salvage combo with fluconazole Long-term OPAT	Relapse on monotherapy Clinical cure with combo therapy, no relapse No ADE

Pechacek J et al., J Antimicrob Chemother. 2022 Aug 25;77(9):2571-2573.
Stack M et al. ID Cases. 2025 April 18;40:e02232
Keck J et al., Infect Dis Ther. 2025 Apr;14(4):889–895.
Löttsch F et al., J Mycol Med. 2025 Mar 16;35(2):101545.

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Keck et al (2025)	NR	Refractory mucosal and VVC	<i>C.albicans</i>	- Ep 1: POS/cbortl troche - Ep 1: POS/NY S85 f/b AND x 14 days - Ep 3: POS → teraconazole, progression → RZF	400/200mg / 6 weeks	Salvage	Clinical resolution by week 4 no recurrence 3-months No ADE
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Other: Extended Treatment Durations

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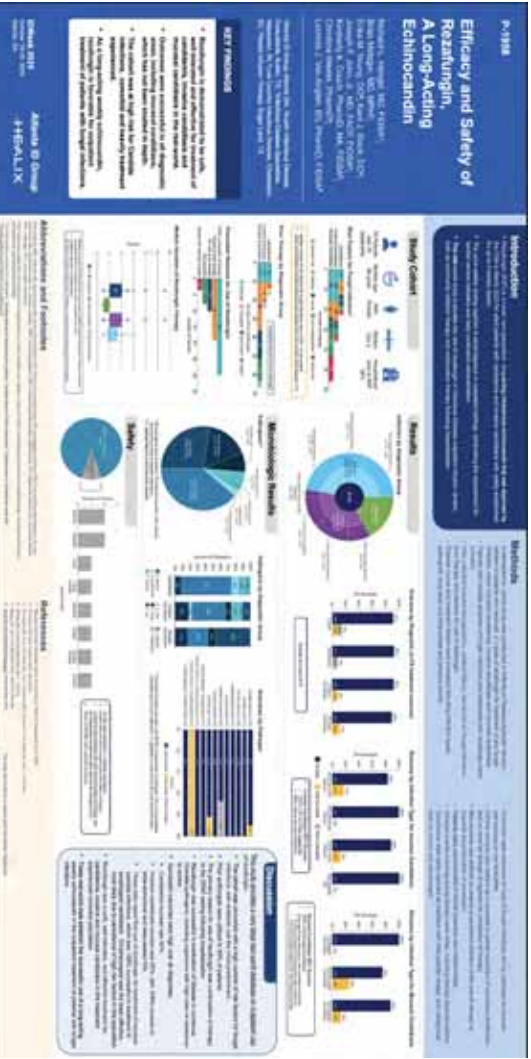
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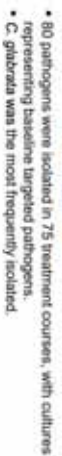
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Outpatient Clinic Use



Infection by Diagnostic Group



Outpatient Clinic Use

P-1958

Efficacy and Safety of Refazungin, A Long-Acting Echinocandin

Richard L. Hengel, MD, FIDSA¹,
Brian Metzger, MD, MPH¹,
Erika M. Young, DO¹, Keril J. Stock, DO¹,
Joseph F. John, Jr., MD, FACP, FIDSA¹,
Kimberly A. Couch, PharmD, MA, FIDSA¹,
Christina Weese, PharmD¹,
Lucinda J. Van Anglen, BS, PharmD, FIDSA¹

Yolanda D. Ornela, Atlanta, GA, (Neuro-Infectious Disease Consultant, Austin, TX; Infectious Disease Specialist, Waco, TX; Case Query Infectious Disease, Charleston, NC; Travel Medicine Therapy, Sugar Land, TX)



- Invasive Candidiasis 92% Success
- 100% in IM and Deep-seated ISI
- 63% in Bone and Joint Infections

• **Mucosal Candidiasis 89% Success**

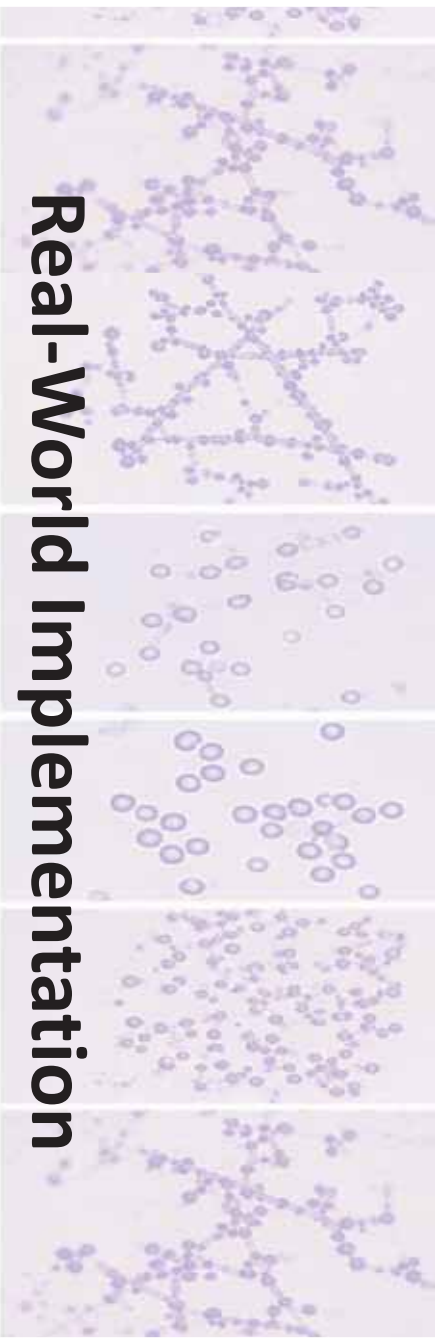
- Microbial Cardiology 89% Success
- 100% in Esophageal Candidiasis
- 3 pts had 5 new infections - all successful outcomes
- 2 VPC due to long-term broad-spectrum ABX for HCV (UTI)

My Conclusions

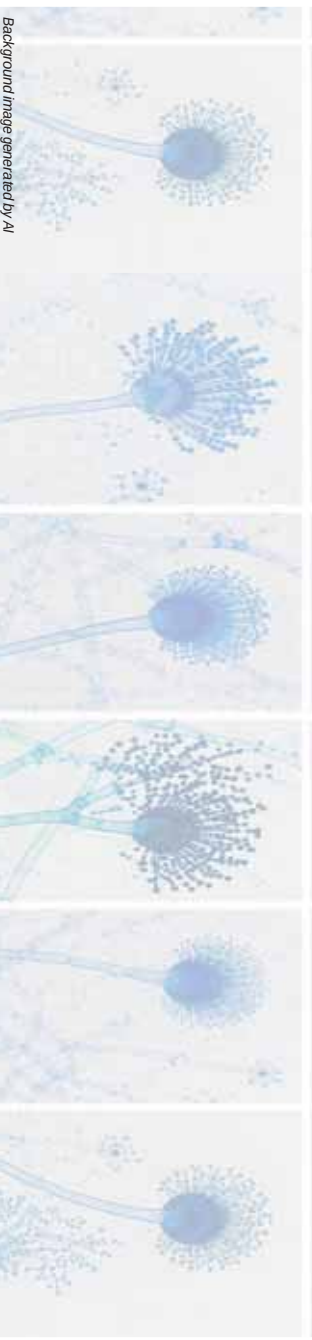
- Rezafungin is safe, effective and advantageous in the right patient
- Course completion or outpatient option for eligible patients to shorten LOS, avoid PICC, minimize clinic visits, caregiver burden, improve QOL

Is there data
for other
indications?

How do we
identify the
right patient?



Real-World Implementation



Background image generated by AI

ICan Discharge Model

European Journal of Clinical Microbiology & Infectious Diseases (2022) 41:1207–1213
<https://doi.org/10.1007/s10096-022-04473-w>

ORIGINAL ARTICLE

Development of the invasive candidiasis discharge [I Can discharge] model: a mixed methods analysis

Jinhwe Jo¹ · Truc T. Tran² · Nicholas D. Beyda¹ · Debora Simmons³ · Joshua A. Hendrickson³ ·
Masaad Saeed Almutairi^{1,4} · Faris S. Alneazary^{1,5} · Anne J. Gonzales-Luna¹ · Edward J. Septimus^{6,7} · Kevin W. Garey¹ 

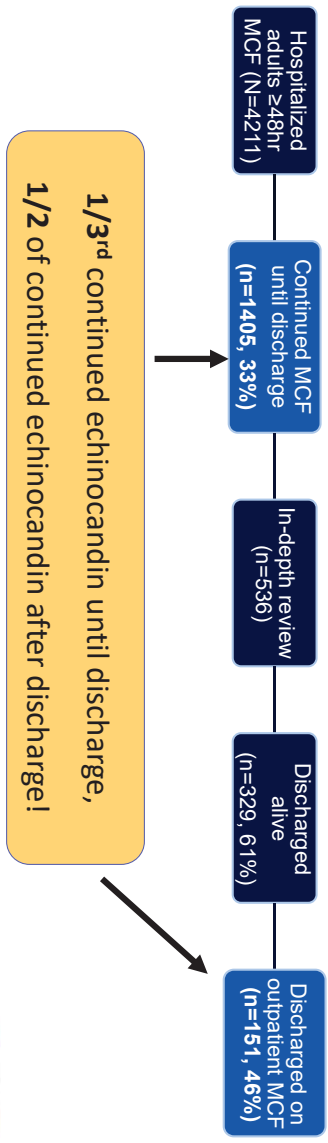
Received: 14 November 2021 / Accepted: 18 July 2022 / Published online: 25 August 2022
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Jo J et al., Eur J Clin Microbiol Infect Dis. 2022;41(10):1207-1213.

ICan Discharge Model

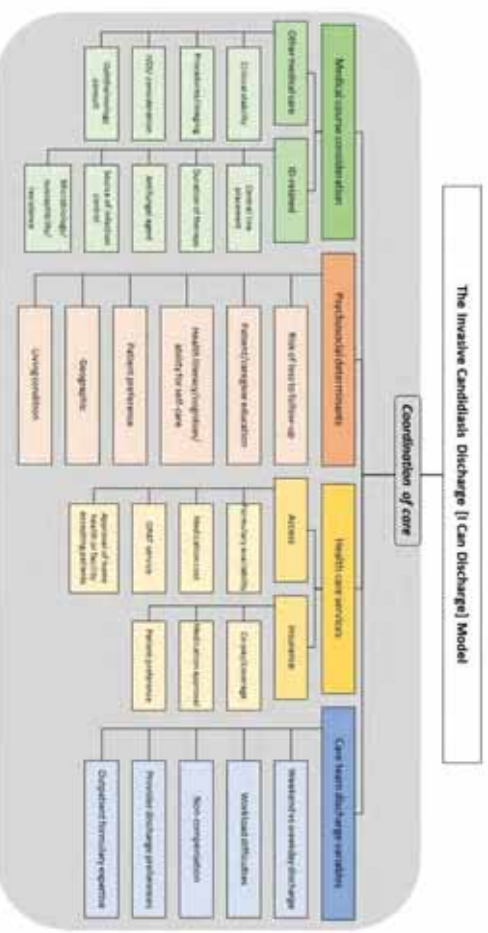
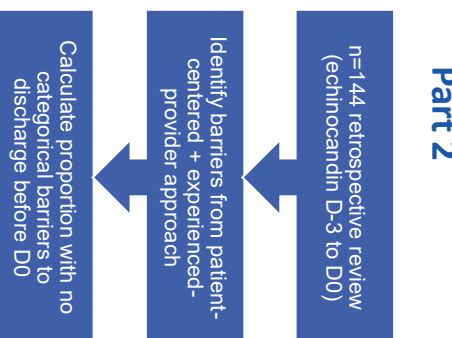
I Can Discharge Model – TOC model for discharge of patients with IC
Multicenter, retrospective study (22 US hospitals, 2017-2019)



Jo J et al., Eur J Clin Microbiol Infect Dis. 2022;41(10):1207-1213.

I Can Discharge Model

Part 2

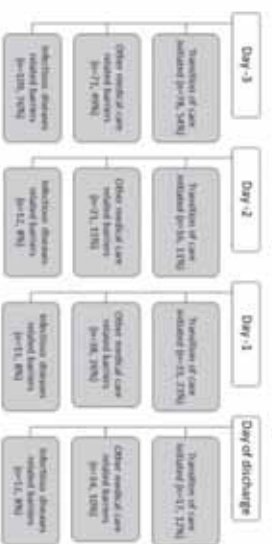


Jo J et al., Eur J Clin Microbiol Infect Dis. 2022;41(10):1207-1213.

I can Discharge Model

Real-World Implementation

A. Presence of Discharge Barriers (From Day -3 to Discharge)



B. Potential Day of Discharge If TOC Completed Earlier



Using IC Model - average excess LOS due to echinocandin-related TOC barriers was **1.7 ± 1.2 days**.

Model can be used to optimize institution-specific barriers to discharge

Identifying Eligible Candidates Early

Lodise et al., (N=1865)

Retrospective, multicenter observational study; PINC AI Healthcare Database (Jan 2016 – Apr 2019)

Hospitalized adults with C/I/C, received **≥3 days echinocandin**

Eligible for discharge if:



Lodise T et al. Open Forum Infect Dis. 2024;11(1):ofad703.

Identifying Eligible Candidates Early

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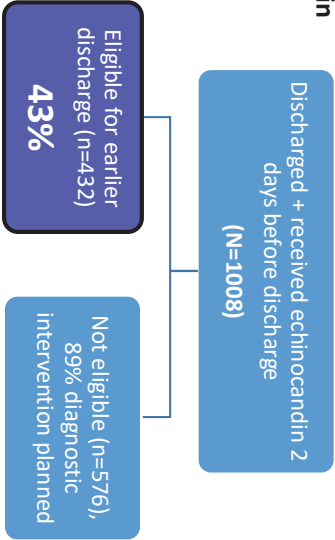
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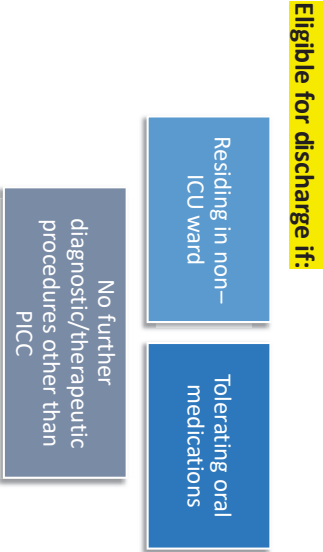
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Real-World Implementation

Rezafungin Identification & Discharge Initiative

Huntsville Hospital (AL, USA)
881-bed flagship facility
Reference and credit for this work:
Jonathan D. Edwards, PharmD., BCPS, BCGP, BCIDP
Advanced Antimicrobial Stewardship Pharmacist
PGY-2 Infectious Diseases Residency Program Director
Huntsville Hospital Department of Pharmacy



Real-World Implementation

Rezafungin Identification & Discharge Workflow



Work informed by:

Jonathan D. Edwards, PharmD, BCPs, BCGP, BCIDP
Advanced Antimicrobial Stewardship Pharmacist
PGY-2 Infectious Diseases Residency Program Director
Huntsville Hospital Department of Pharmacy



Real-World Implementation

Summary – Place in Therapy

Discharge eligible patients with uncomplicated candidemia and/or IC

- Broad screening tool: not in ICU + tolerating PO meds + ≥3 doses formulary echinocandin
- ICan Discharge Model to refine local barriers

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- Long-term antifungal OPAT - avoid PICC/daily IV, ↓ patient/caregiver burden
- Resistance, toxicity, DDI, malabsorption, failure with alternatives

Summary – Place in Therapy

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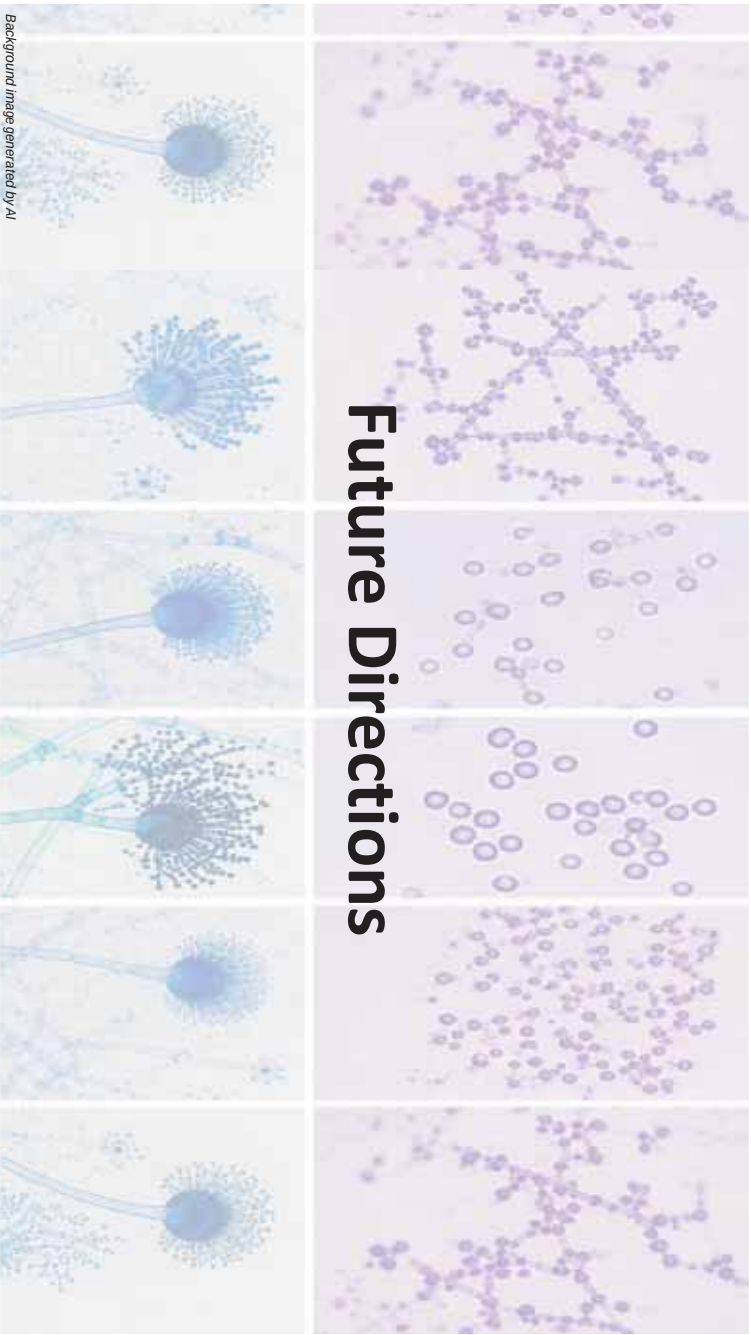
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Compelling indications (continuation)

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Outpatient clinic administration (upfront or continuation)

- **Stewardship mindset:** reserve for failure with or contraindication to alternative options (pharmacologic or patient-centered)



Future Directions

Future Directions

Prophylaxis - HSCT

Study of Rezafungin Compared to Standard Antimicrobial Regimen for Prevention of Invasive Fungal Diseases in Adults Undergoing Allogeneic Blood and Marrow Transplantation (ResPECT)

ClinicalTrials.gov ID  NCT04368559

Phase 3 RCT, rezafungin vs. SOC for IFI prophylaxis in allogeneic HSCT
Candida, *Aspergillus*, *Pneumocystis*

Frontline data released:

- Primary endpoint: 90-day fungal-free survival, RZF 60.7% vs. 59.0% SOC
- Met non-inferiority criteria for EMA and FDA
- Comparable mortality
- Reduced TEAEs

More commentary to come June 2026

<https://cormedix.com/cormedix-therapeutics-announces-positive-topline-results-from-phase-iii-respect-trial-assessing-rezayo-for-the-prophylaxis-of-invasive-fungal-diseases-in-allogeneic-hematopoietic-stem-cell-tran/>



Prophylaxis - SOT

Rezafungin Prophylaxis in Liver Transplant

ClinicalTrials.gov ID  NCT06774144

Sponsor  Fernanda P Silveira, MD, MS

Information provided by  Fernanda P Silveira, MD, MS, University of Pittsburgh (Responsible Party)

<https://cormedix.com/cormedix-therapeutics-announces-positive-topline-results-from-phase-iii-respect-trial-assessing-rezayo-for-the-prophylaxis-of-invasive-fungal-diseases-in-allogeneic-hematopoietic-stem-cell-tran/>



Treatment

Chronic Aspergillosis

Active, not recruiting 

Rezafungin for Treatment of Chronic Pulmonary Aspergillosis (CPA) in Adults With Limited Treatment Options

ClinicalTrials.gov ID  NCT06794554

HIV - PJP Treatment

Recruiting 

Rezafungin for Treatment of Pneumocystis Pneumonia in HIV Adults

ClinicalTrials.gov ID  NCT05835479

Sponsor  Mundipharma Research Limited

Information provided by  Mundipharma Research Limited (Responsible Party)

Shorter Candidemia DOT

A Study Comparing Short-course Antifungal Therapy (SCAT) 7 Day vs Standard 14 Day Antifungal Therapy for Uncomplicated Candidemia (SCAT)

ClinicalTrials.gov ID  NCT0607992

Sponsor  Augusta University

Information provided by  Jose Vazquez, Augusta University (Responsible Party)

Last Update Posted  2025-04-04





Thank you!

Questions?

caroline.rosario@rsfh.com



Background image generated by AI