Once-weekly

REZZAYO™

(rezafungin for injection)

Simplify invasive candidiasis management and move your patient's treatment journey *forward*

REZZAYO™ (rezafungin for injection) is a next-generation echinocandin with a *once-weekly* dosing schedule[1]

For adult patients with candidemia or invasive candidiasis*,[1]

***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 Important Safety Information on Slide 2 and accompanying Prescribing Information for REZZAYO™ (rezafungin for injection).

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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.
- 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.

Adverse Reactions

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

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

High patient mortality, even with current treatments

Candidemia	Invasive candidiasis
10% to 47% attributable mortality rate[2]	**31.4%** mortality rate[3]

Despite availability of new antifungals and progress in diagnostics, mortality is still high.[2]

Candida species prevalence is evolving[4,5]

6% of hospital-associated infections in the United States are attributed to *Candida*[7]

50%

Non-albicans *Candida* species constitute ~50% of all relevant isolates, with rising cases of invasive candidiasis due to *C. glabrata* and *C. parapsilosis*[5,6]

IDSA guidelines recommend echinocandins as first-line therapy for invasive candidiasis[6]

Echinocandins are established antifungal agents recommended by the Infectious Disease Society of America (IDSA) as the initial treatment choice for many different types of patients diagnosed with candidemia or invasive candidiasis.[6]

This preference by IDSA is based on[6]:

- A trend toward better outcomes
- A strong safety profile
- Early fungicidal activity
- The emergence of azole-resistant *Candida* species
- No significant drug-drug interactions
- Convenience

Evaluating the transition from an echinocandin[6]

Key considerations before stepping down[6]:

1. Is the patient **clinically stable**?
2. Do they have **isolates that are susceptible** to fluconazole?
3. Does the patient have **negative repeat blood cultures** following initiation of antifungal therapy?

IDSA guidelines also note that all azole antifungals inhibit cytochrome P450 enzymes to some degree. Thus, clinicians must carefully consider the influence on a patient's drug regimen when adding or removing an azole.[6]

REZZAYO™ (rezafungin for injection) is a next-generation echinocandin treatment[1,8]

1st The 1st new echinocandin in more than 15 years[1,9]

INDICATION

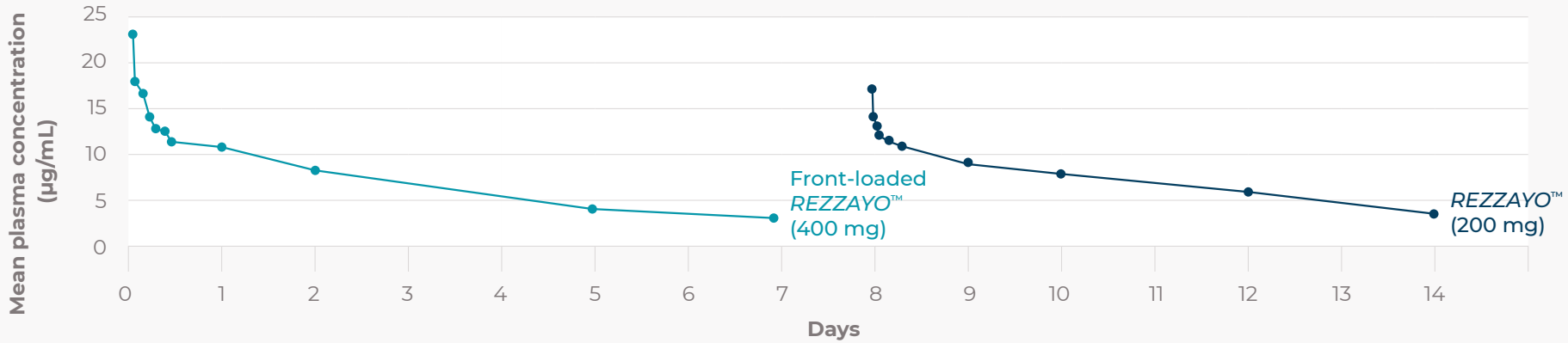
REZZAYO™ is an echinocandin antifungal indicated for the treatment of candidemia and invasive candidiasis in patients 18 years of age or older with limited or no alternative treatment options. Approval of this indication is based on limited clinical safety and efficacy data for *REZZAYO*™.

Familiar echinocandin mechanism of action with a long half-life that allows for *once-weekly* dosing.[1,8]

Hit invasive candidiasis hard and early with high plasma drug concentrations[1]

The first dose of *REZZAYO*™ is 2x greater than subsequent doses—or front-loaded—to yield high plasma drug concentrations early in therapy and give lasting fungicidal coverage.[1,10]

Front-loaded 400 mg *REZZAYO*™ dose and subsequent 200 mg *REZZAYO*™ weekly dose in healthy subjects[11]



Please see Important Safety Information on Slide 2 and accompanying Prescribing Information for REZZAYO™ (rezafungin for injection).

The *once-weekly* dosing schedule of *REZZAYO*™ may help simplify treatment logistics[1,2]:

Allows patients to **avoid an invasive peripherally inserted central catheter** (PICC) but still benefit from echinocandin treatment

Offers patients who cannot take oral medications a *once-weekly* option[6]

Could save time and staff resources associated with daily infusions related to the management of invasive candidiasis

Has the potential to **reduce the number of healthcare touchpoints** for patients needing echinocandin treatment

May help facilitate continuity of echinocandin treatment and reduce unnecessary switching or discontinuation of life-saving medication as the patient moves to lower-intensity care or outpatient treatment

Adherence is of the utmost importance for life-saving medications. The ***once-weekly* HCP-administered dose** of *REZZAYO*™ may provide greater transparency into patient adherence

Treating with *REZZAYO*™ may promote continuity of echinocandin care across treatment settings

Invasive candidiasis management, simplified with *once-weekly REZZAYO*™ (rezafungin for injection)

Patients with invasive candidiasis or candidemia tend to be critically ill and may be on other therapies, such as broad-spectrum antibiotics, corticosteroids, immunosuppressants, or anticancer medications. The choice of antifungal can further complicate these factors.[1,2,12,13]

When you start *REZZAYO*™[1]

No clinically relevant drug-drug interactions

Two clinical studies demonstrated no clinically relevant drug-drug interactions between *REZZAYO*™ and drugs likely to be administered concomitantly, including[1]:

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 hemodialysis.[1]

Invasive candidiasis management, simplified (continued)

No requirement for a PICC or central line

Treatment with other echinocandins requires daily intravenous infusions, often for several weeks before an infection is resolved—a schedule that often necessitates a peripherally inserted central catheter (PICC) or central line.[1,6]

REZZAYO™ treatment does not require a central line—which is a potential source of infection—at clinician discretion and as recommended by IDSA guidelines, with no interruption in treatment or need to switch therapy.[1,6]

No impact on QTc interval

Even at 3.5x the loading dose (1400 mg), *REZZAYO*™ did not prolong or shorten the QTc interval.[1]

Can be used for patients with renal impairment

No clinically relevant effects on the pharmacokinetics were observed in patients with renal impairment (creatinine clearance: 9.3 mL/min to above 120 ml/min).[1]

Administer in a variety of care settings

With a once-weekly hour-long infusion, *REZZAYO*™ can be administered in all care settings without the need for daily specialty infusion processes or equipment.[1]

ReSTORE: pivotal phase 3 study of *REZZAYO*™ (rezafungin for injection)[1,8]

ReSTORE was a prospective, double-blind, randomized, noninferiority phase 3 study of once-weekly intravenous *REZZAYO*™ vs daily caspofungin for the treatment of candidemia and invasive candidiasis in patients 18 and older.[1,8]

Study design[1,8]

mITT N=187

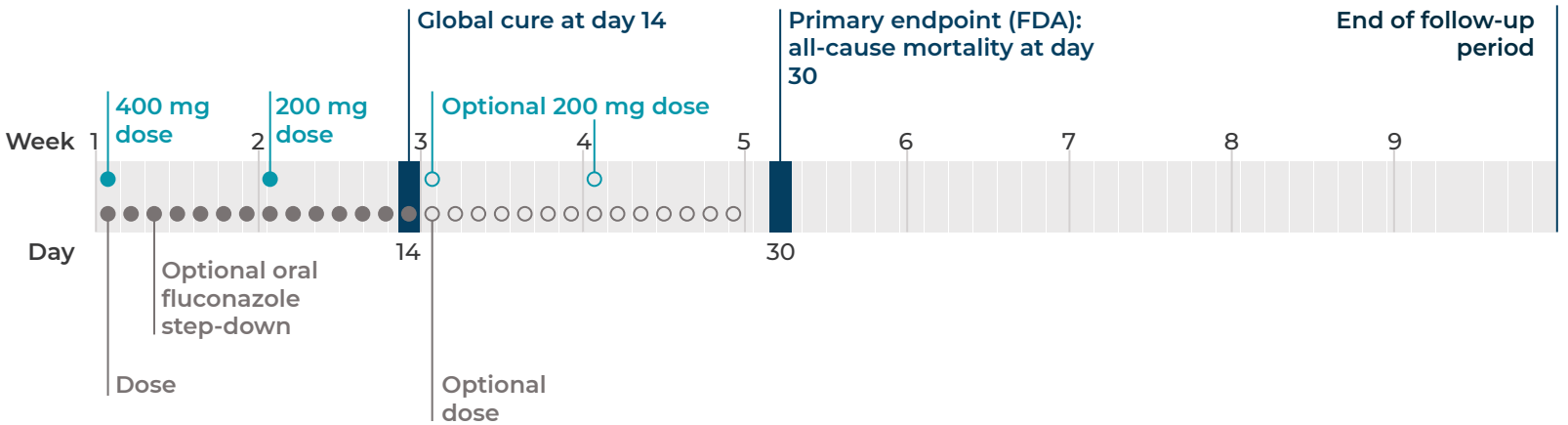
REZZAYO™
n=93

400 mg dose week 1

200 mg dose per week thereafter

Caspofungin
n=94

70/50 mg daily



Number of patients shown in each arm is the modified intent-to-treat population, not the assigned and randomized numbers.

Patients in the *REZZAYO*™ group received IV placebo on other study days to maintain masking.[8]

In the caspofungin group, optional oral fluconazole step-down therapy was permitted after ≥3 days of IV therapy if the patient met the criteria for cure and was preparing for discharge. Patients in the *REZZAYO*™ group who were switched to step-down therapy continued to receive intravenous *REZZAYO*™ once a week and daily oral placebo to maintain the masking.[1,8]

FDA=Food and Drug Administration; mITT=modified intent-to-treat.

ReSTORE: endpoints and patient characteristics

Two primary efficacy endpoints[1,8]:

1. 30-day all-cause mortality (FDA)
2. Global cure* at day 14

	REZZAYO™ n=100	Caspofungin n=99
Mean age	59.5	62.0
Candidemia only	70 (70%)	68 (69%)
Invasive candidiasis†	30 (30%)	31 (31%)

†Includes patients who progressed from candidemia to invasive candidiasis based on radiological or tissue or fluid culture assessment up to day 14.[8]

Isolated *Candida* species were similar across treatment groups[8]

Distribution was consistent with reported US rates, with *C. albicans* the most frequently isolated species followed by *C. glabrata*.[5,8,15]

***Candida* species isolated at baseline from blood and sterile site cultures**	*REZZAYO*™ n=93,‡ (%)	Caspofungin n=94,‡ (%)
C. albicans	39 (42)	40 (43)
C. glabrata	24 (26)	25 (27)
C. parapsilosis	20 (22)	17 (18)§
C. tropicalis	8 (9)	17 (18)§

‡Modified intent-to-treat population.

§One isolate was confirmed only by the local laboratory.[8]

*Global cure defined as[8]:

For patients with invasive candidiasis documented by radiological or imaging evidence at baseline: clinical cure as assessed by the investigator, radiological cure, and mycological eradication, as confirmed for all three by an independent blinded data review committee.

For patients with positive blood culture at screening: mycological eradication was determined by a negative blood culture after the first dose of study drug with no subsequent positive culture.

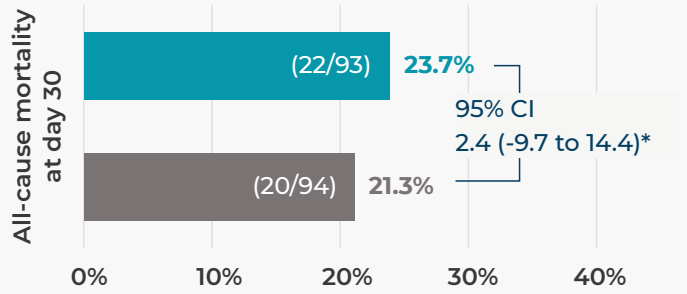
For patients with positive culture from normally sterile site other than blood: mycological eradication was either documented (as determined by a negative culture on the day of assessment [eg, day 5 or day 14]) or presumed (as determined by clinical and radiological cure [for those with evidence of disease on imaging at baseline] if a specimen from the infected site was not available).

Proven echinocandin efficacy now in a *once-weekly* formulation[1,8]

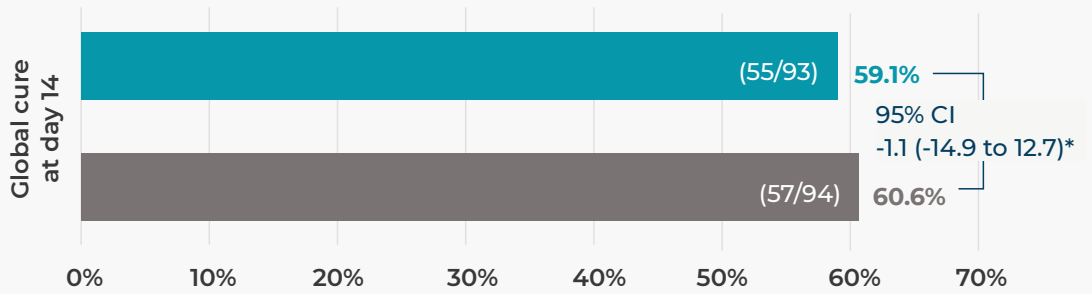
In the phase 3 ReSTORE clinical trial, once-weekly IV infusion of *REZZAYO*™ (rezafungin for injection) was noninferior to daily IV infusions of caspofungin in the mITT population.[1,8]

» **Non-inferiority was to be concluded if the upper bound of the 95% CI was lower than 20%[8]**

REZZAYO™ is noninferior to caspofungin for the primary endpoint of all-cause mortality at day 30[1,8]



Comparable rates of global cure with 2 once-weekly doses of _REZZAYO_™ vs 14 daily doses of caspofungin[1,8]



- *REZZAYO*™ 400 mg/200 mg weekly (n=93)
- Caspofungin 70 mg/50 mg daily (n=94)

- *REZZAYO*™ 400 mg/200 mg weekly (n=93)
- Caspofungin 70 mg/50 mg daily (n=94)

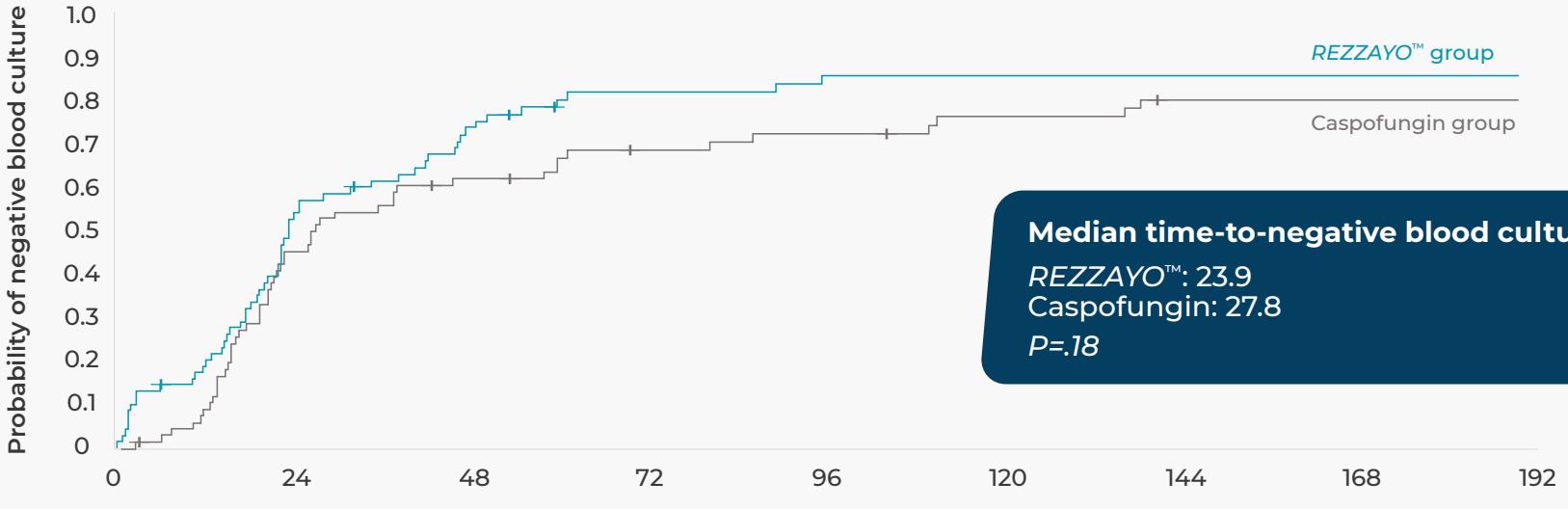
CI=confidence interval; mITT=modified intent-to-treat.

*Two-sided 95% CI for the observed difference (%), *REZZAYO*™ group minus caspofungin group.

Please see Important Safety Information on Slide 2 and accompanying Prescribing Information for REZZAYO™ (rezafungin for injection).

ReSTORE: rapid time to negative blood culture similar to caspofungin

Time to negative blood culture with *REZZAYO*™ or caspofungin*[1,8]



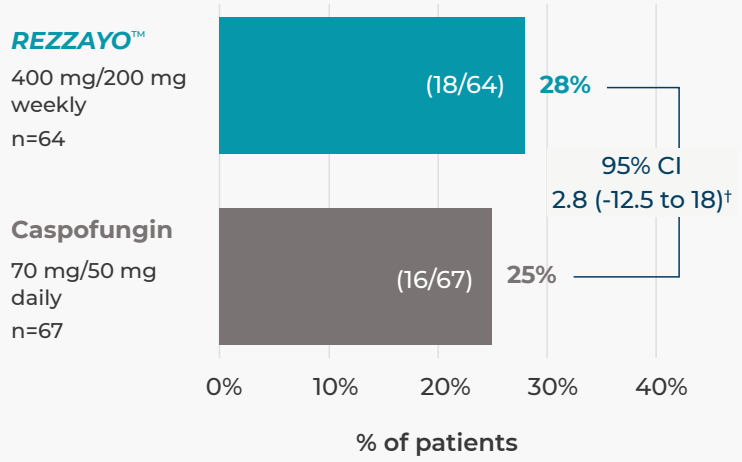
Number at risk (number censored)									
REZZAYO™ group	69(0)	31(2)	17(1)	9(2)	8(0)	7(0)	7(0)	7(0)	7(0)
Caspofungin group	69(0)	35(4)	23(1)	16(3)	14(0)	11(1)	8(1)	8(0)	8(0)

*Time to first negative blood culture (for patients enrolled with a positive blood culture) was a prespecified exploratory outcome of the ReSTORE phase 3 clinical trial and was measured (in hours) from the first dose of study drug to the first negative blood culture without subsequent positive culture.[8]

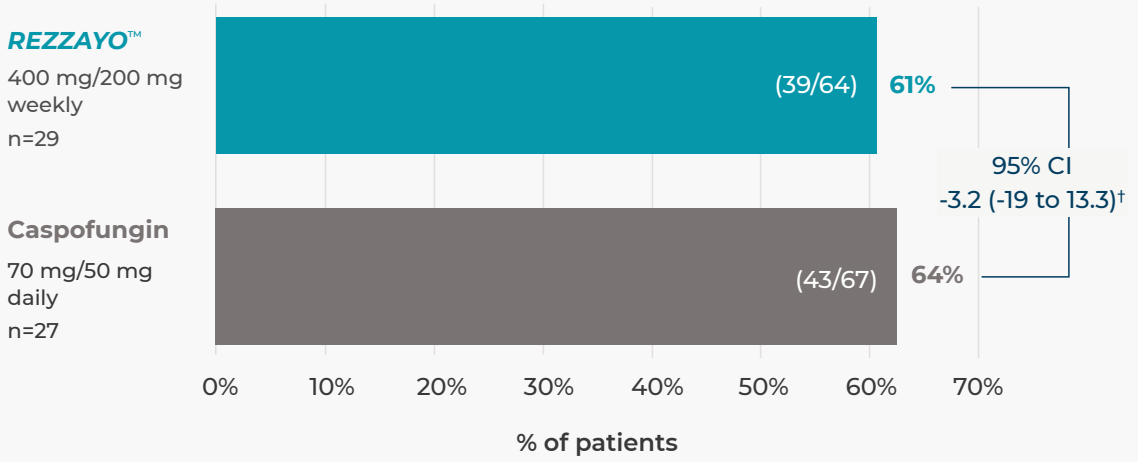
Please see Important Safety Information on Slide 2 and accompanying Prescribing Information for REZZAYO™ (rezafungin for injection).

Primary endpoint outcomes in the candidemia-only subgroup*,[8]

All-cause mortality at day 30 (FDA)[8]



Global cure at day 14[8]



CI=confidence interval.

*Subgroup analysis was not powered to assess noninferiority.[8]

†Two-sided 95% CI for the observed difference (%), *REZZAYO*™ group minus caspofungin group.[8]

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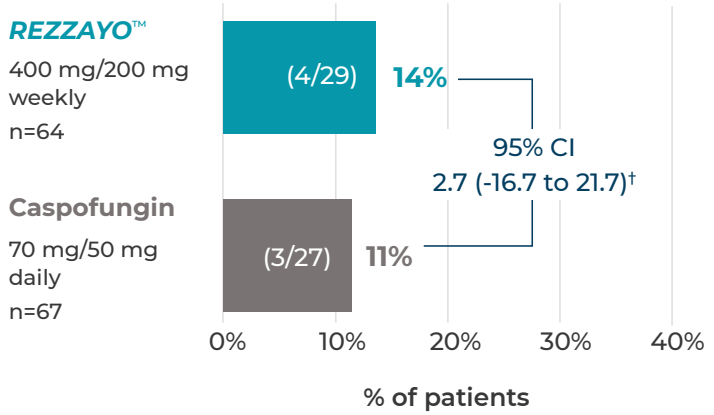
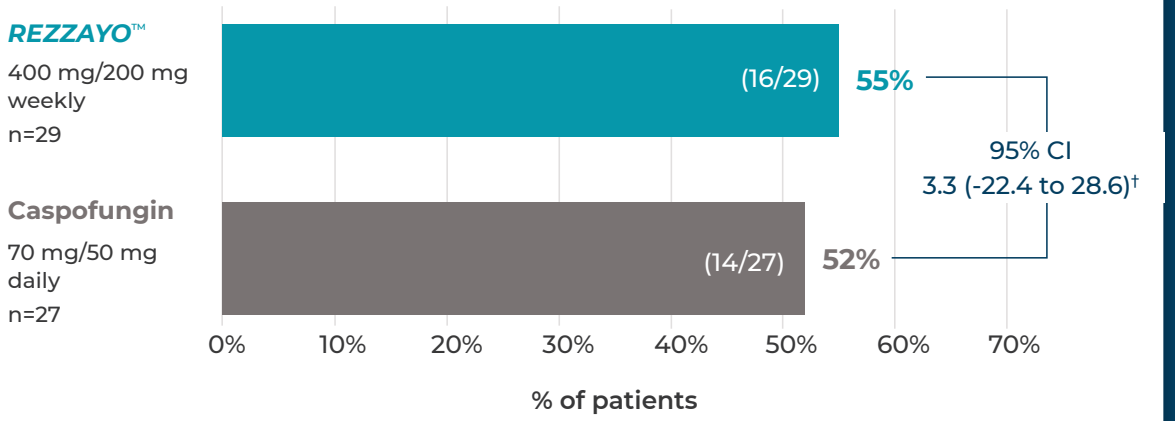
Primary endpoint outcomes in the invasive candidiasis subgroup*,[8]

All-cause mortality at day 30 (FDA)[8]



Global cure at day 14[8]



» **The invasive candidiasis group did not include patients with septic arthritis in a prosthetic joint, osteomyelitis, endocarditis, or myocarditis, meningitis, chorioretinitis, any central nervous system infection, chronic disseminated candidiasis, or urinary tract candidiasis[8]**

CI=confidence interval.

*Subgroup analysis was not powered to assess noninferiority.[8]

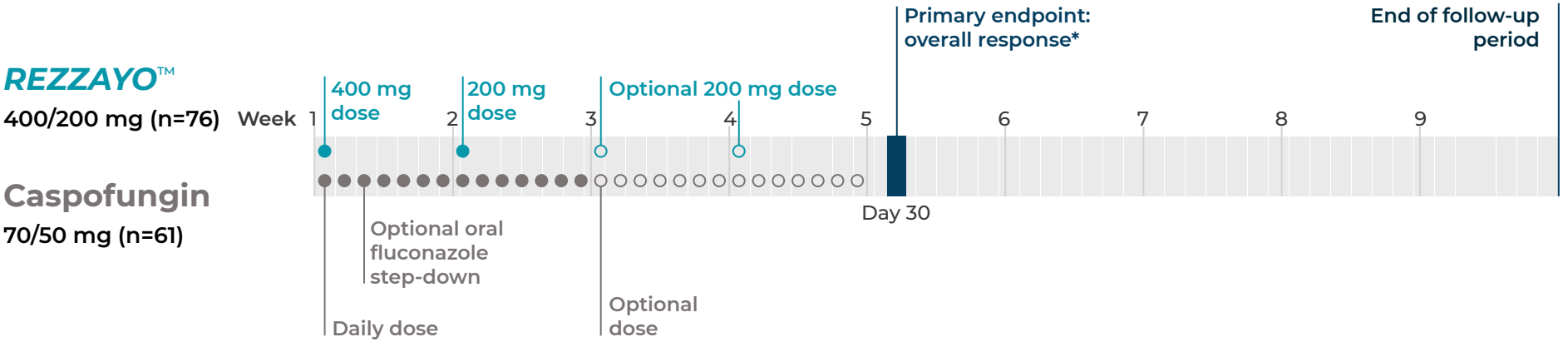
†Two-sided 95% CI for the observed difference (%), *REZZAYO*™ group minus caspofungin group.[8]

STRIVE: a phase 2 study of *REZZAYO*™ (rezafungin for injection)[1,10]

STRIVE was a phase 2 prospective, double-blind, randomized, dose-finding study of once-weekly intravenous *REZZAYO*™ vs daily caspofungin for the treatment of candidemia and invasive candidiasis in patients age 18 and older. The trial was not powered to assess efficacy.[1,10]

Study design[1,10]

mITT N=183



In the caspofungin group, optional oral fluconazole step-down therapy was permitted after ≥3 days of IV therapy if the patient met the criteria for cure and was preparing for discharge. Patients in the *REZZAYO*™ group who were switched to step-down therapy continued to receive intravenous *REZZAYO*™ once a week and daily oral placebo to maintain the blind.[10]

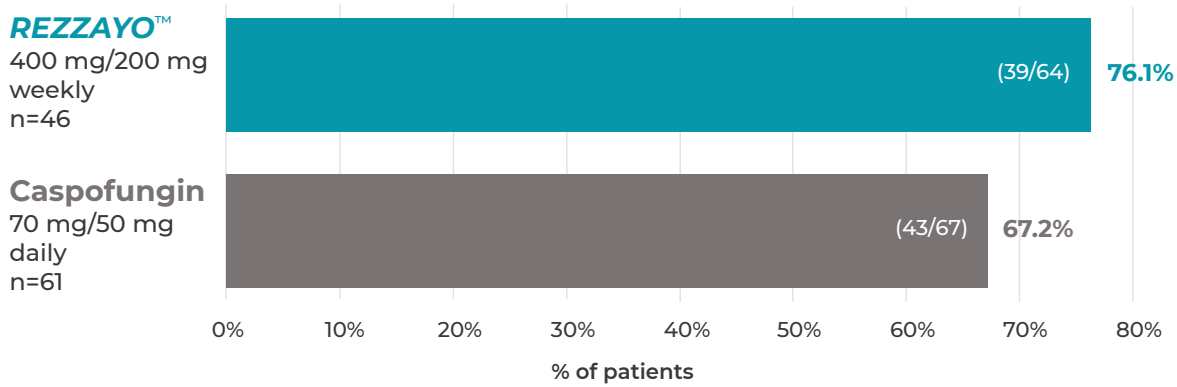
mITT=modified intent-to-treat.

*Overall response defined as overall cure (resolution of clinical signs of candidemia/invasive candidiasis) plus mycological eradication/presumed eradication.[10]

STRIVE: supportive evidence*,[10]

Primary and secondary outcomes

Overall response at day 14 with *REZZAYO*™ (rezafungin for injection) vs caspofungin*,[10]



Similar results in secondary efficacy outcomes between *REZZAYO*™ and caspofungin groups*,[10]

	REZZAYO™ 400 mg/200 mg n=46 n, (%)	Caspofungin 70 mg/50 mg n=61 n, (%)
Overall response, day 5†	34(73.9)	34 (55.7)
Clinical cure, day 14‡	37 (80.4)	43 (70.5)
Mycological success§	35 (76.1)	38 (62.4)

IC=invasive candidiasis.

*The trial was not powered for inferential analysis.

†Patients with mycological success (eradication/presumed eradication) and resolution of attributable systemic signs of candidemia/IC.

‡Investigator's assessment of clinical response based on resolution of attributable systemic signs and symptoms of candidemia/IC, no new systemic signs or symptoms attributable to candidemia/IC, no new systemic antifungal therapy to treat candidemia/IC, and the subject is alive.

§Negative blood culture or culture from a normally sterile site and no change in antifungal therapy for the treatment of candidemia and/or IC. For IC patients, if the normally sterile baseline site of *Candida* infection is not accessible, the patient is presumed to have an eradication if the clinical outcome is a cure.

Fungicidal activity against the most common *Candida* species

ReSTORE: day 14 global cure and mycological eradication by *Candida* species in the mITT population[8,15]

		REZZAYO™ (n=93)		Caspofungin (n=94)	
***Candida* species**		**n/N**	**%**	**n/N**	**%**
C. albicans	Global cure	21/39	53.8%	23/40	57.5%
	Mycological eradication	23/39	59.0%	24/40	60.0%
C. glabrata	Global cure	16/24	66.7%	14/25	56.0%
	Mycological eradication	20/24	83.3%	15/25	60.0%
C. tropicalis	Global cure	14/20	70.0%	10/17	58.8%
	Mycological eradication	15/20	75.0%	10/17	58.8%
C. parapsilosis	Global cure	6/8	75.0%	11 /17	64.7%
	Mycological eradication	6/8	75.0%	14/17	82.4%

CLSI=Clinical and Laboratory Standards Institute; mITT=modified intent-to-treat.

***REZZAYO*™ (rezafungin for injection) shows in vitro antimicrobial activity** against most isolates of species that account for **up to 95%** of invasive *Candida* infections in the United States*[1,4,16]:

- *C. albicans*
- *C. glabrata*
- *C. parapsilosis*
- *C. tropicalis*
- *C. krusei*

REZZAYO™ is the only antifungal with a provisional CLSI susceptibility breakpoint for *C. auris**[17,18]

In vitro data demonstrates that rezafungin is active vs the *C. auris* pathogen. Efficacy of rezafungin in treating infections caused by these fungi has not been established in clinical trials.

*In vitro data does not necessarily correlate with clinical efficacy.

Documented echinocandin safety[1]

Similar rate of adverse reactions with *REZZAYO*™ (rezafungin for injection) compared to caspofungin[1]

Adverse reactions reported in 5% or more of adult patients*,[1]

Adverse reaction	*REZZAYO*™ N=151 n (%)	Caspofungin N=166 n (%)
Gastrointestinal disorders		
Diarrhea	17 (11)	17 (10)
Vomiting	14 (9)	7 (4)
Nausea	13 (9)	8 (5)
Abdominal pain	11 (7)	9 (5)
Constipation	8 (5)	8 (5)
Metabolism and nutrition disorders		
Hypokalemia	22 (15)	17 (10)
Hypomagnesemia	12 (8)	5 (3)
Hypophosphatemia	8 (5)	5 (3)
General disorders and administration site conditions		
Pyrexia	18 (12)	11 (7)
Blood and lymphatic system disorders		
Anemia	15 (10)	13 (8)

*Includes patients from STRIVE and ReSTORE; only those patients who received 400 mg/200 mg of *REZZAYO*™.[1]

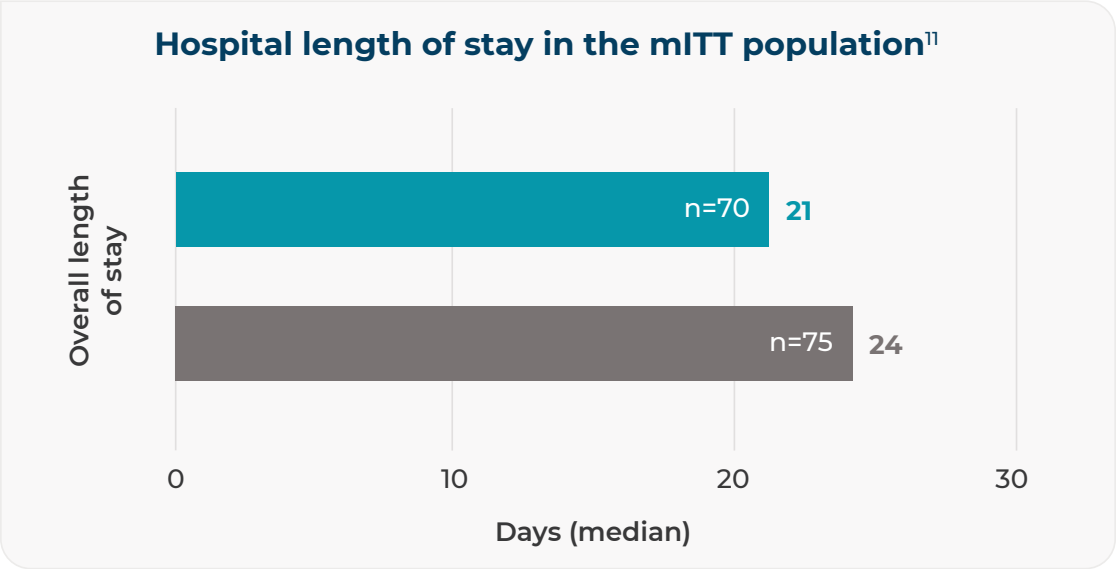
Advise patients about the potential for photosensitivity with *REZZAYO*™[1]

Clinically significant infusion reactions with *REZZAYO*™ may occur[1]

Monitor patients who develop abnormal liver tests and evaluate patients for their risk benefit of continuing *REZZAYO*™ therapy[1]

Hospital length of stay with *REZZAYO*™ (rezafungin for injection)

In a pre-specified exploratory analysis of the phase 3 ReSTORE trial, length of stay with *REZZAYO*™ was 21 days vs 24 days with caspofungin.*[11]



With *once-weekly REZZAYO*™, patients don't need to remain hospitalized to complete their echinocandin therapy

mITT=modified intent-to-treat.

*Analysis was not powered to assess significance of difference.

Simplify their treatment

Enable continuity of echinocandin treatment in all settings

Daily intravenous administration of currently approved echinocandins for invasive candidiasis may delay discharge or limit the continuity of echinocandin therapy through discharge.[2]

Weekly dosing of *REZZAYO*™ (rezafungin for injection) gives patients with invasive candidiasis 7 days of systemic antifungal coverage, which may allow appropriate patients to be discharged from the hospital to complete therapy in the outpatient setting.[1]

Limitations of Use

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

A once-weekly IV infusion of *REZZAYO*™ could[1]:

Allow for earlier discharge of patients on echinocandins who are otherwise dischargeable[11]

Decrease the need for dose modification of concomitant medications due to drug-drug interactions[1]

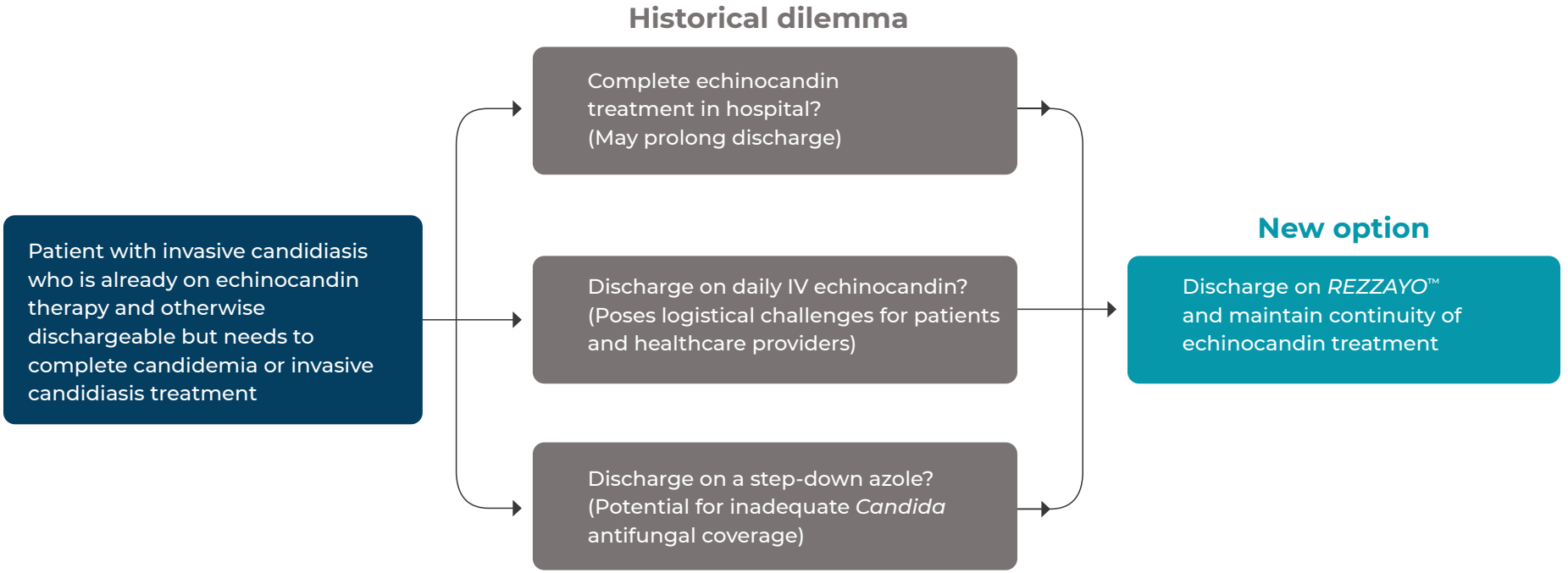
Help minimize the potential for inadequate *Candida* antifungal coverage for patients with azole-resistant isolates or isolates of unknown susceptibility[6]

When patients are ready, you can set them on the path to echinocandin continuity of care with *REZZAYO*™

Envision a new treatment path with *REZZAYO*™ (rezafungin for injection)

IDSA guidelines recommend that systemic antifungal treatment for invasive candidiasis continue for 14 days after there is no evidence of *Candida* in the bloodstream and symptoms have resolved.[6]

REZZAYO™ offers a new option for continuity of echinocandin treatment in the outpatient setting



Please see Important Safety Information on Slide 2 and accompanying Prescribing Information for REZZAYO™ (rezafungin for injection).

Potential benefits of treatment with *once-weekly REZZAYO*™

May be more convenient and manageable for patients to schedule weekly rather than daily infusions[2,19]

No need for a PICC line and associated maintenance, risk of complications, and discomfort from the device[2,19]

May be logistically easier for outpatient infusion vs daily infusions[2,19]

No known clinically significant drug-drug interactions, and no dose adjustment is needed for any known factors[1]

Allows providers to maintain patients on recommended echinocandin therapy until treatment is complete[2,19]

May provide greater transparency into adherence with 7 days of therapy in every dose[1]

Simplified echinocandin dosing and administration

REZZAYO™ **(rezafungin for injection):**
One IV infusion ***once weekly*** for **1 hour**[1]

Administration[1]

- *REZZAYO*™ is for IV use only
- Supplied as a single-dose vial containing 200 mg of rezafungin. Discard any unused portion
- An infusion may be slowed, or paused and restarted at a lower rate if infusion-related reactions occur
- The safety of *REZZAYO*™ has not been established beyond 4 weekly doses
- Infusions take approximately 60 minutes/1 hour to complete
- *REZZAYO*™ reconstituted solution can be stored between 41°F and 77°F for up to 24 hours

Recommended dose[1]

400 mg

400-mg loading dose

200 mg

200-mg dose
once weekly thereafter

References:

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Invasive candidiasis management, simplified.

- The **first *once-weekly* echinocandin** for treating candidemia and invasive candidiasis in patients 18 years or older with limited or no alternative treatment options[1]
- Familiar echinocandin mechanism of action with a long half-life that allows for ***once-weekly* dosing**[1,8]
- **Proven echinocandin efficacy** demonstrated in the phase 3 ReSTORE trial and further supported by the phase 2 STRIVE trial[8,10]
- **Fungicidal activity** against the most common and emerging *Candida* species[1,4,8,15-18]
- **Documented echinocandin safety profile** similar to caspofungin
- Potential for patients to be transitioned to an outpatient setting **while maintaining continuity** of echinocandin treatment

The 1st new echinocandin in more than 15 years[1,9]

Please see Important Safety Information on Slide 2 and accompanying Prescribing Information for REZZAYO™ (rezafungin for injection).

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Once-weekly REZZAYO™ (rezafungin for injection)