CIDARA THERAPEUTICS

ReSTORE PHASE 3 TRIAL RESULTS FOR REZAFUNGIN

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CIDARA THERAPEUTICS

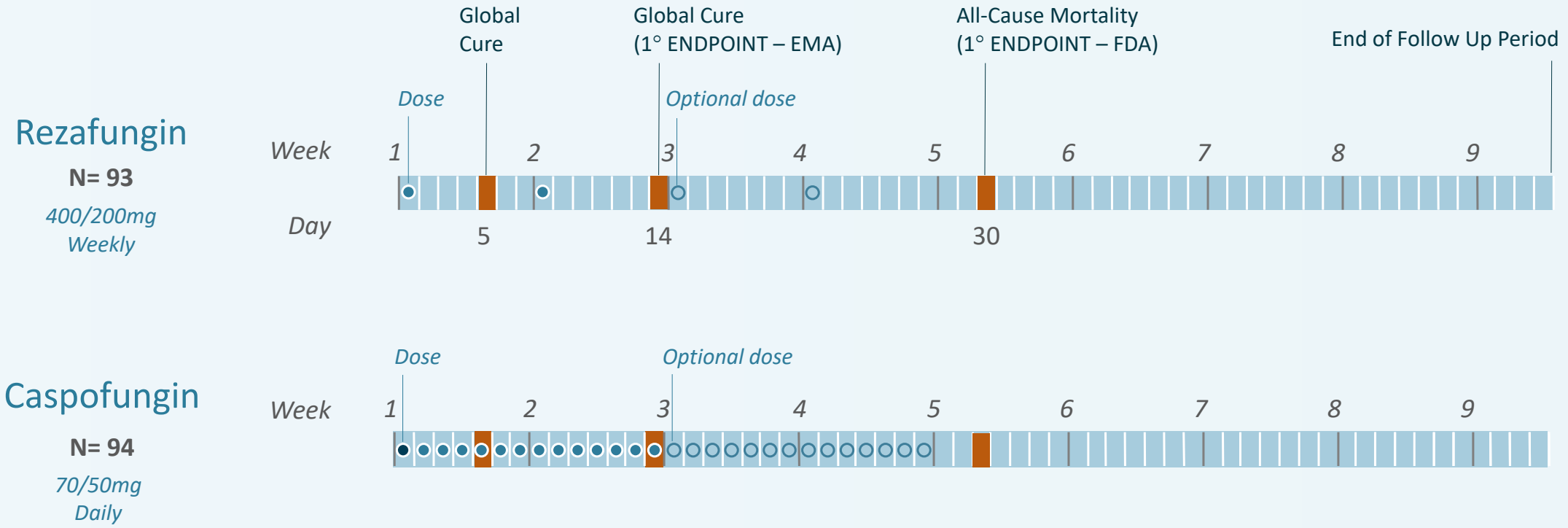
REZAFUNGIN OVERALL PHASE 3 DEVELOPMENT PLAN

	PHASE 3 TREATMENT TRIAL	PHASE 3 PROPHYLAXIS TRIAL
	ReSTORE	ReSPECT
POTENTIAL INDICATION	Treatment of candidemia & invasive candidiasis	Prophylaxis against *Aspergillus*, *Candida* & *Pneumocystis* in allogeneic blood and marrow transplant patients
PHASE 3 SIZE	187 patients[1] (20% NI margin)	462 patients (12.5% NI margin)
OVERALL OBJECTIVE	FDA: Day 30 All-Cause Mortality vs SOC	Day 90 Fungal free survival vs standard of care

1. mITT population.

ReSTORE PHASE 3 TRIAL DESIGN

- A Phase 3, prospective, double-blind, randomized, international, multicenter trial
- Evaluate the efficacy and safety of once-weekly IV rezafungin vs once-daily caspofungin followed by optional oral fluconazole step-down in the treatment of documented candidemia and/or IC
- mITT population: All subjects in safety population who had documented *Candida* infection



Global Cure is defined as Clinical Cure (as assessed by the Primary Investigator), Mycological Eradication and Radiological Cure (for qualifying invasive candidiasis patients only).

ReSTORE PHASE 3 TRIAL RESULTS SUMMARY

Primary Efficacy Endpoints

- Both the FDA All-Cause Mortality at Day 30 as well as the EMA Global Cure at Day 14 endpoints were achieved

Secondary Efficacy Endpoints

- Early efficacy outcomes (Day 5 Global Cure, Day 5 Mycological Eradication) were either similar or trended higher in the rezafungin arm

Exploratory Efficacy Endpoints

- Blood cultures were cleared more quickly in the rezafungin arm though the difference was not significant
- Duration of ICU stay was lower in the rezafungin group compared to caspofungin

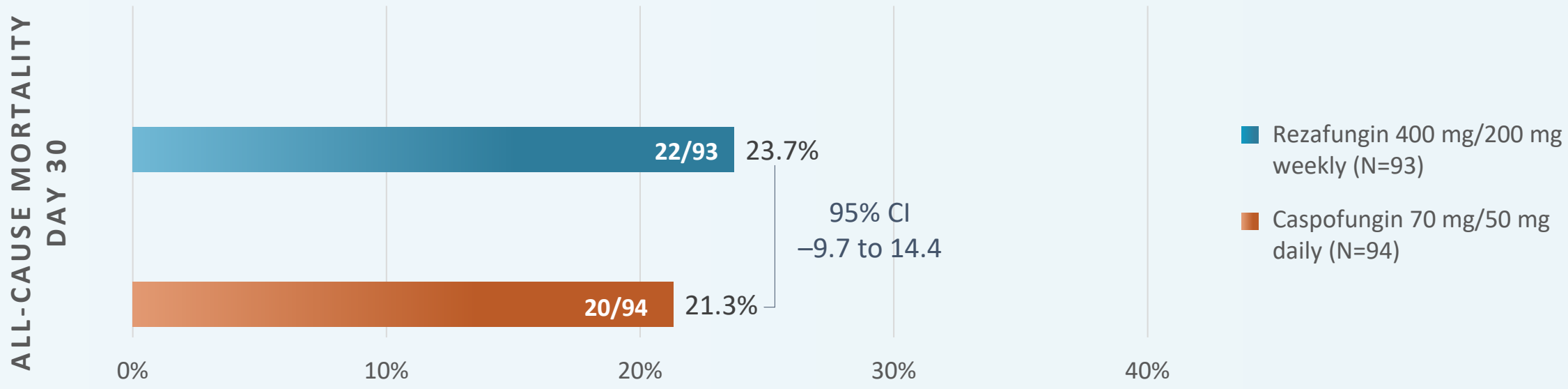
Safety

- Rates of Adverse Events and Serious Adverse Events were similar between the two study arms

KEY BASELINE DEMOGRAPHICS SIMILAR ACROSS ARMS

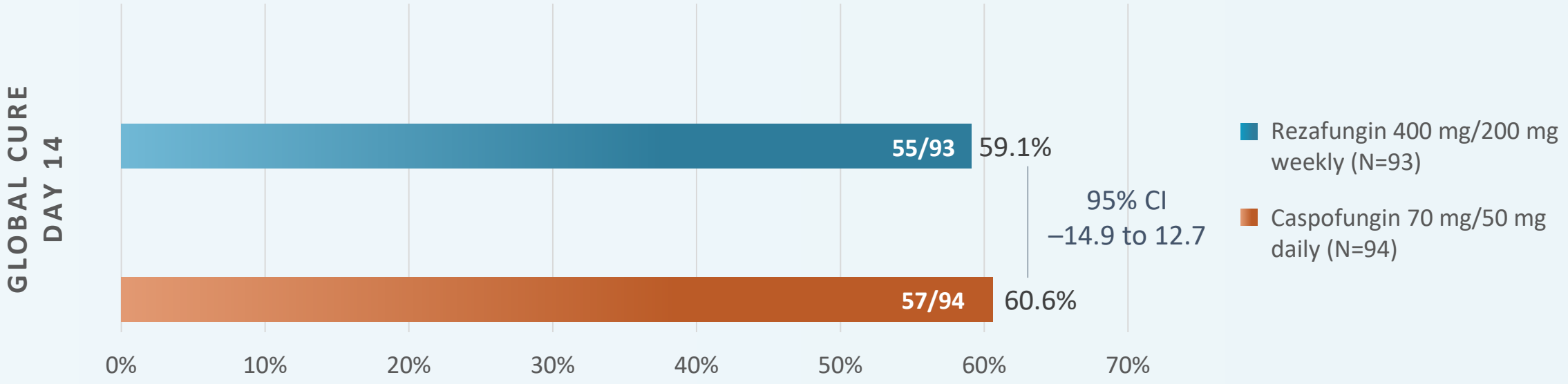
DEMOGRAPHIC OR CHARACTERISTIC	REZAFUNGIN n (%)	CASPOFUNGIN n (%)
Mean Age: ≥65 years	38 (40.9)	38 (40.4)
Sex: Female	31 (33.3)	38 (40.4)
Race		
Asian	23 (24.7)	31 (33.0)
Black or African American	5 (5.4)	4 (4.3)
White	59 (63.4)	55 (58.5)
Other	1 (1.1)	2 (2.1)
Not reported	4 (4.3)	1 (1.1)
Final Diagnosis: Candidemia	64 (68.8)	67 (71.3)
Final Diagnosis: Invasive Candidiasis	29 (31.2)	27 (28.7)
Modified APACHE II score		
≥20	12 (12.9)	17 (18.1)
10–19	42 (45.2)	40 (42.6)
<10	38 (40.9)	37 (39.4)
Absolute neutrophil count <500/µL	7 (7.5)	5 (5.3)

DAY 30 ALL-CAUSE MORTALITY (Primary Endpoint for FDA was Achieved)



The upper limit of the 95% confidence interval for ACM is 14.4%, which is within the noninferiority margin of 20% established with the FDA.

DAY 14 GLOBAL CURE (Primary Endpoint for EMA was Achieved)



The lower limit of the 95% confidence interval for Day 14 Global Cure is –14.9%, which is within the noninferiority margin of –20% established with the EMA.

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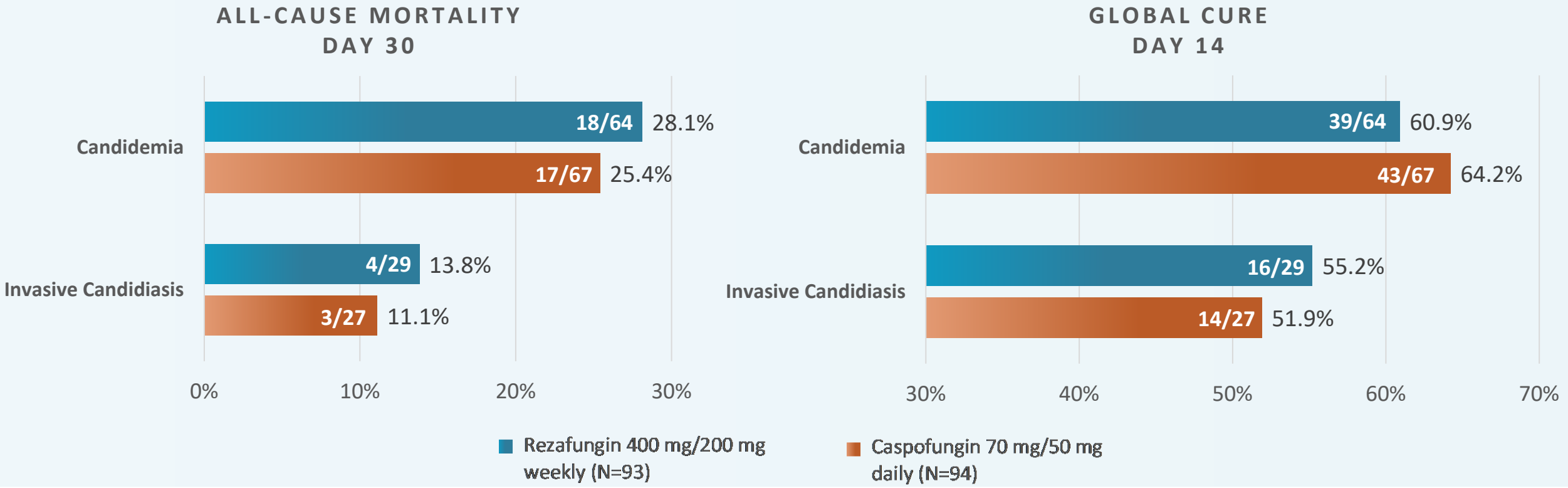
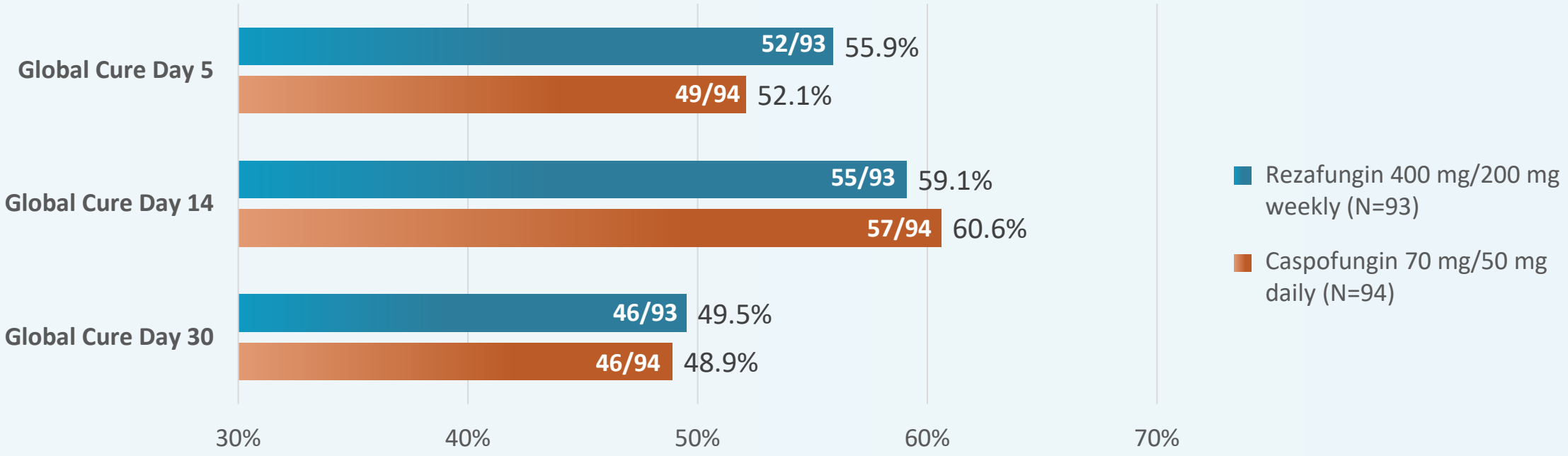
PRIMARY ENDPOINT RESULTS BY SUBGROUP



Day 30 All-Cause Mortality and Day 14 Global Cure were similar for rezafungin and caspofungin across these predefined subgroups.

GLOBAL CURE AT DAY 5, DAY 14, AND DAY 30

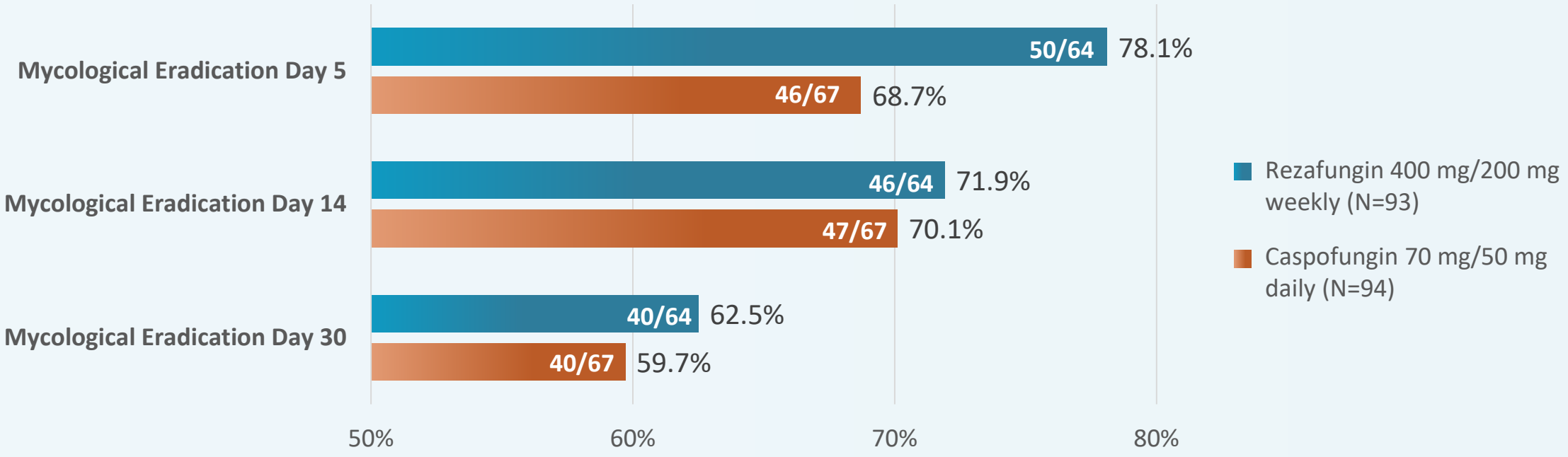
Day 5 and Day 30 are Secondary Endpoints



Global Cures were similar between study arms across multiple timepoints.

MYCOLOGICAL ERADICATION AT DAY 5, DAY 14, AND DAY 30

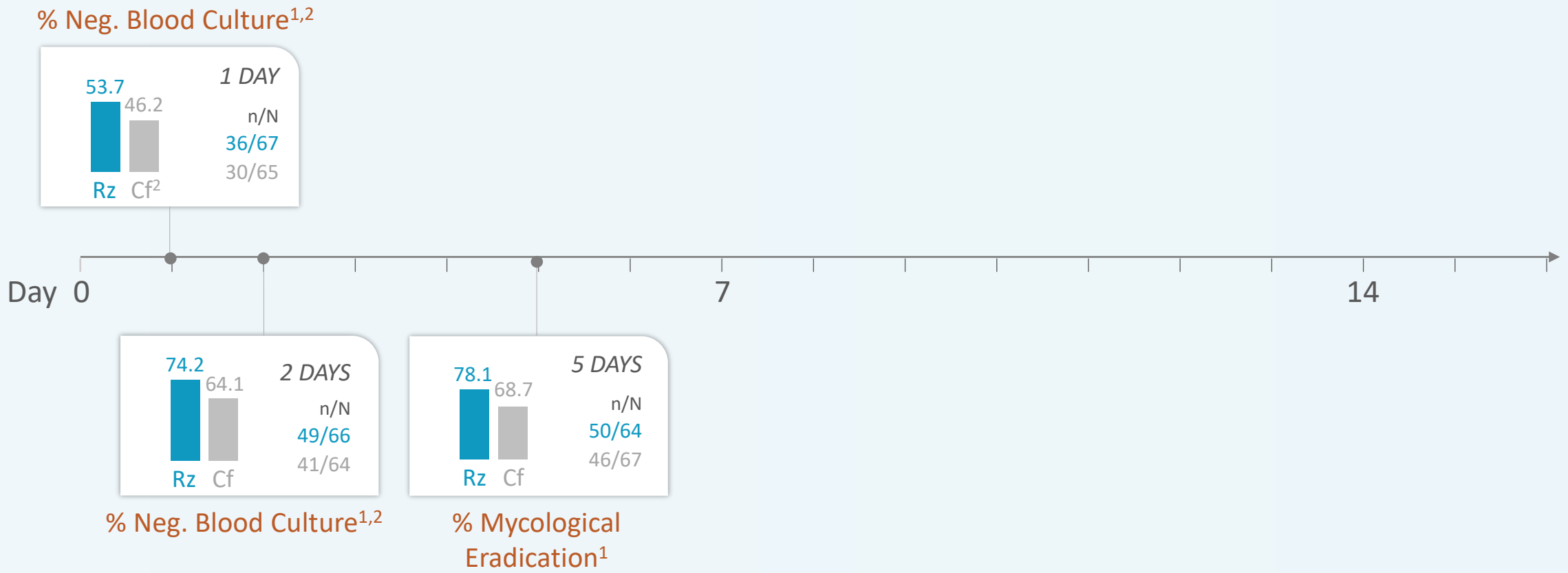
Day 5, Day 14, and Day 30 are Secondary Endpoints, in Candidemia Only



Mycological Eradication was numerically higher for rezafungin at Day 5 and similar across arms at later timepoints.

PHASE 3 EARLY EFFICACY AND MEDIAN ICU STAY

SECONDARY AND EXPLORATORY ANALYSES



1. Patients with candidemia only
2. Not powered for statistical comparison
3. All patients in the ICU on day 1 included except for those who died prior to ICU discharge

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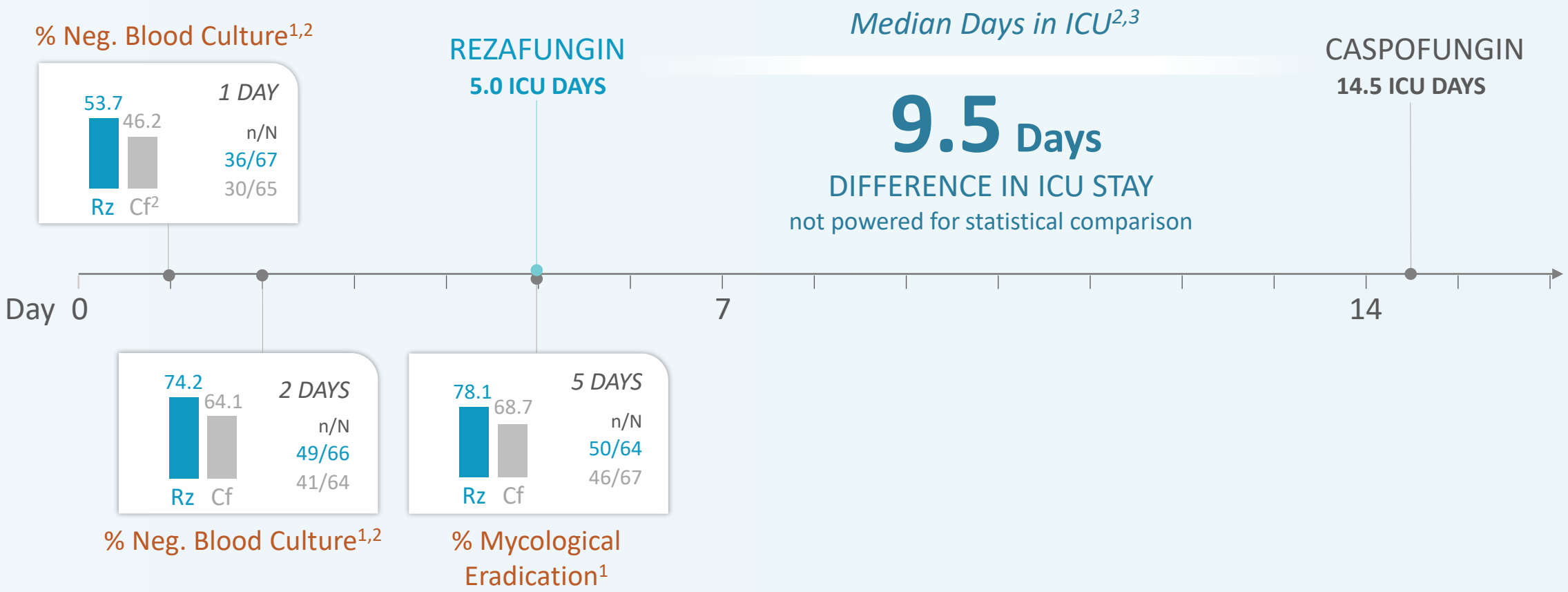

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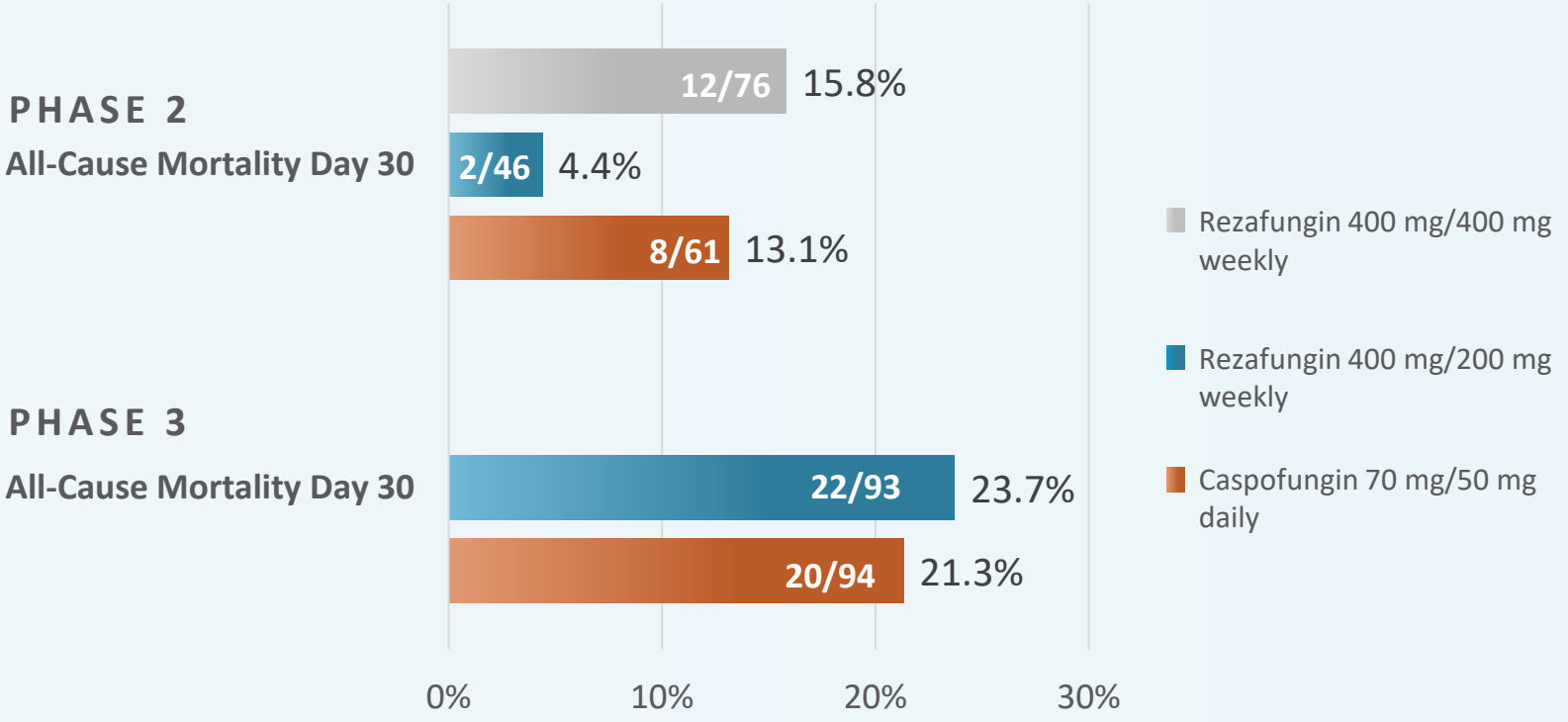
REZAFUNGIN PHASE 2 AND PHASE 3 ALL-CAUSE MORTALITY RESULTS

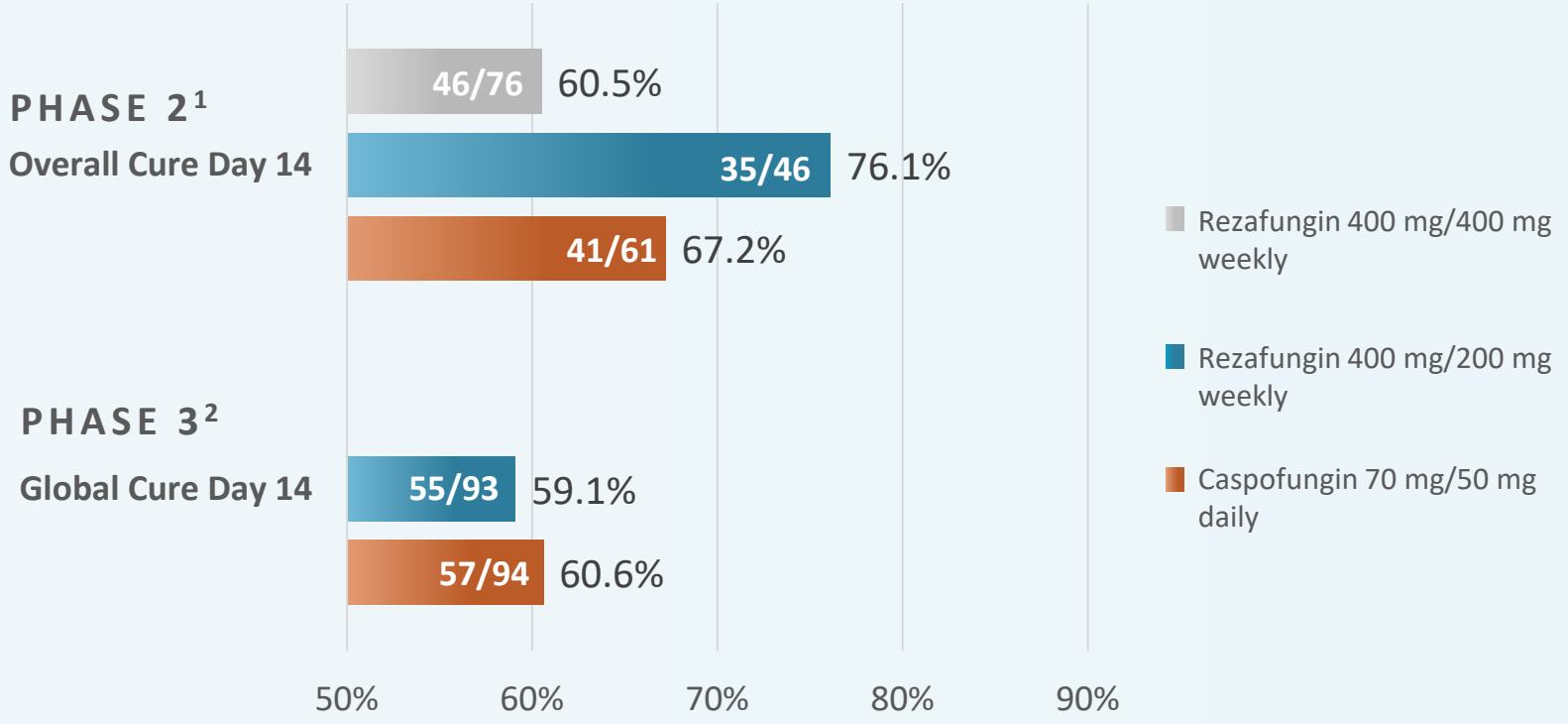


Differences in Trials

- Overall mortality higher in Ph3
- Ph3 enrolled during COVID (75% of Ph3 subjects were enrolled after March 2020)
- Ph2 run in NA and Europe
- Ph3 added Australia, South America, East Asia including China

Impact of the above on study outcomes is unknown

REZAFUNGIN PHASE 2 AND PHASE 3 DAY 14 CURE RESULTS



Differences in Trials

- Overall rates of D14 global cure trended lower in Ph3
- Ph 3 enrolled during COVID
- Expanded regions of enrollment
- Increased rates of IC

Impact of the above on study outcomes is unknown

1. Overall Cure (Phase 2): resolution of systemic signs attributable to candidemia or invasive candidiasis AND mycological eradication as demonstrated by a single tissue/fluid culture or 2 negative blood cultures at least 12 hours apart
2. Global Cure (Phase 3): investigator assessment of clinical cure AND mycological eradication as demonstrated by a single negative blood or tissue/fluid culture AND (if pertinent) improvement or resolution of evidence of invasive candidiasis on radiographic imaging

SAFETY: SUMMARY OF ADVERSE EVENTS

Number of Subjects	REZAFUNGIN 400 mg/200 mg Weekly N=98 n (%)	CASPOFUNGIN 70 mg/50 mg Daily N=98 n (%)
≥1 TEAE	89 (90.8)	83 (84.7)
Study drug-related*	16 (16.3)	9 (9.2)
Serious AE	55 (56.1)	52 (53.1)
Study drug-related*	2 (2.0)	3 (3.1)
AE leading to study drug discontinuation	13 (13.3)	11 (11.2)

* Study drug-related AEs may be considered related to study drug or placebo due to investigator blinding.
5 AEs in the rezafungin arm were considered related to placebo administration.
0 AEs in the caspofungin arm were considered related to placebo administration.

Rezafungin was generally well tolerated and had a similar safety profile to caspofungin.

SAFETY: RELATED SERIOUS ADVERSE EVENTS AS DETERMINED BY THE PIs

Both SAEs in the rezafungin arm were associated with placebo administration

- Rezafungin arm
  - Infusion-related reaction (Day 3)
    - Hypersensitivity reaction during the Day 3 infusion of saline placebo
  - Urticaria (Day 15)
    - Urticarial rash following oral placebo administration

- Caspofungin arm
  - Hypertransaminasaemia (Day 14)
    - High liver function tests
  - Liver injury (Day 8)
    - High liver function tests
  - Anaphylactic shock (Day 3)
    - Anaphylactic reaction to Day 3 study drug infusion

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ReSTORE PROVIDES EXCELLENT FOUNDATION FOR COMMERCIALIZATION

REZAFUNGIN

- No new treatments for IC in 15 years
- NDA and EMA Filing expected mid-2022
- Go-to-market strategy optionality while preparing
- Highly efficient market
- Supply chain in place and launch supplies on hand
- Fast Track, QIDP, Orphan designation for C/IC
- Validated by Mundipharma partnership

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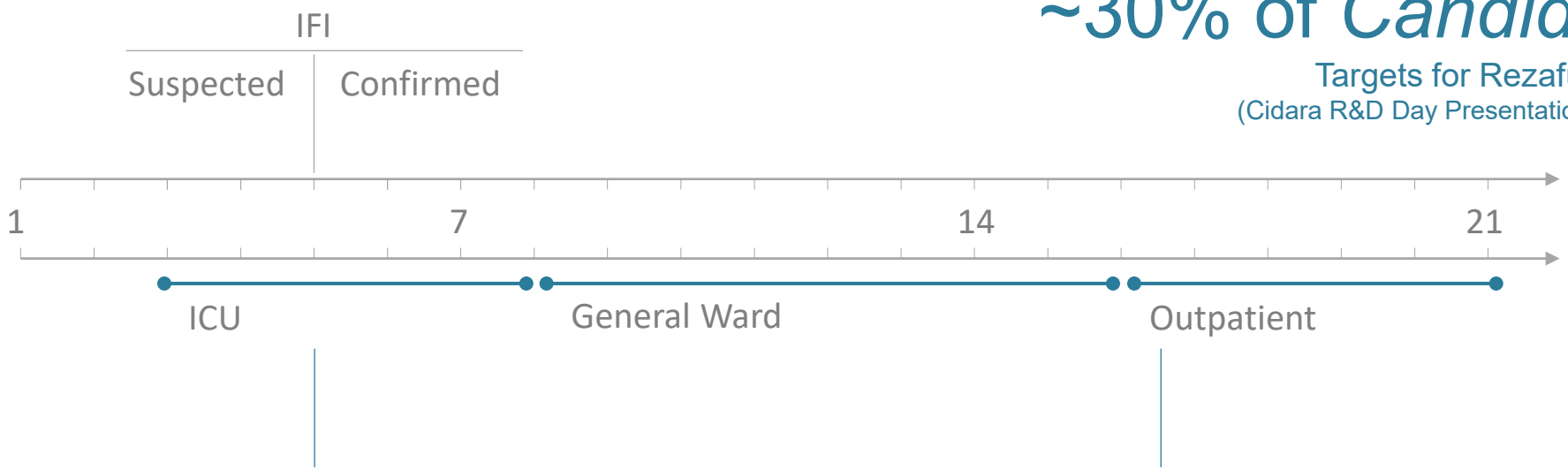
ADVANTAGES

- ✓ Only drug in development successfully compared head-to-head in Ph3 with standard of care echinocandin in 1st line *Candida* treatment
- ✓ 1st and only once-weekly antifungal candidate
- ✓ High front-loaded dosing for rapid *Candida* clearance
- ✓ Substantial tissue and organ penetration
- ✓ No DDIs across two studies with relevant drugs
- ✓ May enable early discharge (ICU and Hospital)
- ✓ Active against tough to treat *Candida* strains including *C. auris* and azole-resistant *Candida*

ReSTORE DATA AND MARKET INPUT DEFINE CLEAR PATIENT OPPORTUNITIES

~30% of *Candida* patients

Targets for Rezafungin
(Cidara R&D Day Presentation Sept 2021)



INPATIENT REZAFUNGIN TARGETS

1. Documented *Candida* (not empiric)
2. Higher front-loaded dosing may be of benefit in critically ill (ICU, etc.)
3. Cannot step down (azole issues)[2]
4. Potential for early discharge (ICU and Hospital), increasing importance with COVID pandemic

OUTPATIENT REZAFUNGIN TARGETS

1. Remain on echinocandin due to azole resistance
2. Remain on echinocandin due to azole tox/DDI
3. Unknown *Candida* pathogen
4. Once-weekly facilitates administration and adherence

1. 30% of patients with *Candida* receive therapy for documented disease whereas 70% receive empiric therapy only (Internal estimate).
2. 30% of patients who start on an echinocandin are still on an echinocandin on the last day of hospitalization because they could not be stepped down. Sofjan, Garey et al. Journal of Antimicrobial Resistance. Vol14, Sept 2018

REZAFUNGIN: TWO PHASE 3 PROGRAMS VS STANDARDS OF CARE

Candida Treatment Focus:

1^{0} – Infectious Disease
2^{0} – Hem/Onc

ReSTORE Complete
NDA Mid-2022

+

Antifungal Prophylaxis Focus:

1^{0} – Hem/Onc
2^{0} – Infectious Disease

ReSPECT Ongoing

Rezafungin is the only antifungal in clinical stage development for both 1st-line treatment and prophylaxis...

…Fluconazole and voriconazole, which sold $1B and $800M at peak[1,2] respectively, had a similar approach

1. Source: IQVIA
2. Peak year annual sales estimates for fluconazole and voriconazole are presented for illustrative purposes only and are not a forecast of potential rezafungin sales or revenue.

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QUESTIONS

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THANK YOU