



ID Week 2022

Leading the Science of Protection

CIDARA THERAPEUTICS OVERVIEW

Product	Indications	Phase 1	Phase 2	Phase 3	NDA Filed
REZAFUNGIN	Treatment of Candidemia and Invasive Candidiasis Partnered with Melinta (U.S.) and Mundipharma (Ex-U.S. and Ex-Japan)				»
REZAFUNGIN	Prevention of Invasive Fungal Disease in Blood & Marrow Transplant Patients Partnered with Melinta (U.S.) and Mundipharma (Ex-U.S. and Ex-Japan)			»	

CLOUDBREAK® DRUG-Fc CONJUGATES

Program	Indications	Discovery	Preclinical	IND-Enabling	Phase 1
CD388	Prevention of Seasonal Influenza Partnered with Janssen (Worldwide License)				»
SARS-CoV-2 DFC	SARS-CoV-2		»		
ONCOLOGY DFC CD73	Solid Tumors		»		
ONCOLOGY DFC A2AR	Solid Tumors		»		
ONCOLOGY DFC Other Targets	Solid Tumors		»		



Rezafungin

- Filed NDA July 22, partnered with Melinta Therapeutics and Mundipharma

Cloudbreak DFCs

- CD388 Flu DFC
Ph1 read out 4Q22, partnered with J&J
- Pre-clinical POC for Oncology & SARS DFCs unpartnered

Phase 3 development plan for rezafungin

	Phase 3 treatment trial	Phase 3 prophylaxis trial
		
TARGET INDICATION	Treatment of candidemia & invasive candidiasis ¹	Prophylaxis against IFD caused by <i>Aspergillus</i> , <i>Candida</i> & <i>Pneumocystis</i> in allogeneic blood and marrow transplant patients ²
TRIAL SIZE	187 patients* (20% noninferiority margin)	462 patients (12.5% noninferiority margin)
COMPARATOR	Caspofungin with optional step down to fluconazole	Fluconazole, posaconazole (if GVHD) and trimethoprim/sulfamethoxazole
TRIAL STATUS	Complete [†]	Ongoing

FDA, US Food and Drug Administration; GVHD, graft-versus-host disease; IFD, invasive fungal disease; mITT, modified intent-to-treat population; SOC, standard of care.

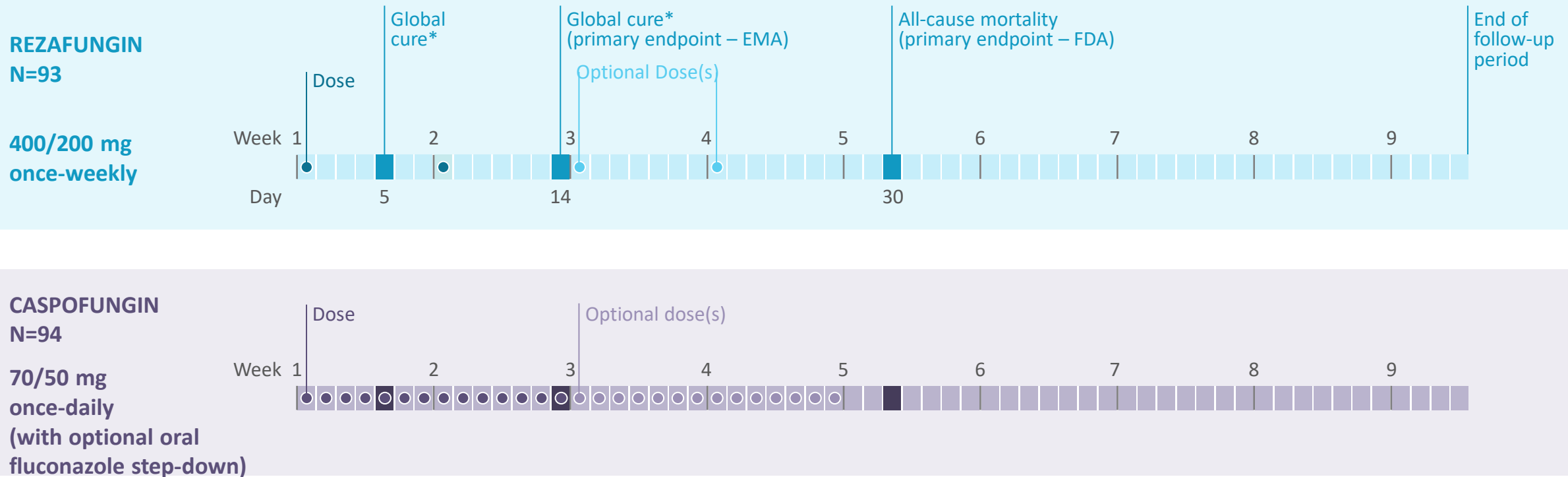
*mITT population. †Study sites in China are still recruiting patients for submission of rezafungin to the Center for Drug Evaluation in China.

1. Thompson GR III, et al. 2022 ECCMID LB0244. 2. Clinicaltrials.gov NCT04368559 accessed 20 April 2022.

ReSTORE Phase 3 trial design



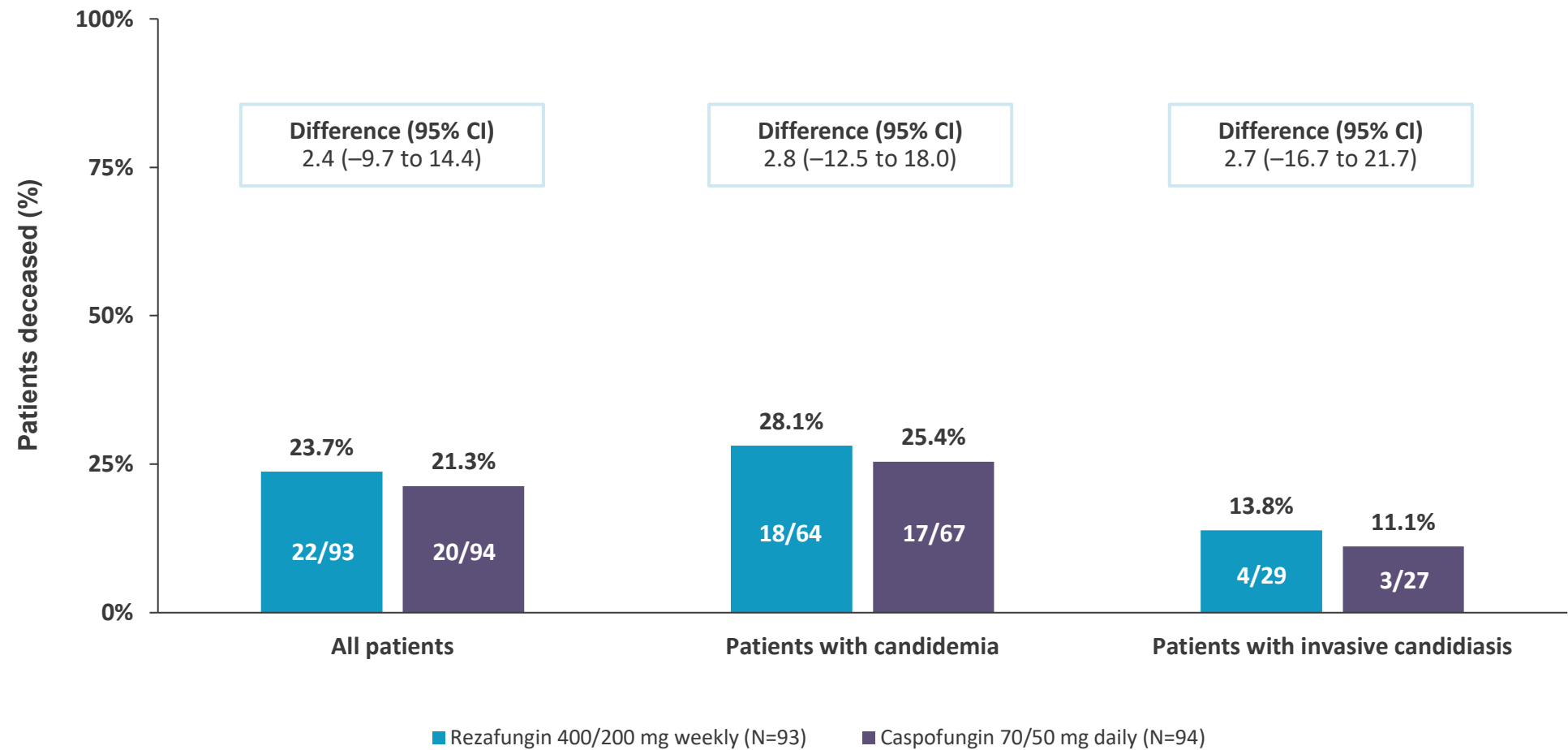
- A Phase 3, prospective, double-blind, randomized, international, multicenter trial
- Evaluate the efficacy and safety of once-weekly IV rezafungin vs once-daily caspofungin followed by optional oral fluconazole step-down in the treatment of documented candidemia and/or IC
- mITT population: All subjects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



EMA, European Medicines Agency; FDA, US Food and Drug Administration; IC, invasive candidiasis; IV, intravenous; mITT, modified intent-to-treat

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

Phase 3 ReSTORE Trial met FDA primary endpoint : All-cause mortality at Day 30 (-2 days) in the mITT population



CI, confidence interval; FDA, US Food and Drug Administration; IC, invasive candidiasis; mITT, modified intent-to-treat.
Cidara Therapeutics Inc. Data on file (ReSTORE Tables) 2022.
ECCMID 2022



Phase 2 STRIVE and Phase 3 ReSTORE Studies

Baseline demographics/characteristics in the pooled mITT population

Characteristic	Rezafungin 400/200 mg weekly (N=139)	Caspofungin 70/50mg daily (N=155)
Age, years, mean \pm SD, (range)	59.8 \pm 15.7 (19, 91)	60.8 \pm 15.0 (20, 93)
Age, years, mean		
≥ 65 years, n (%)	57 (41.0)	63 (40.6)
Female, n (%)	49 (35.3)	65 (41.9)
BMI, kg/m ² , mean \pm SD	25.78 \pm 7.8	25.12 \pm 6.02
Race, n (%)		
Asian	24 (17.3)	34 (21.9)
Black or African American	11 (7.9)	8 (5.2)
White	95 (68.3)	106 (68.4)
Other*	9 (6.5)	7 (4.5)
Final diagnosis: Candidemia only, n (%)	100 (71.9)	115 (74.2)
Final diagnosis: Invasive candidiasis, n (%)	39 (28.1)	40 (25.8)
Modified APACHE II SCORE		
≥ 20 n (%)	21 (15.1)	26 (16.8)
< 20 n (%)	116 (83.5)	126 (81.3)
Geographic region, n (%)		
United States	43 (30.9)	46 (29.7)
Europe/Israel/Turkey	67 (48.2)	76 (49.0)
Asia-Pacific (excluding China and Taiwan)	21 (15.1)	27 (17.4)
China/Taiwan	8 (5.8)	6 (3.9)

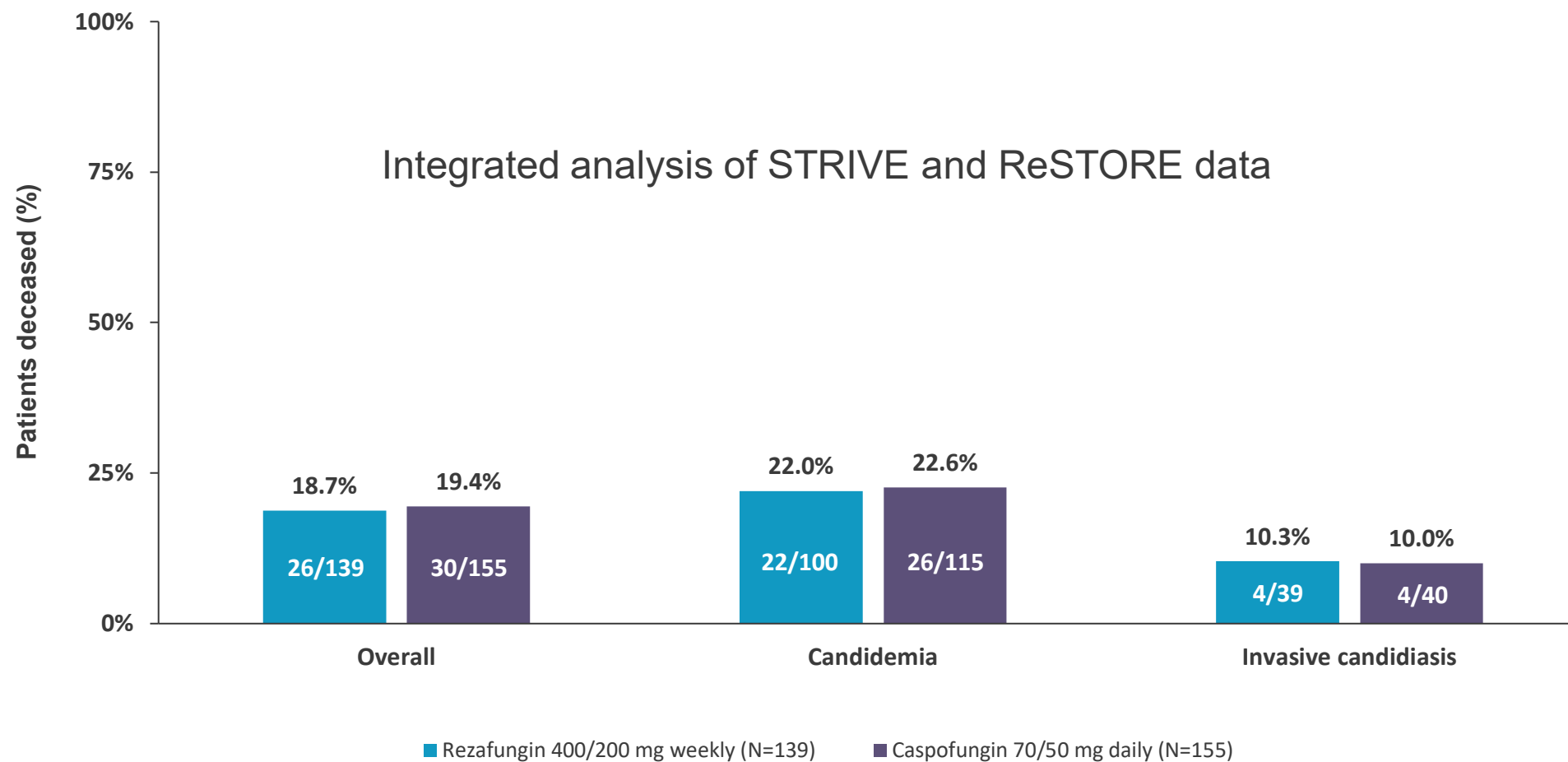
Candida species distribution: 39% albicans, 24% glabrata, 18% tropicalis, 12% parapsilosis, 2% dubliniensis, 2% krusei, 3% other

APACHE II, Acute Physiology and Chronic Health Evaluation II; BMI, body mass index; mITT, modified intent-to-treat; SD, standard deviation.

*Includes American Indian or Alaska native and not reported.

ECCMID 2022

All-cause mortality (FDA primary endpoint): Pooled Ph3 + Ph2 mITT population



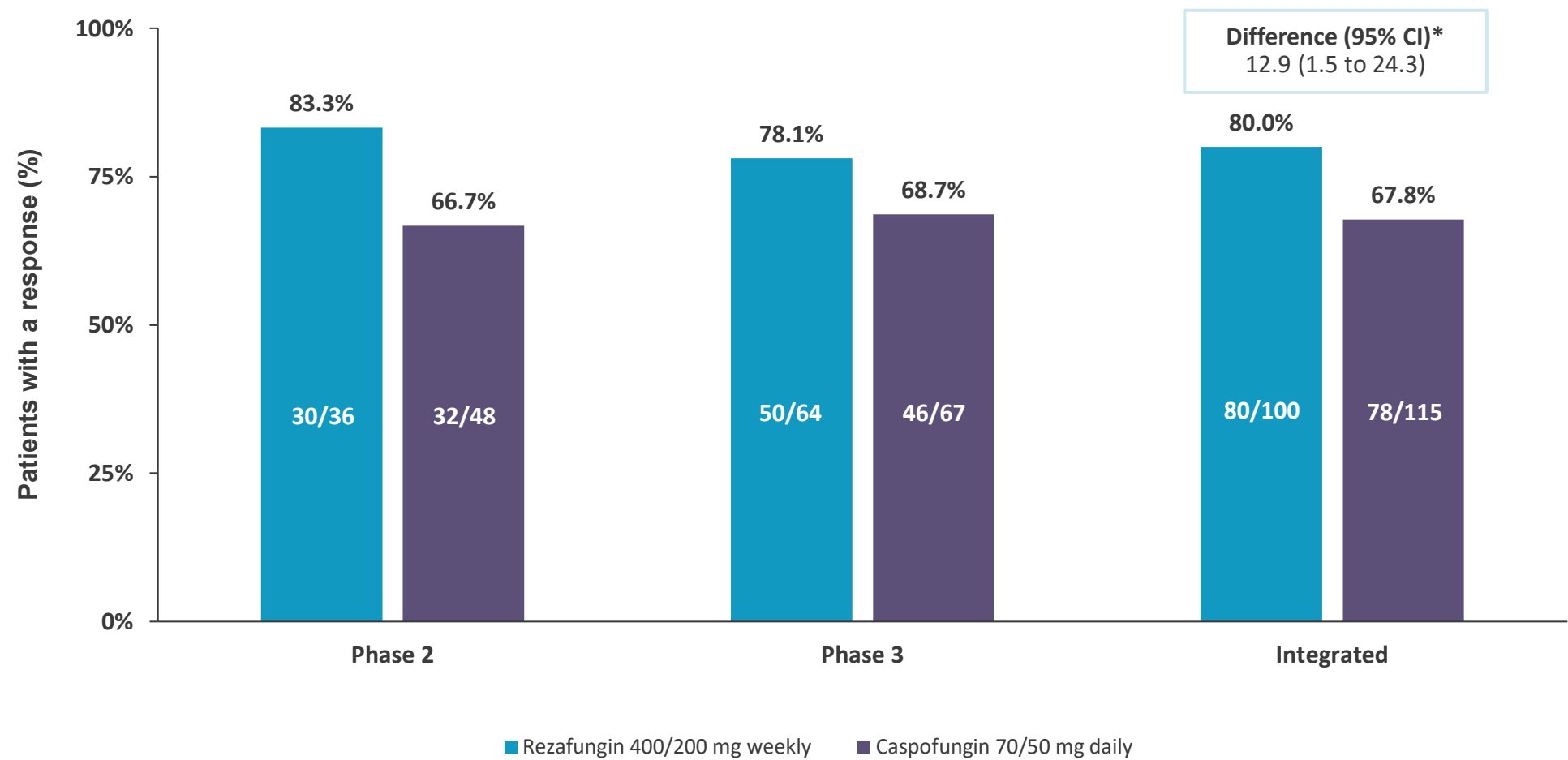
Integrated analysis from STRIVE + ReSTORE: ECCMID 2022

Estimate from a stratified analysis by study.

mITT, modified intent-to-treat.

Mycological eradication at Day 5: Phase 2, Phase 3, and Integrated

- mITT population – patients with candidemia



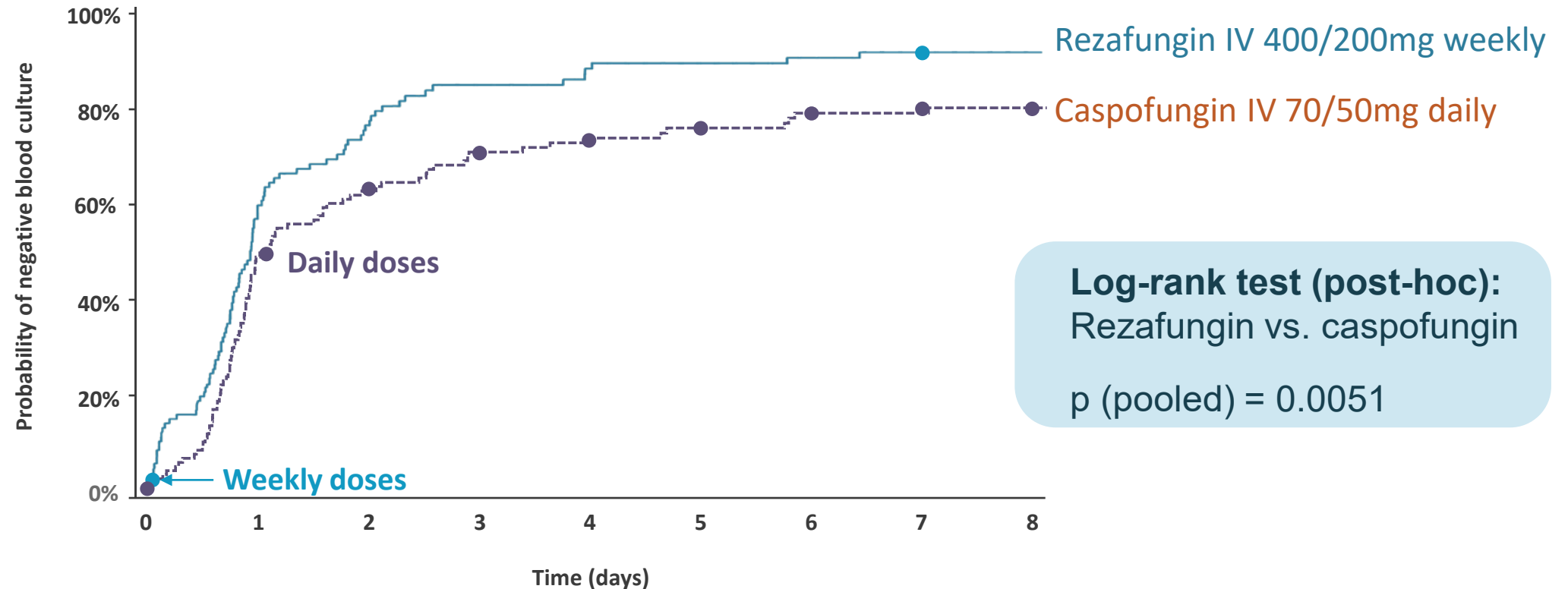
Integrated analysis from STRIVE + ReSTORE: ECCMID 2022

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

*Calculated using stratified analysis by study and by part A and B of STRIVE.

Front-loaded dosing: Phase 2 + Phase 3 integrated analysis

STRIVE Ph2 + ReSTORE Ph3: Time to negative blood culture¹



Once-weekly front-loaded dose of rezafungin eradicated fungi earlier than caspofungin administered daily

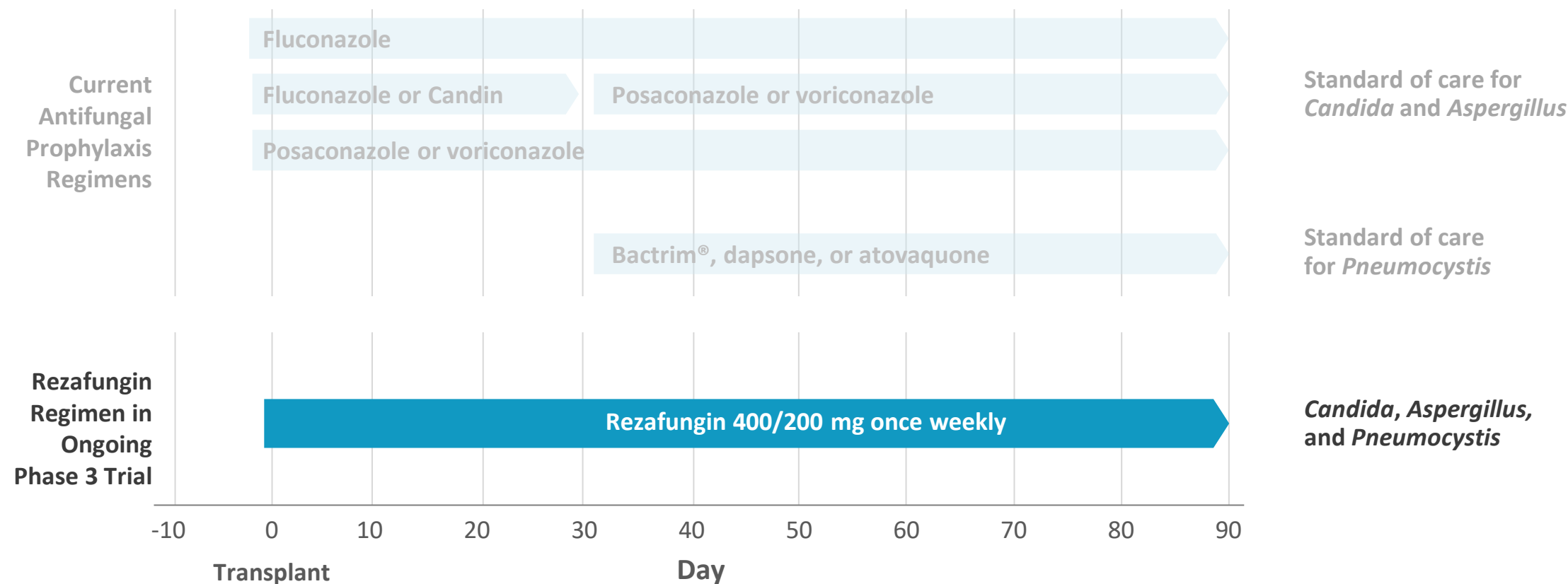


Rezafungin Phase 3 Prophylaxis Trial in Allogeneic BMT



Rezafungin: Potential For a Simplified Single Antifungal Prophylaxis Paradigm in BMT

Antifungal Prophylaxis in Allogeneic Blood and Marrow Transplant Setting^{1,2}



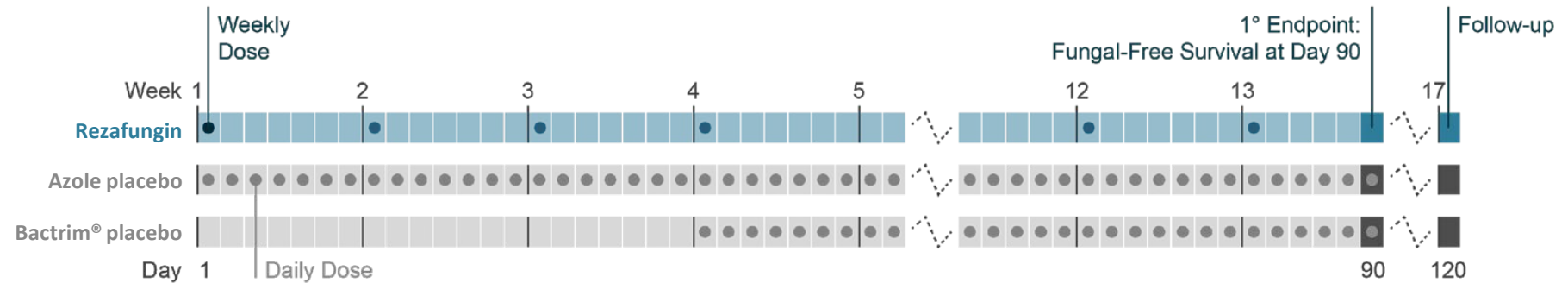
Rezafungin prophylaxis targets prevention of *Candida*, *Aspergillus*, and *Pneumocystis* infections—including drug-resistant species

Trial Design¹

REZAFUNGIN

(N≈300)

400/200 mg once weekly

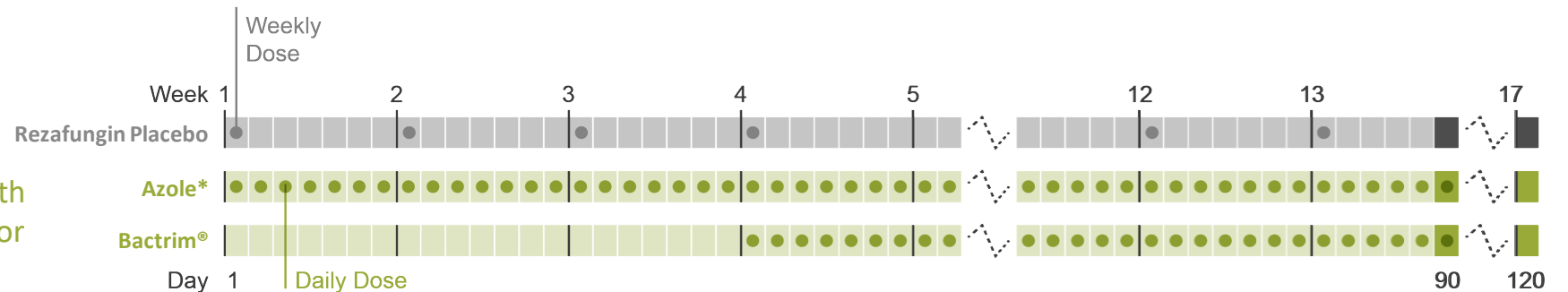


COMPARATOR

(N≈150)

400 mg fluconazole once daily, with optional switch to Posaconazole for patients with acute GVHD

80 mg TMP/400 mg SMX once daily



Rezafungin Summary – A Next Generation Once-Weekly Echinocandin

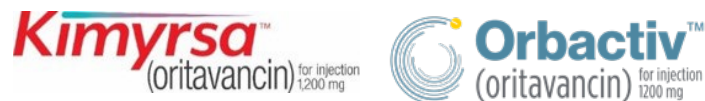
- **Potent and broad-spectrum activity against *Candida*, *Aspergillus*, and *Pneumocystis***
- **Safety and Drug-Drug Interaction (DDI) profile of the echinocandin class**
No DDIs, no hepatic and renal toxicity, no impact on QT interval
- **Optimized PK, Dosing and administration**
133hr t_{1/2}, once-weekly dosing, 400 mg wk 1 and 200 mg wkly thereafter for all pts. No therapeutic drug monitoring.
No dose adjustments
- **Efficacy**
Phase 2 and 3 randomized, blinded global treatment trials demonstrated efficacy against candidemia and invasive candidiasis with enhanced speed of fungal clearance.
- **NDA/MAA filed for *Candida* treatment**
- **Phase 3 ReSPECT global prophylaxis trial ongoing**
ReSPECT: 1st-line prophylaxis of *Candida*, *Aspergillus*, and *Pneumocystis* in alloBMT, ± GVHD, vs fluconazole/posaconazole/Bactrim®, over first 90 days following transplant



New Collaboration between Cidara and Melinta Therapeutics for Rezafungin

- If approved by the FDA, Melinta Therapeutics will be responsible for commercializing rezafungin in the U.S.
- Cidara to continue rezafungin clinical development and regulatory activities
- About Melinta Therapeutics
 - **Mission:** Provide innovative therapies to people impacted by acute and life-threatening illnesses
 - **Vision:** All people who need our therapies receive them
 - US Based with offices in Parsippany, NJ & Lincolnshire, IL
 - Diverse portfolio treats infections caused by antibiotic-resistant pathogens

Gram-Positive



Gram-Negative



- Will leverage existing Medical Affairs, Commercial, Patient Support infrastructure





Thank you

Leading the Science of Protection