







## **STRIVE Part A Phase 2 topline data**

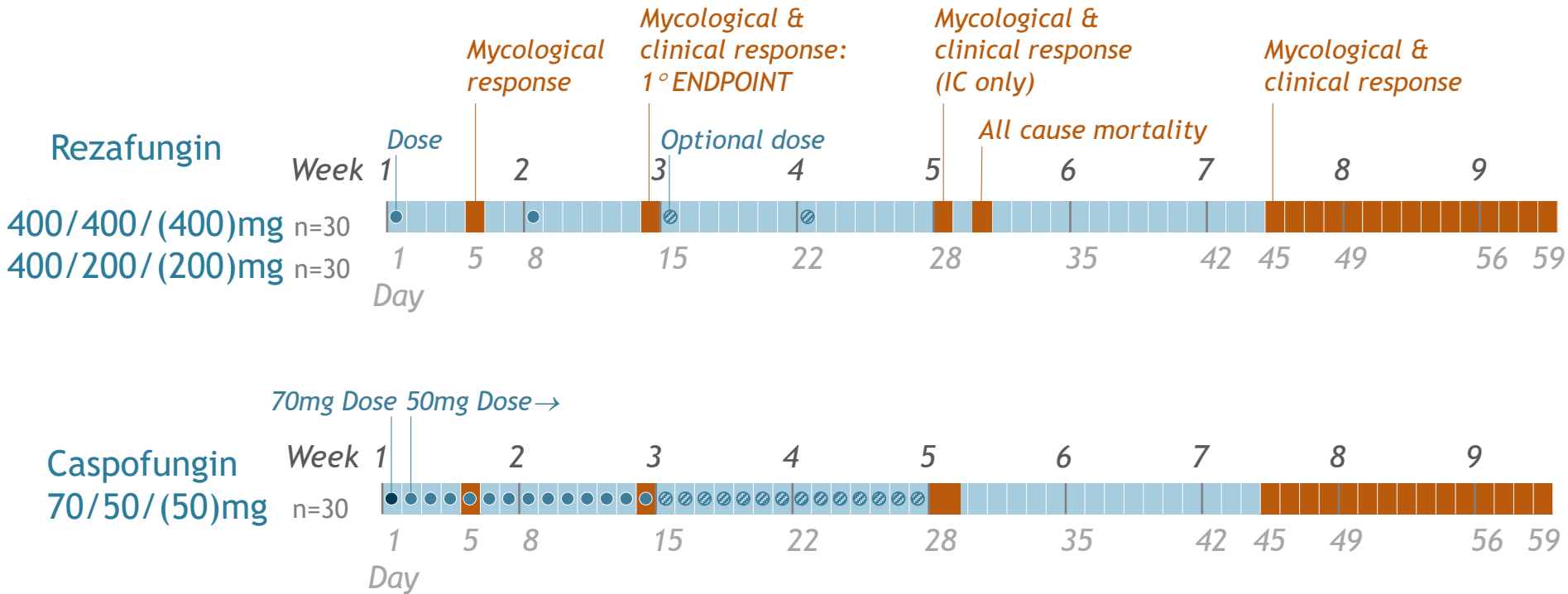
March 2018

# Cidara Pipeline

Programs	Indication	Discovery	Research/ <i>in vitro</i>	<i>in vivo</i>	IND Enabling	Phase 1	Phase 2	Phase 3	
Rezafungin	Treatment ( <i>Candida</i> )								
Rezafungin	Fungal Prophylaxis in alloBMT								
<b>Cloudbreak™ Immunotherapy Platform</b>									
Cloudbreak Antibody Drug Conjugates (ADC)	Gram (-) Infections								

# STRIVE Part A: Candidemia & Invasive Candidiasis STRIVE

*Not powered for inferential statistics.*



## Analysis Populations:

- The Intent-to-treat (ITT) population: all randomized subjects
- The Safety population: all subjects who received any amount of study drug
- The Microbiological Intent-to-treat population (mITT): all subjects in safety population who had documented *Candida* infection

# Major objectives of STRIVE Part A

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**Select a dosing regimen for STRIVE Part B and Phase 3 based on:**

- Clinical and mycological cure by time, severity and empiric treatment
- Tolerability, safety and adverse events
- Relative performance vs caspofungin in light of 20% NI margin in Phase 3

# Topline Baseline Characteristics

## ITT Population

Parameter		Rezafungin 400 mg/400 mg (QWk) N= 35	Rezafungin 400 mg/200 mg (QWk) N= 36	Caspofungin 70 mg/50 mg (QD) N= 36
		n (%)		
Age	Mean age, yrs (SD)	56.9 (15.90)	57.0 (14.26)	60.7 (17.23)
	[Range]	[24.0, 88.0]	[26.0, 84.0]	[24.0, 93.0]
Diagnosis	Candidemia	32 (91.4)	31 (86.1)	33 (91.7)
	IC	3 (8.6)	5 (13.9)	3 (8.3)
APACHE II score	0-9	12 (34.3)	9 (25.0)	9 (25.0)
	10-19	16 (45.7)	18 (50.0)	21 (58.3)
	≥20	6 (17.1)	8 (22.2)	3 (8.3)
	Missing	1 (2.9)	1 (2.8)	3 (8.3)

# Topline Overall Response (Primary Outcome)

## Day 14 - mITT Population

Response	Rezafungin 400 mg/400 mg (QWk) N= 33	Rezafungin 400 mg/200 mg (QWk) N= 31	Caspofungin 70 mg/50 mg (QD) N= 28
	n (%)		
Success	19 (57.6)	22 (71.0)	18 (64.3)
Failure	7 (21.2)	6 (19.4)	8 (28.6)
Indeterminate	7 (21.2)	3 (9.7)	2 (7.1)
	<b>Excluding Indeterminate Response*</b>		
Success	19/26 (73.1)	22/28 (78.6)	18/26 (69.2)
Failure	7/26 (26.9)	6/28 (21.4)	8/26 (30.8)

\*Indeterminate response indicates inability to assess outcome due to missing data point(s)

# Topline Investigator Assessment of Clinical Response

## Day 14 - mITT Population

- Outcome most closely approximating primary outcome from prior IC clinical trials

Response	Rezafungin 400 mg/400 mg (QWk) N= 33	Rezafungin 400 mg/200 mg (QWk) N= 31	Caspofungin 70 mg/50 mg (QD) N= 28
	n (%)		
Clinical Cure	25 (75.8)	24 (77.4)	20 (71.4)
Clinical Failure	7 (21.2)	4 (12.9)	8 (28.6)
Indeterminate	1 (3.0)	3 (9.7)	0
	<b>Excluding Indeterminate Response</b>		
Clinical Cure	25/32 (78.1)	24/28 (85.7)	20/28 (71.4)
Clinical Failure	7/32 (21.9)	4/28 (14.3)	8/28 (28.6)

# Topline Overall Response

## Day 5 - mITT Population

- Comparing single dose of Rezafungin to five doses of Caspofungin

Response	Rezafungin 400 mg/400 mg (QWk) N= 33	Rezafungin 400 mg/200 mg (QWk) N= 31	Caspofungin 70 mg/50 mg (QD) N= 28
	n (%)		
Success	19 (57.6)	21 (67.7)	15 (53.6)
Failure	10 (30.3)	8 (25.8)	12 (42.9)
Indeterminate	4 (12.1)	2 (6.5)	1 (3.6)
	<b>Excluding Indeterminate Response</b>		
Success	19/29 (65.5)	21/29 (72.4)	15/27 (55.6)
Failure	10/29 (34.5)	8/29 (27.6)	12/27 (44.4)



# Topline Overall Success by Severity and Prior Therapy

## Day 14 - mITT Population

Population		Rezafungin 400 mg/400 mg (QWk)	Rezafungin 400 mg/200 mg (QWk)	Caspofungin 70 mg/50 mg (QD)
		n/N (%)		
Overall Response		19/33 (57.6)	22/31 (71.0)	18/28 (64.3)
High APACHE II score	≥15	6/10 (60)	8/10 (80)	7/12 (58.3)
Prior antifungal therapy	No	8/11 (72.7)	10/10 (100)	7/9 (77.8)
	Yes	11/22 (50)	12/21 (57.1)	11/19 (57.9)

# Topline Day 30 All-Cause Mortality (1° Endpoint for Ph3)

## mITT Population

Parameter	Rezafungin 400 mg/400 mg (QWk) N= 33	Rezafungin 400 mg/200 mg (QWk) N= 31	Caspofungin 70 mg/50 mg (QD) N= 28
Deaths, n (%)	5 (15.2)	3 (9.7)	5 (17.9)
Deaths at Day 30 (%)	5 (15.2)	1 (3.2)	3 (10.7)

# Topline Summary of Adverse Events

## Safety Population

Parameter	Rezafungin 400 mg/400 mg (QWk) N= 35	Rezafungin 400 mg/200 mg (QWk) N= 36	Caspofungin 70 mg/50 mg (QD) N= 33
	n (%)		
≥1 TEAE	31 (88.6)	34 (94.4)	27 (81.8)
Severe	13 (37.1)	10 (27.8)	13 (39.4)
Study-drug related TEAE	4 (11.4)	6 (16.7)	4 (12.1)
TEAE leading to study drug discontinuation	4 (11.4)	1 (2.8)	1 (3.0)
Serious AE	13 (37.1)	18 (50.0)	13 (39.4)
Study-drug related SAE	0	1 (2.8)	1 (3.0)

AE=adverse event

TEAE=treatment-emergent adverse event: AE that occurs after the first dose of study drug is administered

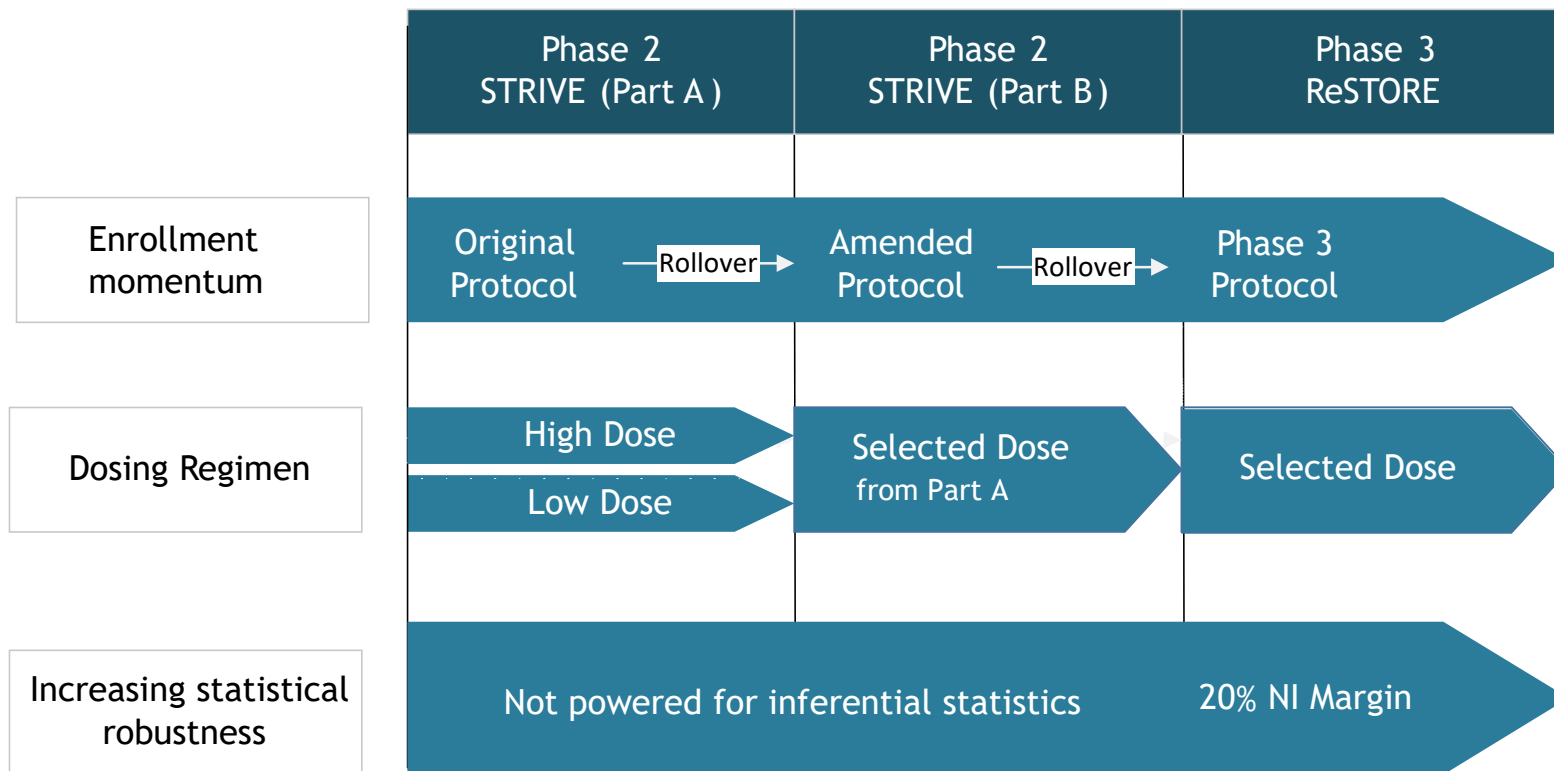
# STRIVE A Topline Conclusions

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- Based on topline data, Phase 2 STRIVE trial met objectives with favorable safety and efficacy data for RZF in candidemia/IC to support advancing to Phase 3 clinical trials
- 400 mg/200 mg: Efficacy trended the highest in all assessments
  - Higher rates on all response endpoints compared to CSF
  - Lower rates for overall mortality and all-cause 30-day mortality (the primary outcome measure in planned Phase 3 study) compared to CSF
  - Trends towards improved efficacy outcomes despite >2-fold prevalence of most severely ill patients compared to CSF
- No concerning AE trends: RZF appears to be safe and well-tolerated
  - No deaths related to study drug
- Topline results strongly support advancing RZF into Phase 3 trials
  - And selection of 400/200mg for ReSTORE (RZF Phase 3 treatment trial)

# STRIVE Part B provides an early read on treatment Phase 3

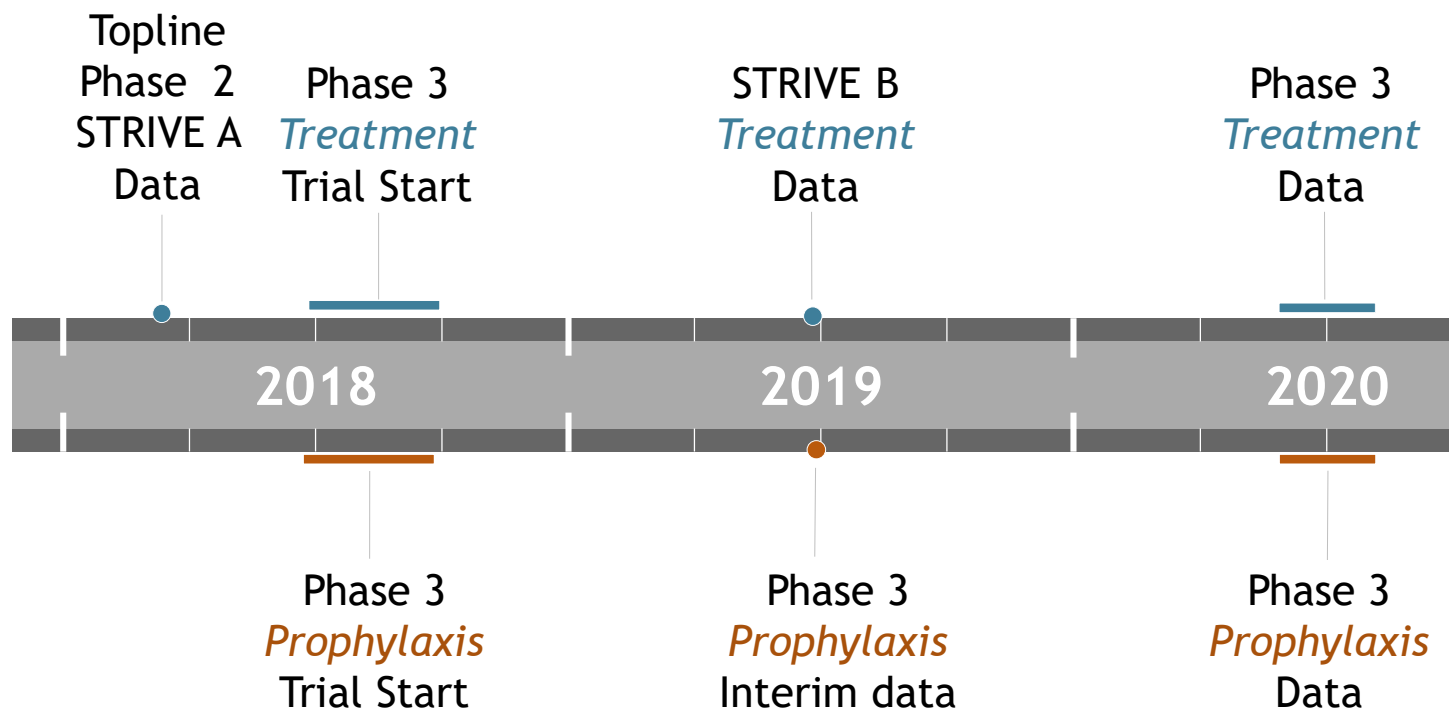
## Seamless Phase 2 to Phase 3 Strategy



The patient populations from STRIVE and ReSTORE will bolster the global safety database needed for regulatory filings.

# STRIVE Program Enables Phase 3 Treatment *and* Prophylaxis

...two P3 studies, one in each population, with distinct commercial opportunities



# Rezafungin Overall Phase 3 Development Plan

Based on meetings with FDA in 4Q17

ReSTORE 

ReSPECT 

## Phase 3 Treatment Trial

## Phase 3 Prophylaxis Trial

Indication

Treatment of  
Candidemia & Invasive  
Candidiasis in patients with  
limited treatment options

Prophylaxis of *Aspergillus*,  
*Candida* & PCP in patients  
undergoing allogeneic bone  
marrow transplant

Phase 3  
Size

~ 150 patients

~450 patients  
w/ adaptive design

Duration of therapy,  
Endpoints and  
Comparators

2-4 week treatment  
Day 30 all-cause mortality  
Caspofungin

90 day prophylaxis  
90 day fungal free survival  
Fluconazole, Posaconazole,  
Bactrim

Timing  
for initiation  
and data

Mid-2018  
Mid-2020

Mid-2018  
Mid-2020