



Cytokinetics

EMPOWERING  
**MUSCLE**  
EMPOWERING  
**LIVES**

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# Our Mission

We are developing potential medicines to improve the healthspan of people with devastating cardiovascular and neuromuscular diseases of impaired muscle function.

# Sarcomere-Directed Research Goals

C  
A  
R  
D  
I  
A  
C

## ACTIVATE MYOSIN

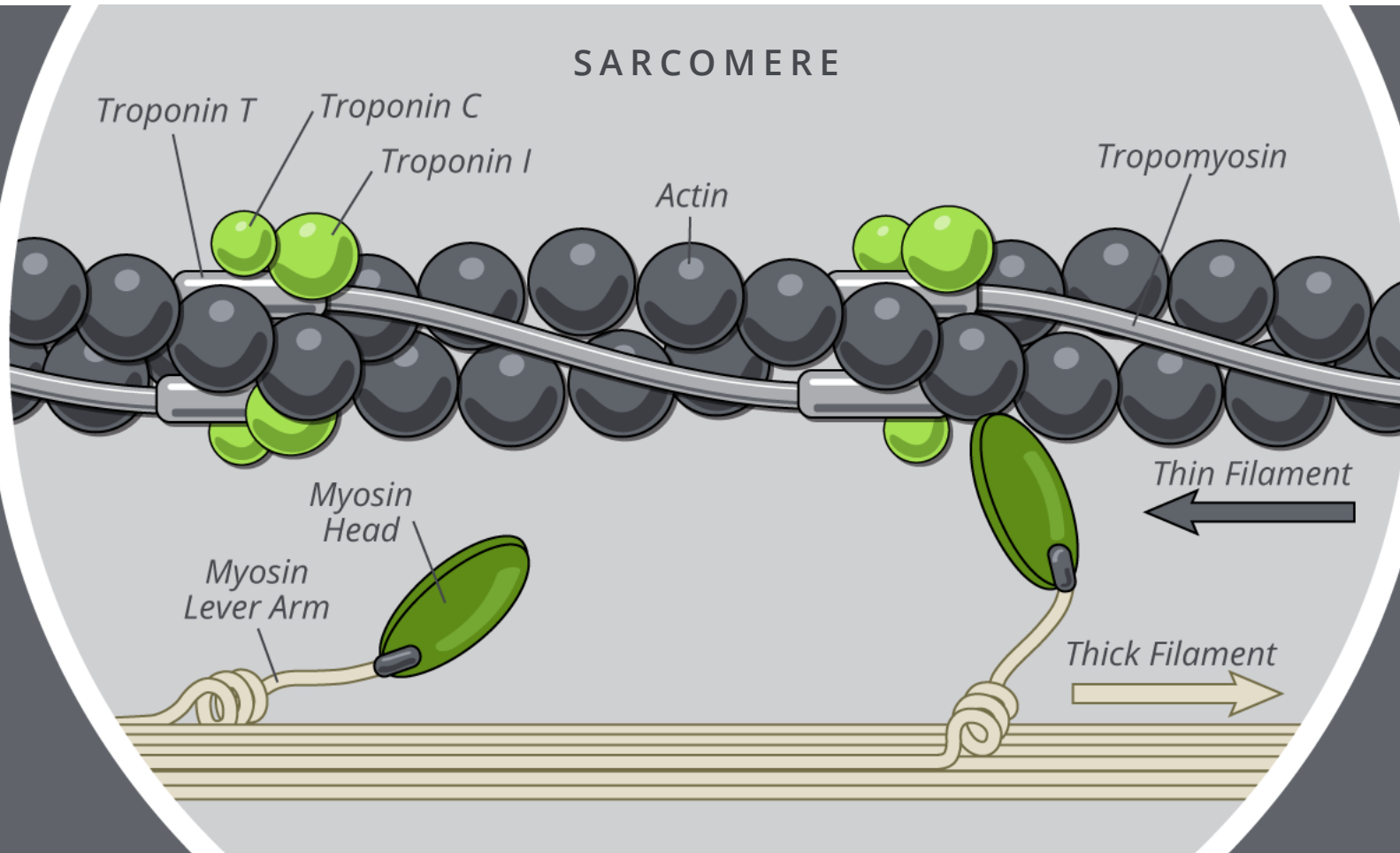
*Omecamtiv  
Mecarbil*

## INHIBIT MYOSIN

CK-274

## ACTIVATE TROPONIN

AMG 594



## ACTIVATE TROPONIN

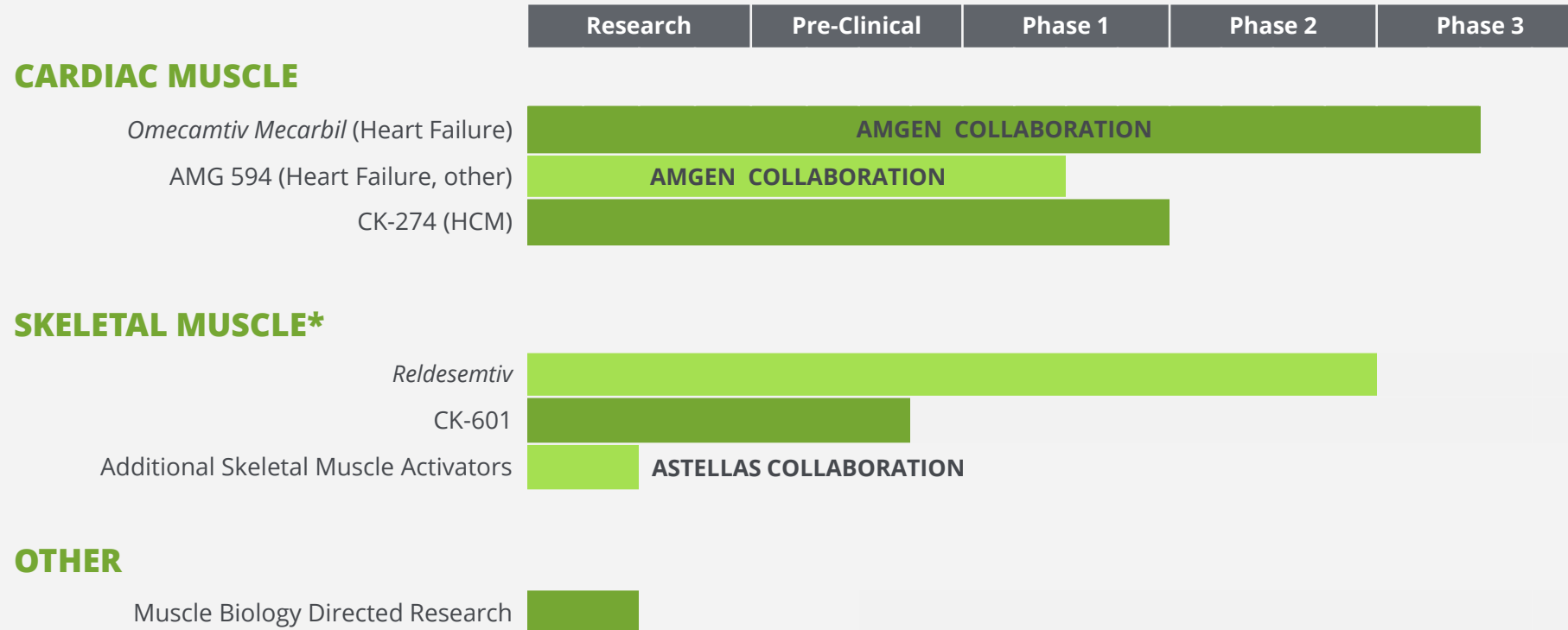
*Reldesemtiv*

## ACTIVATE TROPONIN

CK-601

S  
K  
E  
L  
E  
T  
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L

# Pipeline of Novel Muscle-Directed Compounds



*Investigational products – not approved as safe or effective for any indication.*  
\*Development of *tirasemtiv* has been suspended. A managed access program remains underway for patients who completed participation in VITALITY-ALS.



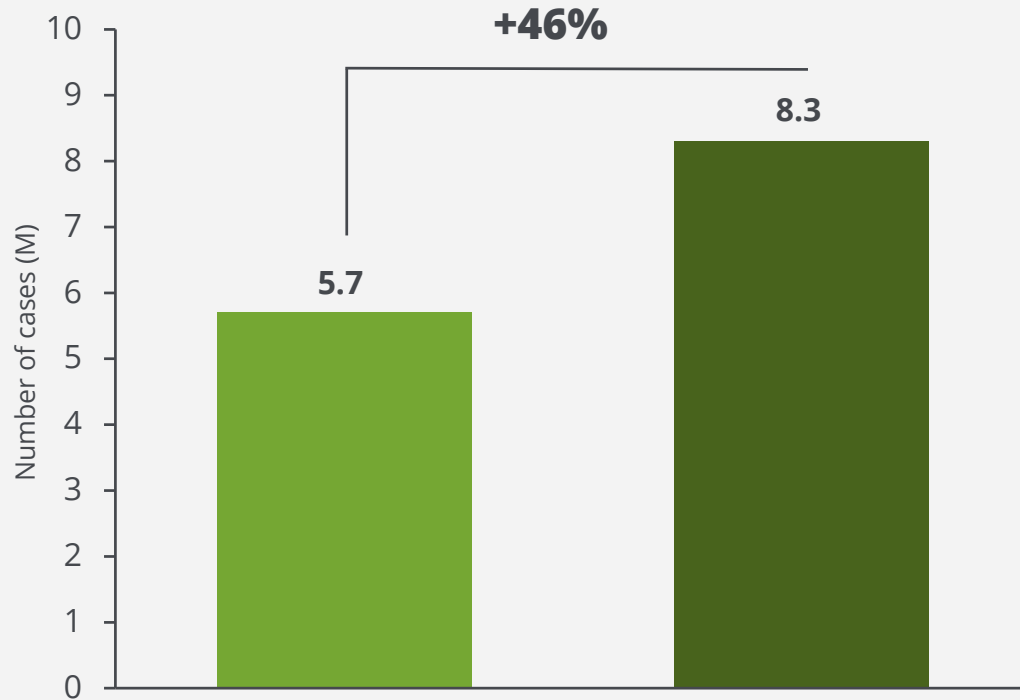
# CARDIAC MUSCLE

*Omecamtiv Mecarbil*  
CK-274



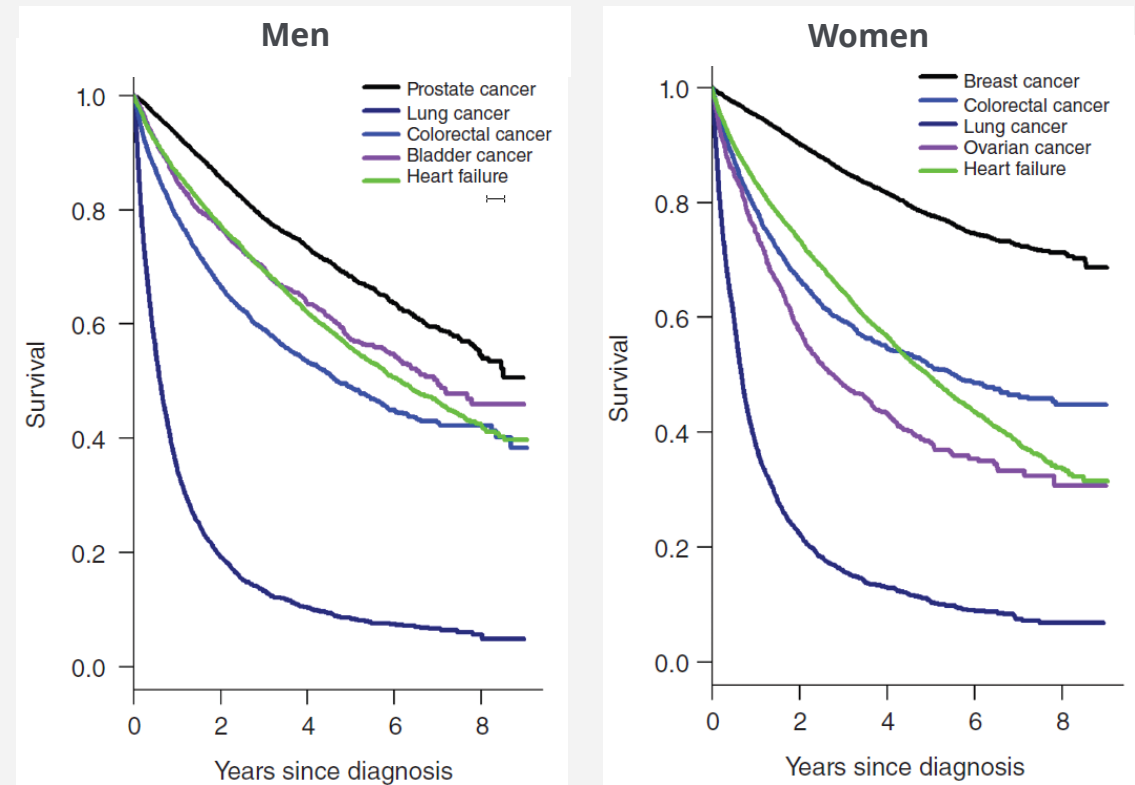
# Heart Failure: Growing Prevalence and Low Survival Rate

6M People Have HF; Prevalence Expected to Increase by 46% from 2012 - 2030



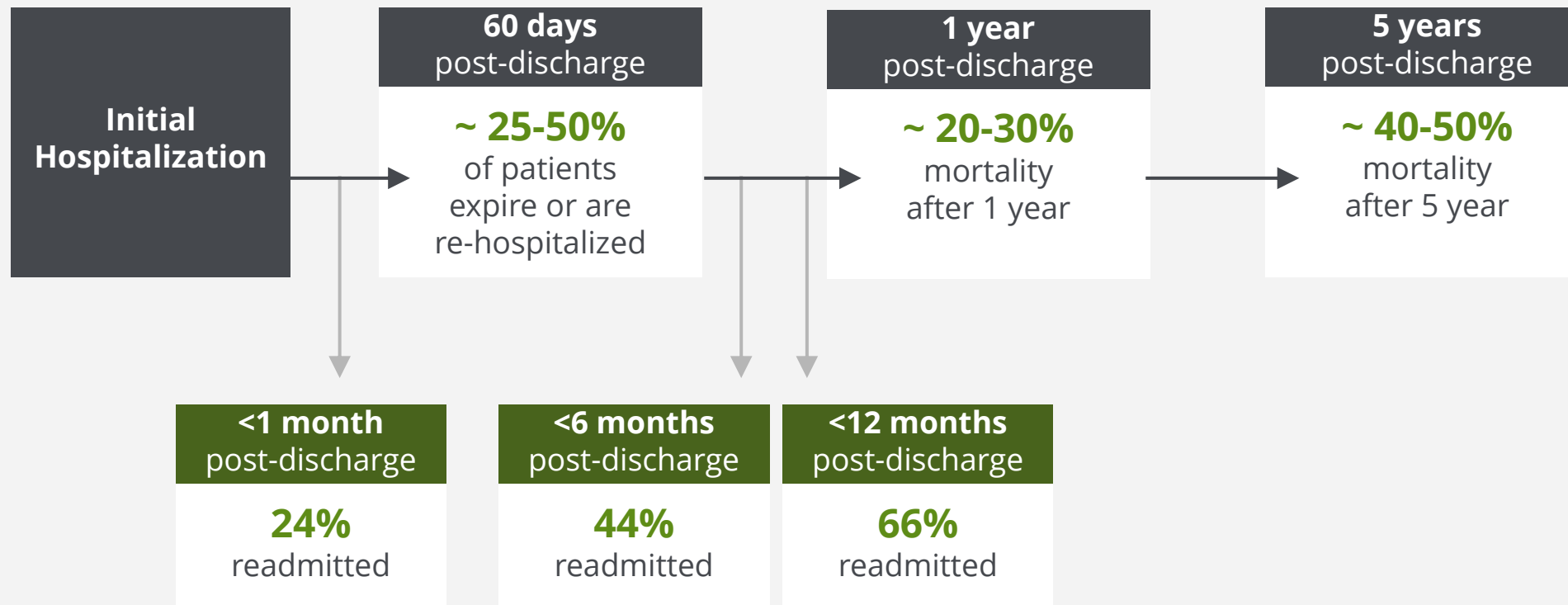
Mozzafarian, et al. *Circulation* 2016; 133: e38-360

HF Survival Rates Worse than Some Prevalent Cancers



Mamas MA, et al. Do patients have worse outcomes in heart failure than in cancer? *European Journal Heart Failure* 2017

# High Mortality and Hospital Readmission Rates



Mozzafarian, et al. *Circulation* 2016; 133: e38-360  
Shahar, et al. *J Card Fail* 2004 Oct 1;10(5):374-9.

Roger et al. *Circulation* 2012;125:32-220  
Chen et al. *JAMA* 2011;306:1669-78

Mamas et al. *Eur J Heart Fail.* 2017 Sep;19(9):1095-104.  
Adams et al. *Am Heart J* 2006; 149:209-16  
Dickstein et al. *Eur Heart J* 2008;29:2388-442

Whellan et al. *Circulation* 2010 Jan;3(1):33-40.  
Krumholz HM, et al. *Arch Intern Med* 1997;15799 - 105  
Loehr et al. *Am J Cardiol* 2008;101:1016-22

Acute heart failure is the most frequent cause of hospitalization in people > 65

1 of 2 hospitalized HF patients are readmitted within 6 months

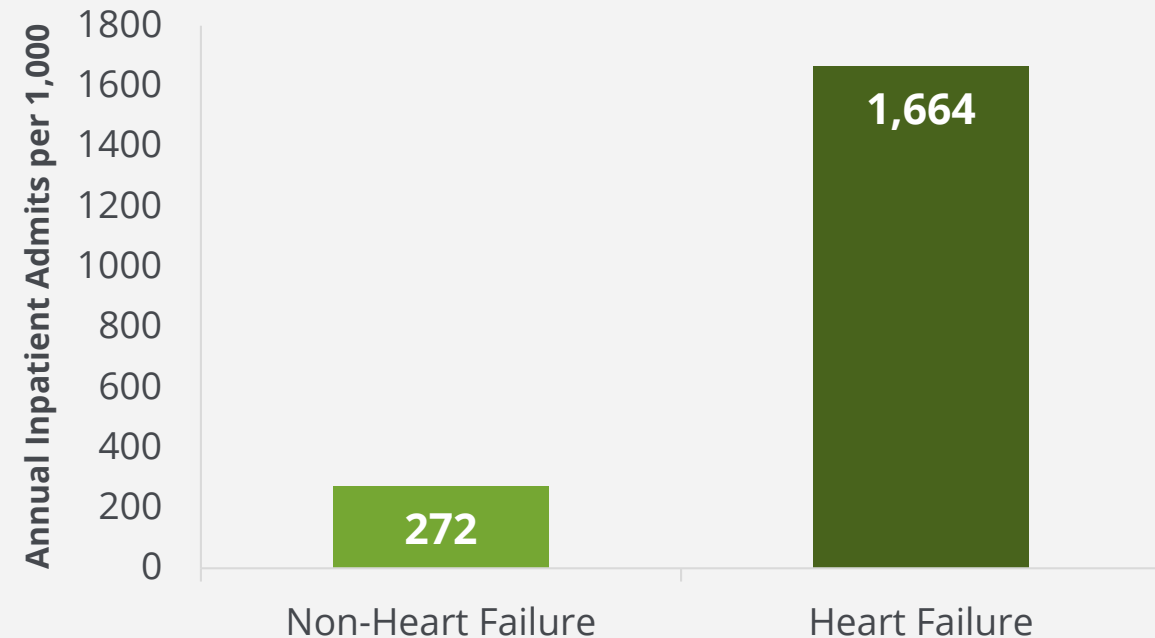


# High Economic Burden of Heart Failure

Heart failure costs ~\$123 billion annually, which represents **33% of total Medicare budget**

Heart failure is the most frequent diagnosis for hospitalized Medicare patients in the US

**Inpatient Admission Rates for HF Patients  
6X Higher than Non-HF Patients**



Source: Milliman Analysis of Medicare 5% Sample 2011-2012 (2012 index year, 2011 look back year)

Source: Milliman Analysis of Medicare 5% Sample (2014 index year, 2013 look back year) and Office of the Actuary 2016 Board of Trustees Report. The costs only include Part A & B costs.

# Significant Unmet Need in Heart Failure with Reduced Ejection Fraction

## Reduction in mortality & hospital visits

Physicians say Entresto has prolonged survival, decreased hospital visits, but still **see need for other therapies that reduce mortality**

## Drugs that do not affect renal function

Most physicians recognize negative effect therapies such as aldosterone antagonists have **on renal function**

## Drugs that do not affect BP

BP often limiting factor for up titration and therapy initiation;  
Need efficacious drugs **that do not result in hypotension**

## Drugs with molecular targets & inotropic agents

Need drugs that target **novel/more specific molecular targets**;  
Need targets other than the neurohormonal pathway;  
Need for inotropic drugs as support agents

## Disease modifying therapies

Need therapies **that offer contractile support**  
Increased EF most frequently mentioned desired measure

## Drugs that increase QoL

Patient management will improve **with drugs that increase QoL**;  
Patient QoL decreases as they lose the ability to perform daily tasks

Proprietary Market Research Suggests  
Need for Novel Therapy

# *Omecamtiv Mecarbil*: Clinical Trials Program

**11**

**Phase 1 Studies**

**324**

**Subjects Enrolled**

**Well characterized safety,  
tolerability and PK/PD data**

**Robust  
Clinical  
Trials  
Program**

**7**

**Phase 2 Studies**

**1,414**

**Subjects Enrolled**

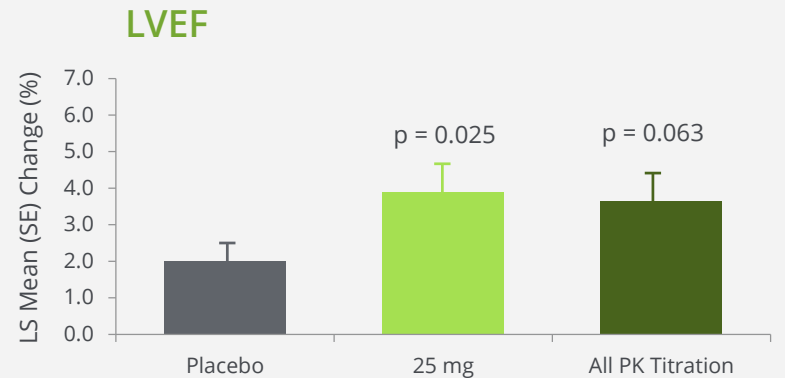
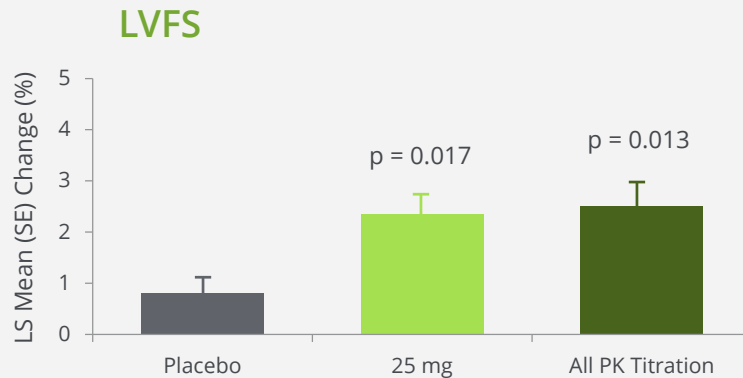
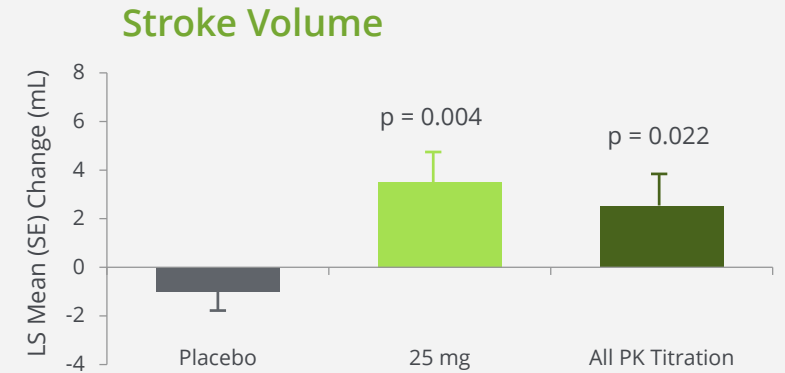
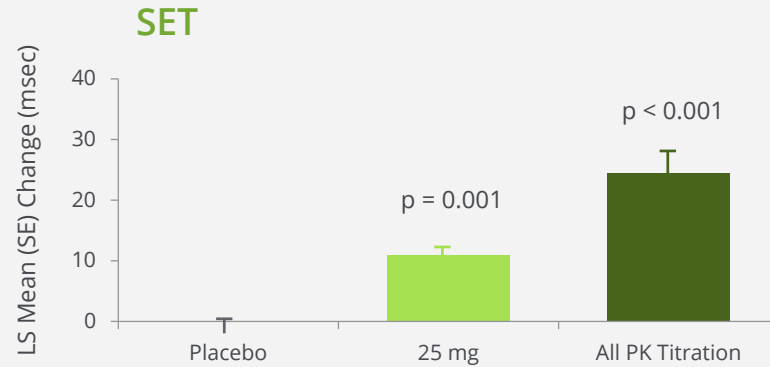
**COSMIC-HF showed statistically  
significant improvements in  
measures of cardiac function**



# Dose-Dependent Increases Observed in Cardiac Output

## Pharmacodynamic Data Observed in COSMIC-HF

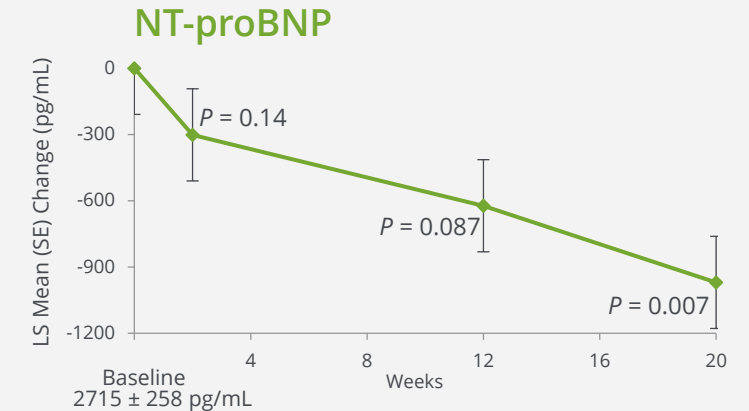
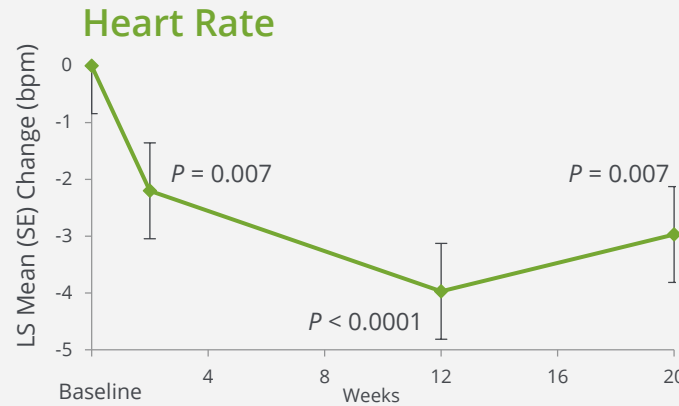
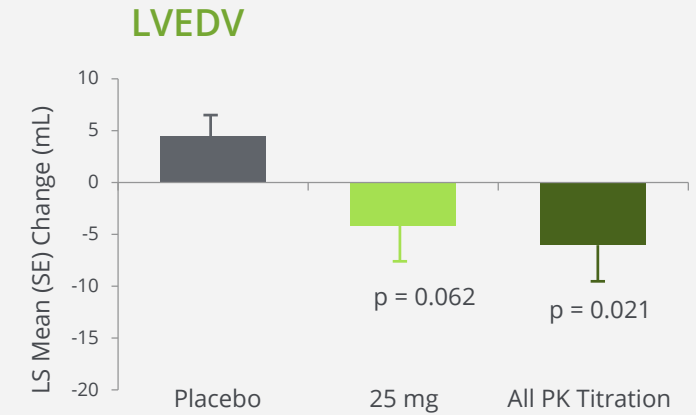
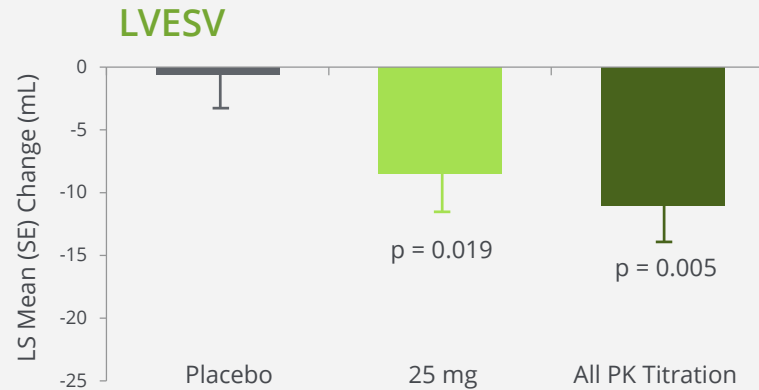
LVEF, left ventricular ejection fraction; LVFS, left ventricular fractional shortening; SE, standard error; SET, systolic ejection time; all p values are nominal without multiplicity adjustment.



# Decreases Observed in Physiology & Cardiac Risk

Reductions in Heart Volume, Oxygen Demand & Wall Stress Observed in COSMIC-HF

LVESV left ventricular end systolic volume  
LVEDV left ventricular end diastolic volume  
All p values are nominal without multiplicity adjustment



# Prognostic Implications: NT-proBNP and Remodeling

## Prognostic Implications of Changes in N-Terminal Pro-B-Type Natriuretic Peptide in Patients With Heart Failure

Michael R. Zile, MD,<sup>a</sup> Brian L. Claggett, PhD,<sup>b</sup> Margaret F. Prescott, PhD,<sup>c</sup> John J.V. McMurray, MD,<sup>d</sup> Milton Packer, MD,<sup>e</sup> Jean L. Rouleau, MD,<sup>f</sup> Karl Swedberg, MD,<sup>g</sup> Akshay S. Desai, MD,<sup>b</sup> Jianjian Gong, PhD,<sup>c</sup> Victor C. Shi, MD,<sup>c</sup> Scott D. Solomon, MD,<sup>c</sup>



### ABSTRACT

**BACKGROUND** Natriuretic peptide levels predict outcomes in patients with heart failure. The purpose of this study was to quantitatively assess the relationship between therapy-induced changes in left ventricular (LV) remodeling and longer-term outcomes in patients with left ventricular dysfunction (LVD).

**OBJECTIVES** The authors assessed the prognostic implications of a decrease in HF hospitalization and mortality.

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doi:10.1016/j.jacc.2010.05.011

### QUARTERLY FOCUS ISSUE: HEART FAILURE

## Quantitative Evaluation of Drug or Device Effects on Ventricular Remodeling as Predictors of Therapeutic Effects on Mortality in Patients With Heart Failure and Reduced Ejection Fraction A Meta-Analytic Approach

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Boston, Massachusetts

### Objectives

The purpose of this study was to quantitatively assess the relationship between therapy-induced changes in left ventricular (LV) remodeling and longer-term outcomes in patients with left ventricular dysfunction (LVD).

### Background

Whether therapy-induced changes in left ventricular ejection fraction (LVEF), end-diastolic volume (EDV), and end-systolic volume (ESV) are associated with mortality in patients with LVD is not established.

Zile et al. JACC 2016; 68(22): 2425-2436 Kramer et al. JACC 2010;56(5):392-406

Analysis of PARADIGM-HF showed decreases from baseline in NT-proBNP were strongly correlated with reductions in combined endpoint of time to first HF hospitalization or CV death

Meta-analysis of 30 mortality trials of 25 drugs/device therapies found that in patients with left ventricular dysfunction, short-term therapeutic effects of a drug or device on left ventricular remodeling were associated with longer-term effects on mortality





# Phase 3 Clinical Trial Completed Enrollment

## Study Overview

- Enrolled over 8,200 patients at ~1,000 sites in 35 countries

## Primary endpoint

- Composite of time to CV death or first HF event\*, whichever occurs first

## Secondary endpoints

- Time to CV death
- Change in Kansas City Cardiomyopathy Questionnaire Total Symptoms Score (KCCQ TSS) from baseline to Week 24
- Time to first HF hospitalization
- Time to all-cause death

\*An HF event defined as the presentation of the subject for an urgent, unscheduled clinic/office/ED visit, or hospital admission, with a primary diagnosis of HF, where the patient exhibits new or worsening symptoms of HF on presentation, has objective evidence of new or worsening HF, and receives initiation or intensification of treatment specifically for HF (Hicks et al, 2015). Changes to oral diuretic therapy do not qualify as initiation or intensification of treatment.

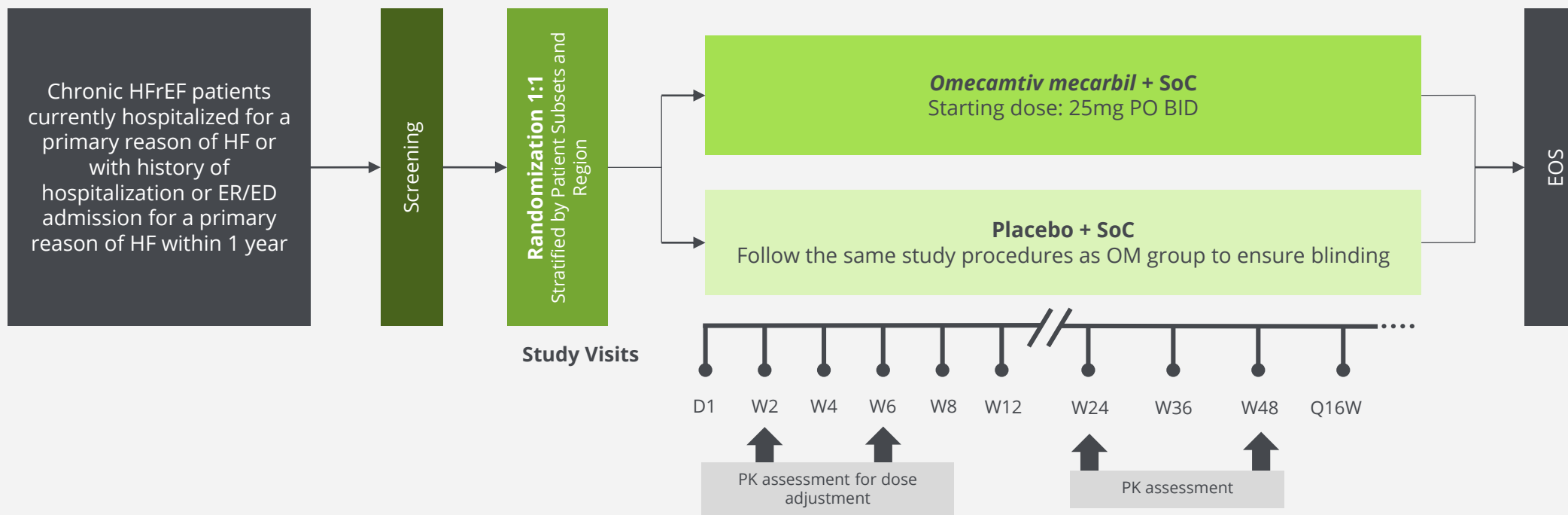
## Key Design Points

- Dose optimization based on trough concentration of *omecamtiv mecarbil* at 2 weeks and 6 weeks
  - Starting Dose = 25 mg BID
  - Escalation (or not) at Week 4 to 37.5 mg or 50 mg BID based on plasma concentration of *omecamtiv mecarbil* at Week 2
  - Recheck at Week 6, adjust dose downward if necessary
- Enroll patients from time of hospitalization to within 1 year of discharge
  - In-hospital enrollment target is approximately 25% of total enrollment
  - Stratify on randomization setting
- Event driven with 90% power based on secondary endpoint of CV Death

GALACTIC-HF  
Continuing  
Following Planned  
Interim Analysis  
Conducted by DMC  
  
Second Interim  
Analyses Expected  
in Q1 2020

# Clinical Trial Overview

2 years enrollment, approx. 4 years total follow-up/study period





# Second Phase 3 Clinical Trial Underway

## Primary endpoint

- Change in peak  $\text{VO}_2$  on CPET from baseline to Week 20

## Secondary endpoints

- Change in total workload during CPET from baseline to Week 20
- Change in ventilatory efficiency ( $V_E/V_{\text{CO}_2}$  slope) during CPET from baseline to Week 20
- Change in the average daily activity units measured over a 2 weeks from baseline to Week 18-20

## Exploratory Endpoints

- Change from baseline to Week 20 in oxygen uptake efficiency slope ( $\text{VO}_2/\log V_E$  slope), ventilatory threshold (by the V-slope method),  $\text{VO}_2$  recovery kinetics, percent predicted  $\text{pVO}_2$ , and exercise duration
- Change from baseline in the average daily activity units at Week 6-8 and at Week 12-14
- Change from baseline in the KCCQ Total Symptom Score and its sub-domains from baseline to Week 20

$\text{VO}_2$  = Oxygen Uptake; CPET = Cardio-Pulmonary Exercise Testing;  $V_E$  = Ventilatory Efficiency

## Multicenter Exercise Tolerance Evaluation of *Omecamtiv Mecarbil* Related to Increased Contractility in Heart Failure

### 9 Countries in North America & Europe

#### METEORIC-HF Steering Committee:

Greg Lewis (Co-lead, US)

Michael Felker (Co-lead, US)

John Teerlink (US)

David Whellan (US)

Justin Ezekowitz (Canada)

Adriaan Voors (Netherlands)

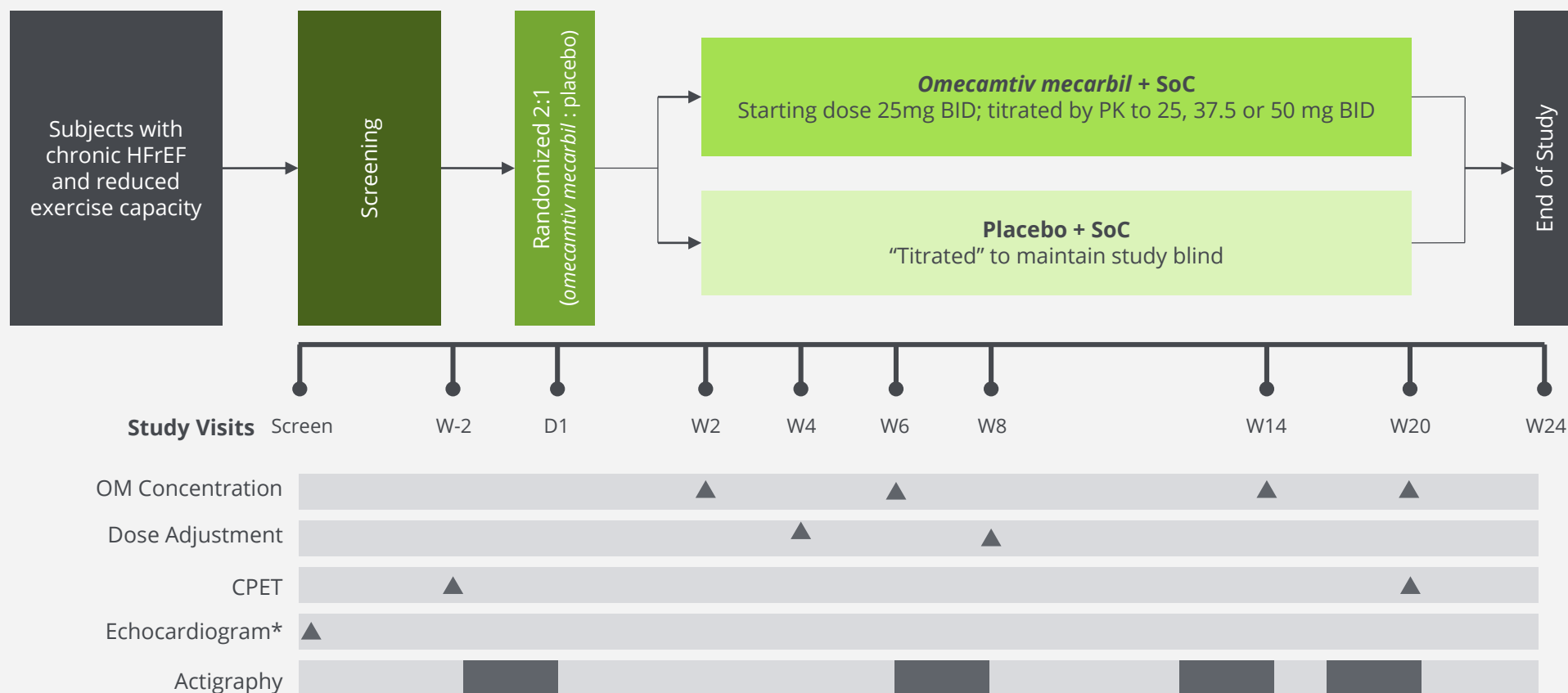
Alain Cohen-Solal (France)

Piotr Ponikowski (Poland)

Michael Böhm (Germany)

Marco Metra (Italy)

# Clinical Trial Overview



~270 subjects  
90% power

5 months of  
treatment (same as  
COSMIC-HF)

Dose titration of  
*omecamtiv mecarbil*  
same as  
GALACTIC-HF

\* Screening echocardiogram is not required if an appropriate LVEF assessment has been performed within one year

# Collaborations & Agreements

## Amgen Collaboration

Purchase Option: 2006  
Exercise Option Ex-Japan: 2009  
Expanded to Include Japan/Purchase Equity: 2013  
**Received >\$220M over 12 Years**

**Amgen** responsible for development and commercialization subject to Cytokinetics' participation rights\*

**Cytokinetics** could earn over \$600 mm in milestone payments

\*Servier has a sub-license from Amgen to commercialize *omecantiv mecarbil* in Europe and certain other countries.

### COMMERCIALIZATION:

- Cytokinetics may receive escalating double-digit royalties
- Cytokinetics to co-fund Phase 3 development program
- Co-fund enables co-promote NA
- Cytokinetics reimbursed for certain sales force activities

## Royalty Pharma Agreement

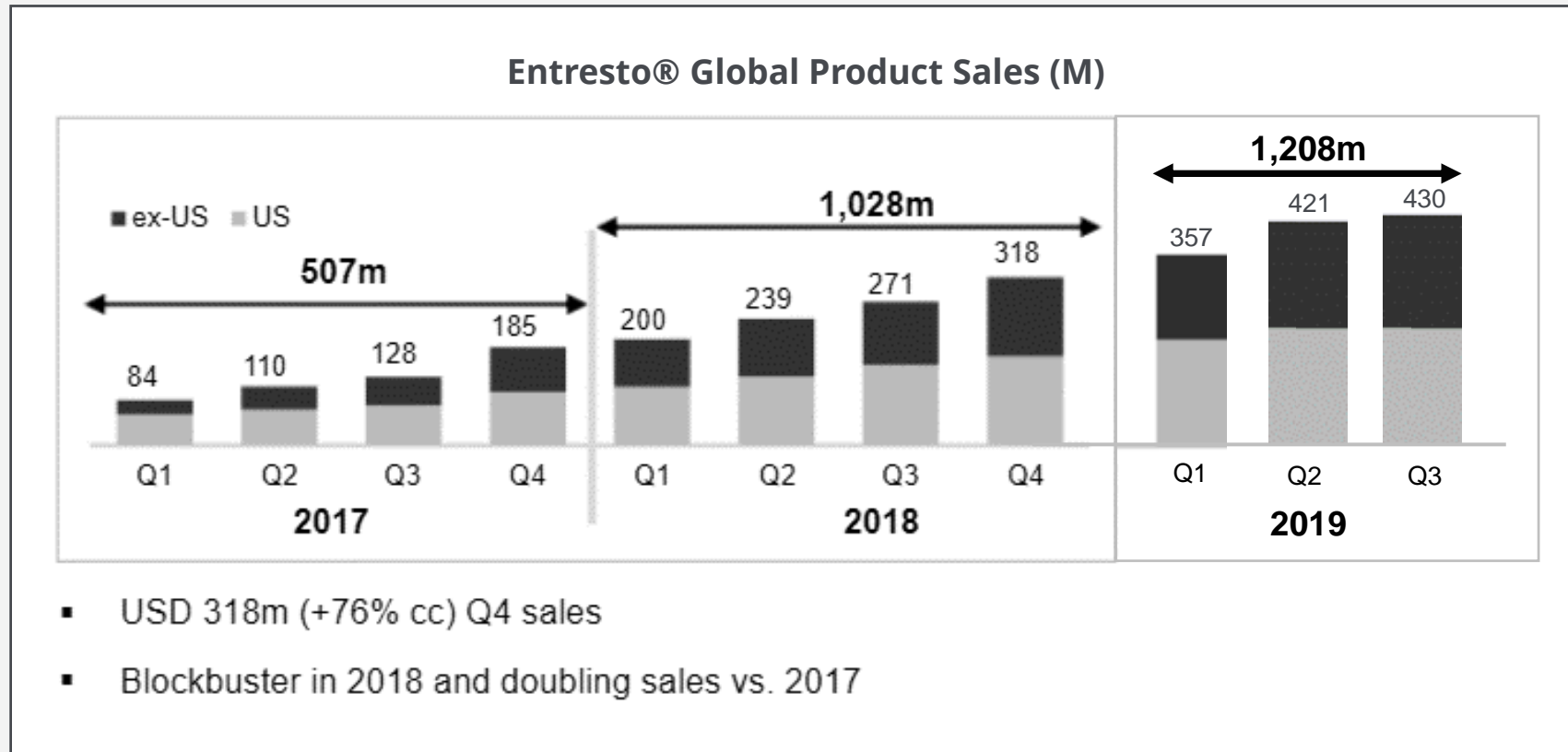
**Paid \$100M for 4.5% royalty on worldwide sales of *omecantiv mecarbil*: 2017**

**Cytokinetics** gains right to co-promote *omecantiv mecarbil*, if approved, in institutional care settings in North America, with reimbursement from Amgen for certain sales force activities

**Joint commercial** operating team responsible for commercialization program

- Royalty rate may increase up to additional 1% associated with timing of US approval
- Cytokinetics agreed to exercise option to co-invest \$40M in Ph 3 development program in exchange for up to incremental 4% royalty on increasing worldwide sales outside of Japan
- Cytokinetics retains right to receive >\$600M in additional potential milestone payments and escalating double-digit royalties that may exceed 20% on tiered worldwide sales outside Japan; lower royalty rate in Japan

# Commercial Opportunity for New Heart Failure Therapy



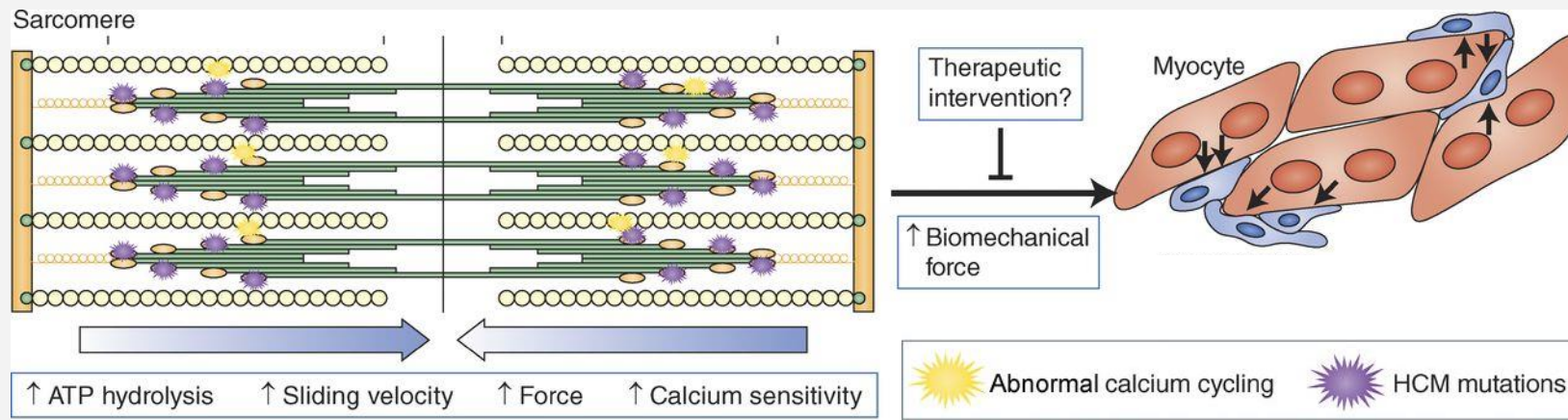
Sources: Novartis Q4 and FY18 results presentation, January 2019; Novartis Q1 2019 results presentation, April 2019; Novartis Q2 2019 results presentation, July 2019; Novartis Q3 2019 results presentation, October 2019

\*As with all products in P3, the product profile achieved by omecamtiv mecarbil in GALACTIC-HF is required to provide a better understanding of the expected revenue.



# HCM: Lack of Therapy Targeting Underlying Disease Biology

## HCM is a Disease of the Sarcomere



Teekakirikul et al., JCB 2012

### Current Medical Therapy:

- Indirect mechanisms of action with systemic side effects
- Variable efficacy, often inadequate
- Treatment failure means resorting to surgical myomectomy or percutaneous ablation

# CK-274: Potential Next-In-Class Cardiac Myosin Inhibitor

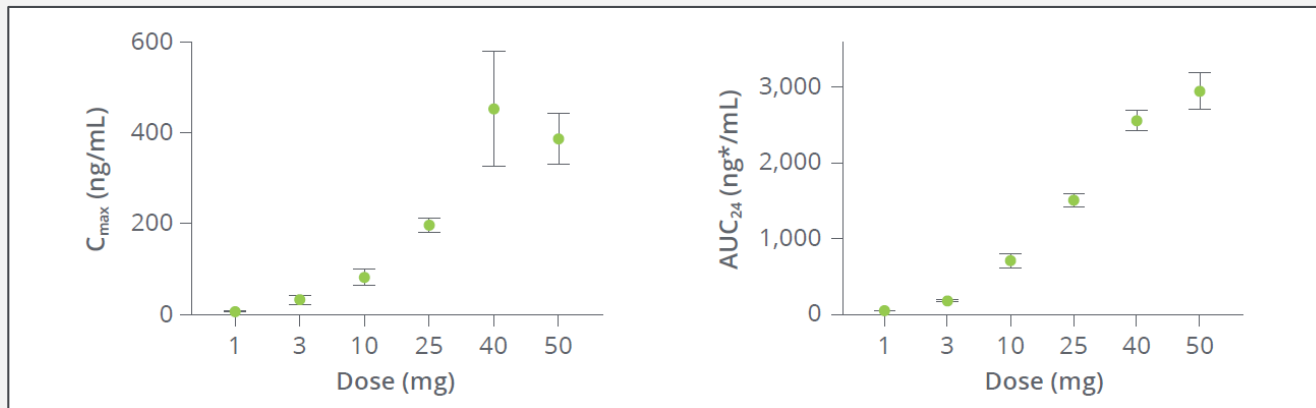
- Favorable pharmacokinetic / pharmacodynamic properties and other candidate selection criteria
  - Selective allosteric inhibitor of cardiac myosin
  - Potential *in vivo* pharmacodynamic advantages related to distinctive binding
  - No inhibition of smooth muscle myosin observed
  - Favorable ADME properties with no significant CYP inhibition or CYP induction observed
  - Favorable oral bioavailability observed across pre-clinical species
    - Favorable permeability observed without efflux
  - Clear pharmacokinetic/pharmacodynamic (PK/PD) relationship observed
  - **Projected once daily dosing to reach steady state rapidly in patients**
  - **Shallow dose response curve seen in pre-clinical/clinical studies may translate to favorable therapeutic window in patients, broaden clinical utility**

Discovered by  
Company Scientists  
Independent of  
Collaborations

Selected from  
Multiple Potential  
Development  
Candidates (PDCs)

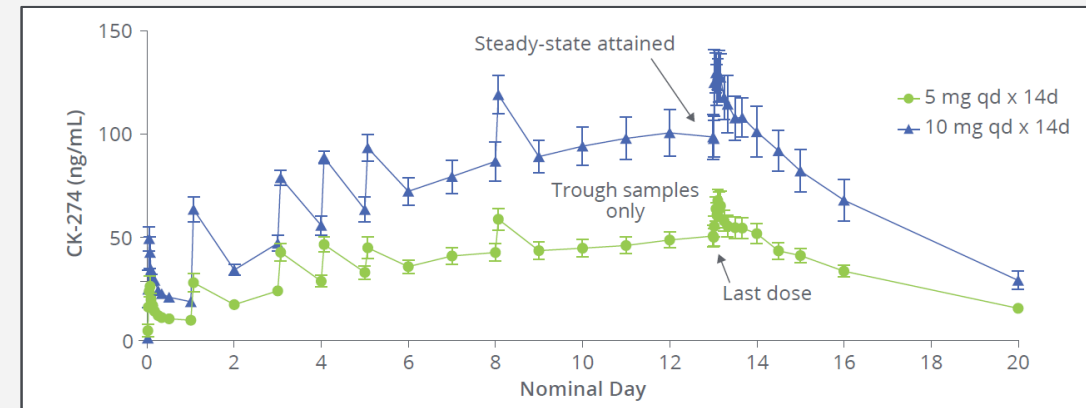
# Phase 1 Study: SAD & MAD Pharmacokinetics

## SAD Pharmacokinetics Appeared Generally Dose Proportional



Data points represent mean  $\pm$  standard error of the mean.  
 $C_{max}$ , maximum drug plasma concentration;  $AUC$ , area under the plasma concentration curve;  
SAD, single ascending dose.

## Steady-State Appeared Evident After 14 Days of Dosing



Data points represent mean  $\pm$  standard error of the mean.  
d, day; qd, once daily.

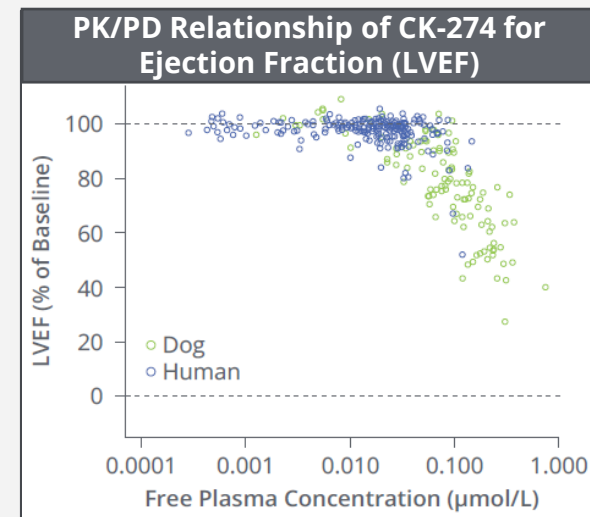
# Phase 1 Study: MAD Pharmacokinetic Parameters

Half-Life of CK-274 at Steady-State was ~81 hours (3.4 days) On Average

Shallow Exposure-Response Relationship Observed Preclinically Appears to Have Translated to Humans, May Enable Flexible Dose Optimization in Humans

Dose (n)	PK Parameter, Geometric Mean (%CV)*				
	C <sub>max</sub> (ng/mL)	t <sub>max</sub> (h)	AUC <sub>24</sub> (ng•h/mL)	t <sub>1/2</sub> (h)	AR
5 mg (6)	69 (23.2%)	2.75 (1.5–4)	1,320 (23.0%)	86.3 (11.9)	4.71
7.5 mg (6)	148 (39.5%)	1.0 (0.5–5)	2,518 (25.8%)	76.9 (14.5)	4.50
10 mg (6)	141 (19.7%)	2.5 (0.5–3)	2,631 (22.8%)	79.7 (14.1)	4.79

\* Except data for t<sub>max</sub> shown as median (minimum-maximum), and t<sub>1/2</sub> shown as the arithmetic mean (standard deviation). AR (accumulation ratio) calculated as (AUC<sub>24</sub> on Day 14 or 17)/(AUC<sub>24</sub> on Day 1). %CV, percent coefficient of variation; C<sub>max</sub>, maximum plasma concentration; AUC<sub>24</sub>, area under the plasma concentration curve; MAD, multiple ascending dose; t<sub>1/2</sub>, apparent plasma terminal elimination half-life; t<sub>max</sub>, time to maximum observed plasma concentration.

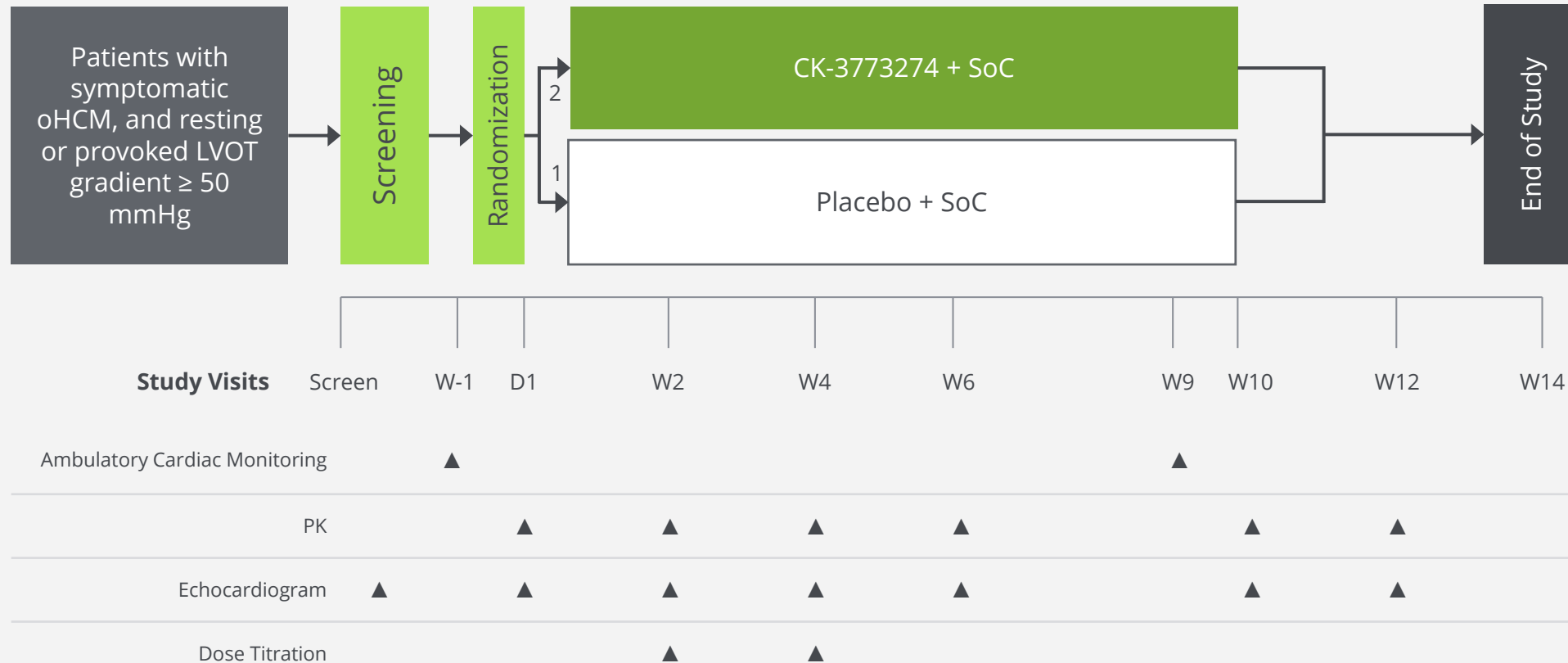


- Graphs show LVEF as a function of exposure; data points represent observed values in dogs and humans
- Decrease in LVEF as function of exposure is similar in humans and dogs

# CK-274: Phase 1 Data Support Progression to Phase 2

- CK-274: well tolerated in healthy participants; no SAEs; no clinically meaningful changes in vital signs, ECGs, or lab tests
- Criteria for stopping dose escalation were reached after single dose of 75 mg and after 14 days of a daily 10 mg dose
- Decreases in ejection fraction below 50% readily reversible within 6 hours following single doses, within 24-48 hours following 14 days of dosing
- Pharmacokinetics ( $C_{max}$  and  $AUC_{24}$ ) generally dose linear; steady-state appeared evident after 14 days of daily dosing
- Shallow exposure-response relationship observed preclinically appears to have translated to humans and may enable flexible dose optimization in humans
- Phase 1 data support progression into placebo-controlled, double-blind Phase 2 study in patients with oHCM who:
  - Remain on their background therapy for HCM
  - Can undergo echo-guided dose titration every 2 weeks

# REDWOOD-HCM: Phase 2 Clinical Trial Design



REDWOOD-HCM  
Expected to Begin  
in Q4 2019

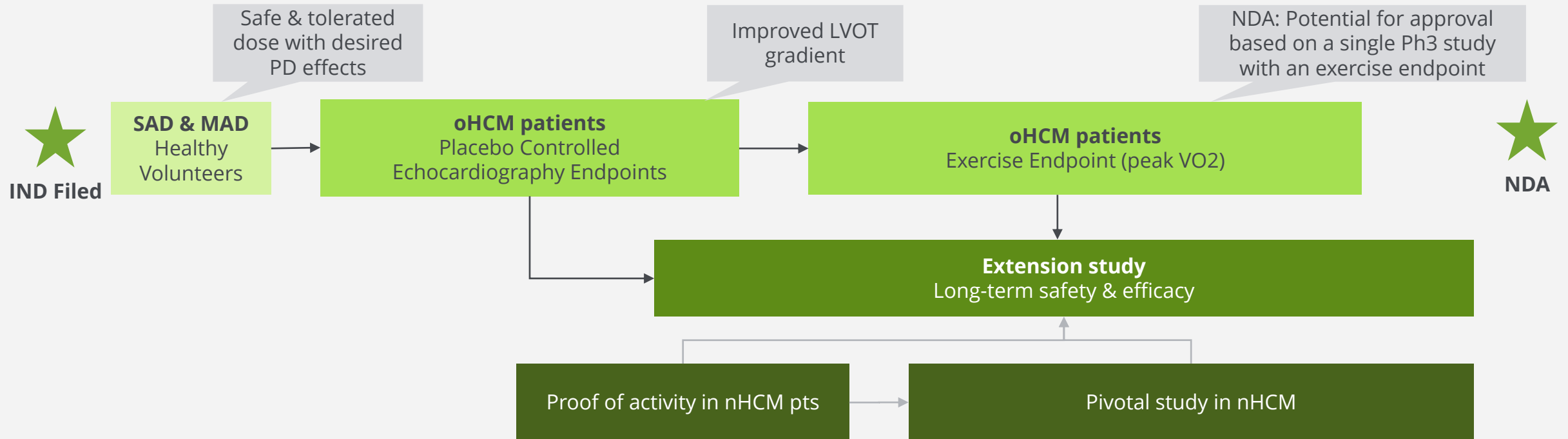


# CK-274: Clinical Development Plan for HCM

**Phase 1**  
Safety, PK & PD

**Phase 2**  
Proof of Concept, Dose Finding

**Phase 3**  
Pivotal Studies



# Cardiac Muscle: Upcoming Milestones

Continue to Conduct GALACTIC-HF through 2019;  
Expect Second Interim Analyses in Q1 2020

Continue Enrollment in METEORIC-HF Through 2019

Expect to Initiate REDWOOD-HCM in Q4 2019

Continue to Conduct Phase 1 Study of AMG 594 through 2019

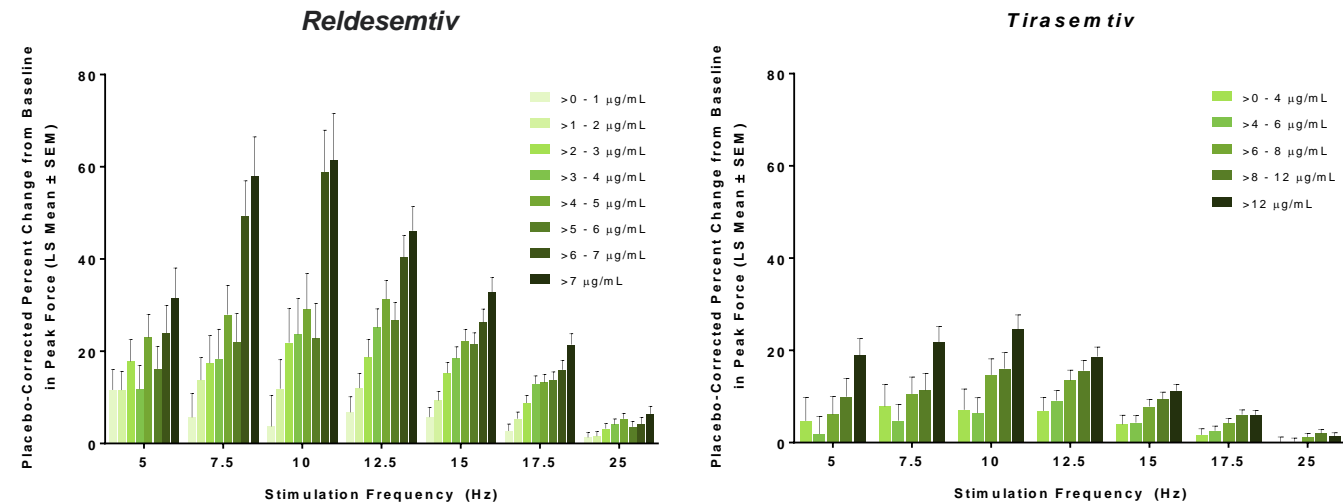
# SKELETAL MUSCLE

*Reldesemtiv*



# *Reldesemtiv*: Potentially More Potent, Well Tolerated Than *Tirasemtiv*

- *Reldesemtiv* increased the force generated by the tibialis anterior muscle versus placebo in response to nerve stimulation in a dose, plasma concentration, and frequency-dependent manner
- The overall largest increase from baseline in peak force, compared to placebo, was **58.7** (10.2)% (least-squares mean [SE]) at a stimulation frequency of 10 Hz
- The largest response *tirasemtiv* produced in a comparable study was a **24.5** (3.1)% increase in peak force at 10 Hz
- Single doses of *relde**semtiv* were well-tolerated in healthy volunteers at doses up to 4000 mg. No SAEs were reported, AEs were mild or moderate



## Results from Three Phase 1 Studies of *Reldesemtiv* Published in *Muscle & Nerve*

Andrews JA, Miller TM, Vijayakumar V, Stoltz R, James JK, Meng L, Wolff AA, Malik FI. CK-2127107 amplifies skeletal muscle response to nerve activation in humans. *Muscle & Nerve*. 2017 Nov 18.

For informational purposes only: no head-to-head studies have been conducted comparing *relde**semtiv* to *tirasemtiv*. Differences between the two studies may limit the conclusions that can be drawn from comparisons.

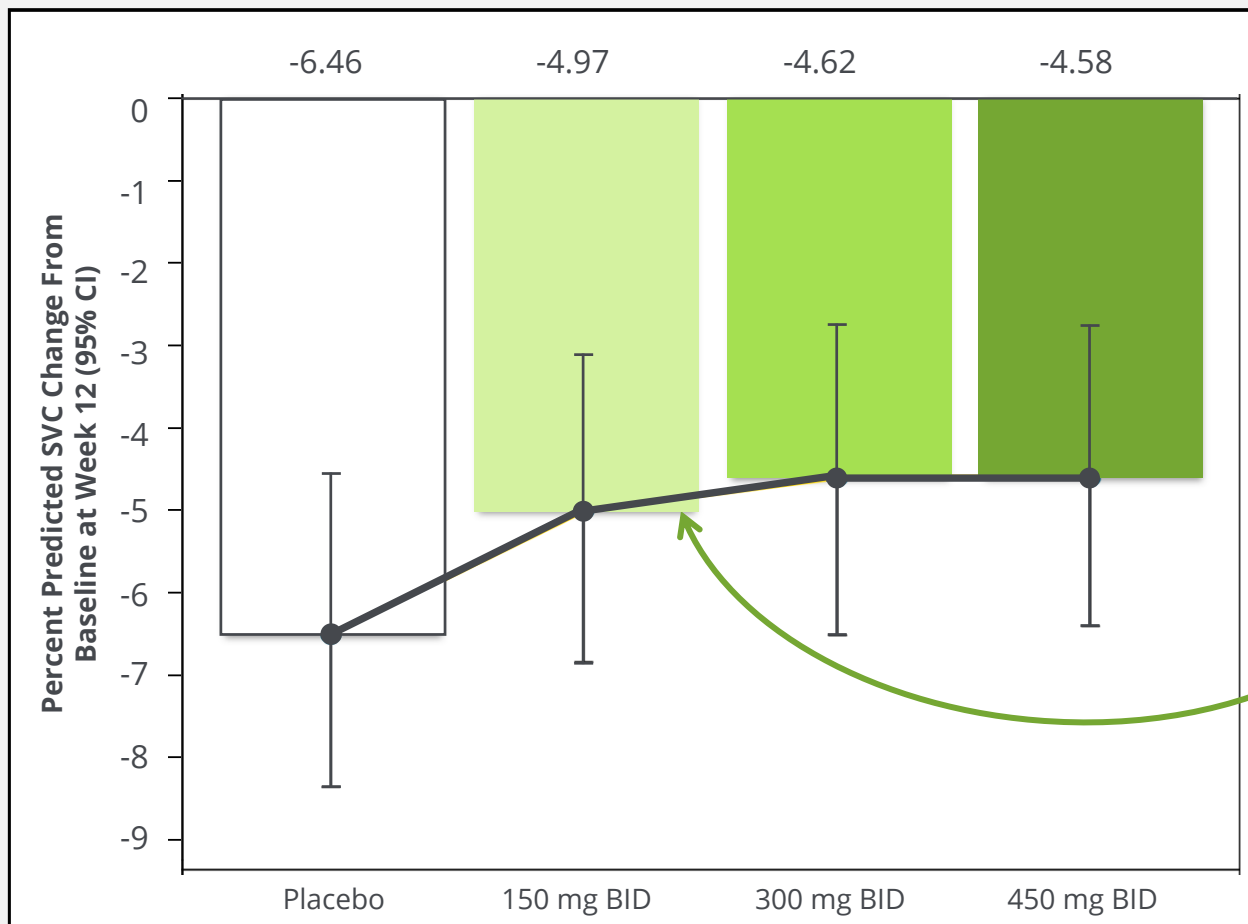
# Phase 2 Clinical Trial in ALS



**F**unctional  
**O**utcomes in a  
**R**andomized  
**T**rial of  
**I**ncvestigational  
**T**reatment with CK-107  
to **U**nderstand  
**D**ecline in  
**E**ndpoints in  
**ALS**

Parallel group, dose ranging study enrolling 450 patients with ALS in the US and Canada, evaluating change from baseline in the percent predicted slow vital capacity (SVC) at 12 weeks of treatment with *reldesemtiv* or placebo

# Primary Endpoint: SVC



## Primary Analysis

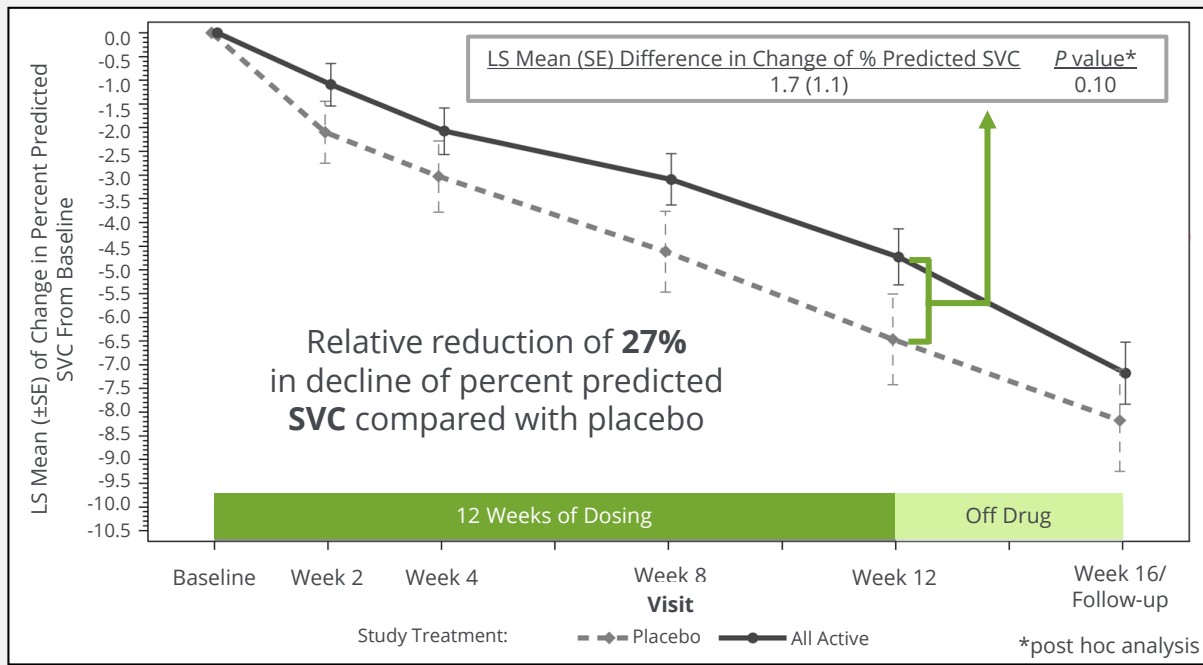
$P = 0.11$   
for weighted  
dose-response  
relationship\*

Change from  
Baseline in  
Percent  
Predicted SVC  
at Week 12

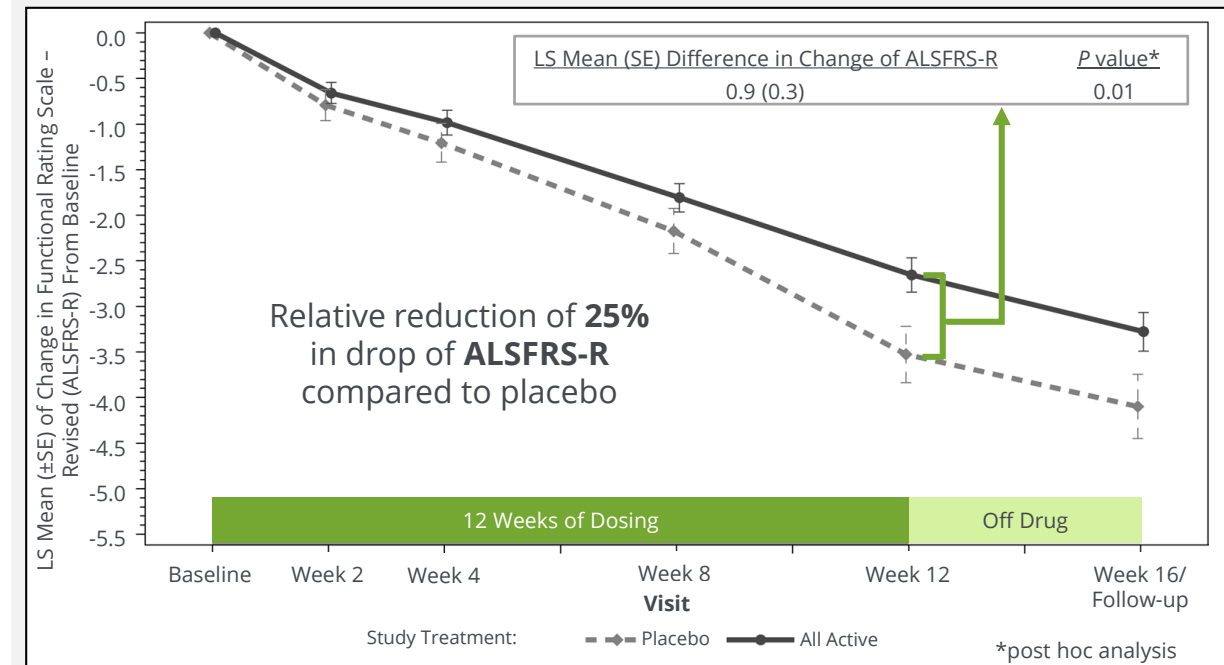
\*Based on Mixed Model for Repeated Measures (MMRM) with the contrasts of (-5, -1, 3, 3) for placebo, reldesemtiv 150 mg, 300 mg and 450 mg BID, respectively

# Change From Baseline: All Active vs Placebo\*

## SVC Change From Baseline (All Active vs Placebo)



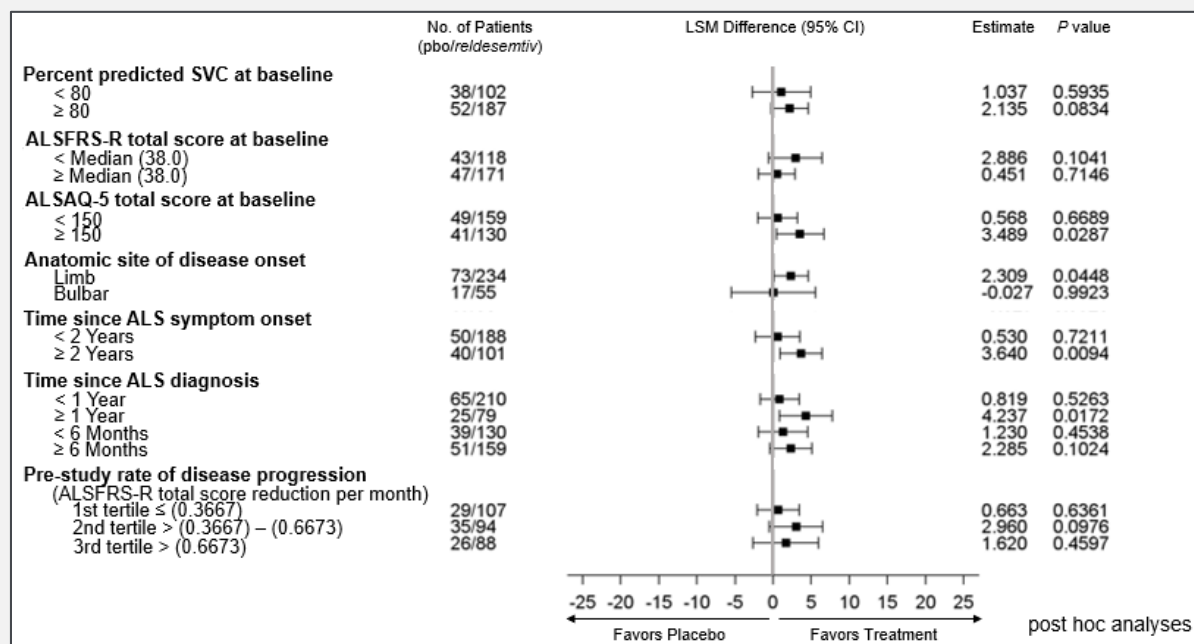
## ALSFRS-R Change From Baseline (All Active vs Placebo)



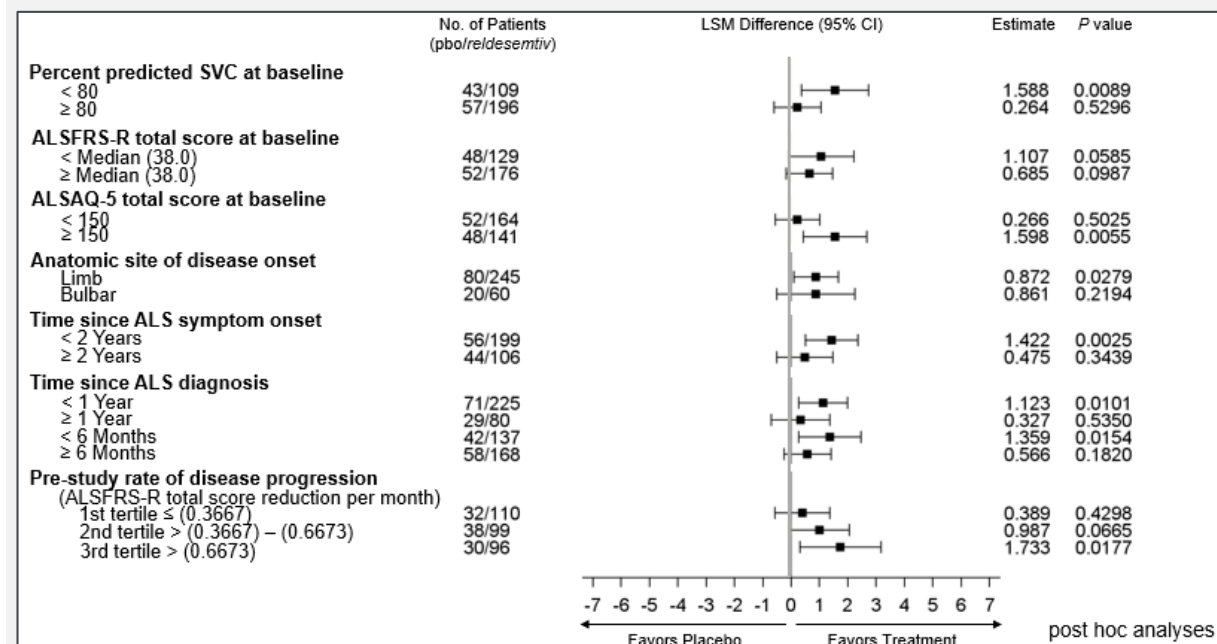
\*FORTITUDE-ALS did not achieve statistical significance, but patients on all dose groups of *rel-desemtiv* declined less than patients on placebo

# Pre-Specified Subgroup Analyses\*

## Percent Predicted SVC



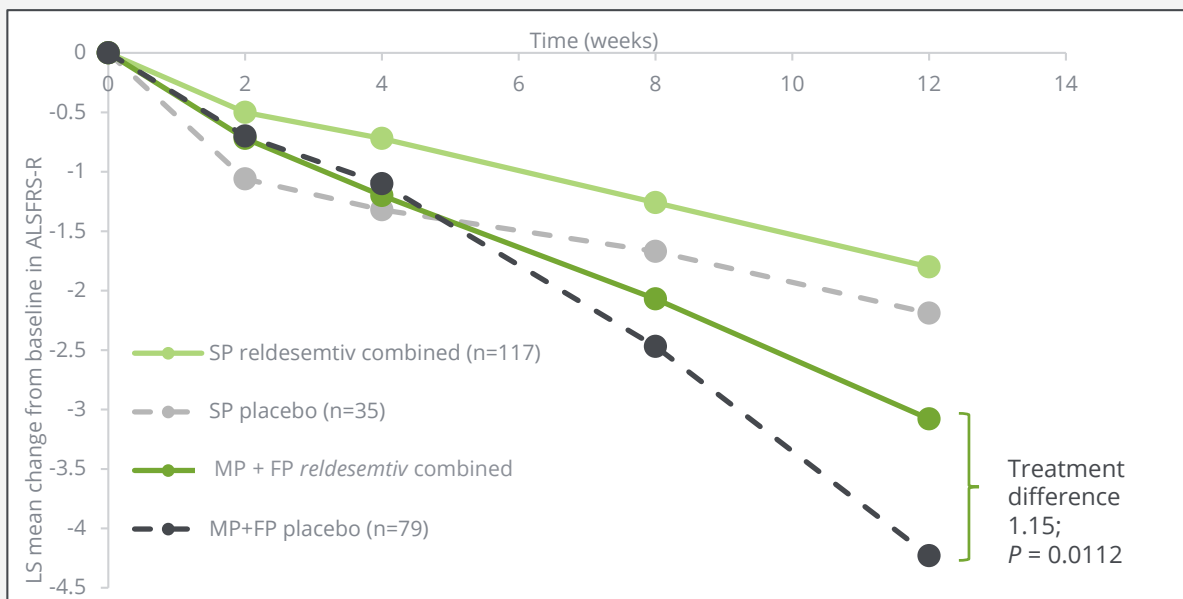
## ALSFRS-R Total Score



\*FORTITUDE-ALS did not achieve statistical significance, but patients on all dose groups of *reldesemtiv* declined less than patients on placebo

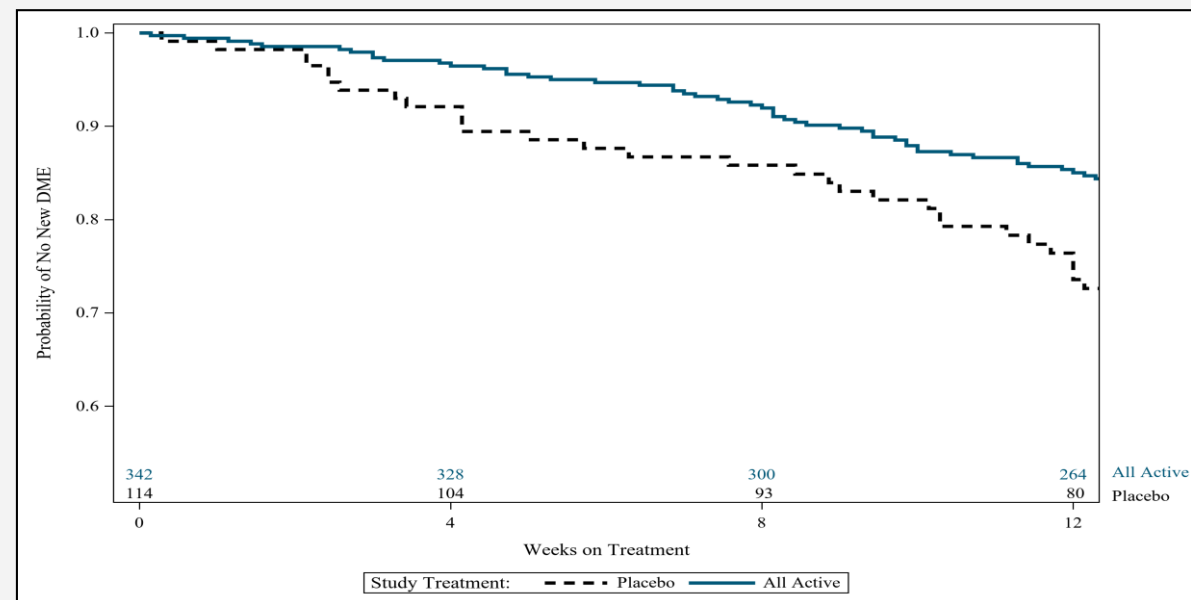


## Change From Baseline in ALSFRS-R by Progressor Tertiles



## Probability of No New DME Use Over Time With *Reldesemtiv*

(DME: Manual wheelchair, power wheelchair, NIV, Augmentative Language Device, PEG)



# CORPORATE **PROFILE**

# Cytokinetics Financing History

Strategic Partners  
and Institutional  
Investors Have  
Committed  
Approximately  
Equal Amounts of  
Capital to  
Cytokinetics

		Equity	Upfront Cash, Option, and Milestones	R&D Reimbur.	Total
Investors	Private Investors (VCs)	\$116M			
	IPO	\$94M			
	Public Post-IPO/Other	\$420M			
	<b>Total</b>	<b>\$630M</b>			<b>\$630M</b>
Strategic Partners & Grants	Astellas	\$10M	\$130M	\$92M	\$232M
	Amgen	\$43M	\$145M	\$40M	\$228M
	Royalty Pharma	\$10M	\$90M		\$100M
	GSK	\$24M	\$22M	\$33M	\$79M
	AstraZeneca			\$2M	\$2M
	MyoKardia			\$2M	\$2M
	Global Blood			\$2M	\$2M
	Grants (ALS Assoc / NINDS / other)		\$6M		\$6M
	<b>Total</b>	<b>\$87M</b>	<b>\$393M</b>	<b>\$171M</b>	<b>\$651M</b>

*Note: Figures above exclude current debt outstanding of \$45M.*

# Q3 2019 Condensed Balance Sheet

	9/30/19 (in millions)
Cash and investments	\$166.0
Other assets	<u>\$21.4</u>
Total assets	\$187.4
Debt	\$44.8
Liability related to sale of future royalties	\$137.7
Other liabilities	<u>\$24.8</u>
Total liabilities	\$207.3
Working capital	\$155.0
Accumulated deficit	-\$834.4
Stockholders' Equity (Deficit)	-\$19.9
<b>Basic shares outstanding</b>	<b>58.6</b>

# 2019 Financial Guidance

	(in millions)
<b>Cash Revenue</b>	<b>\$28 - 32</b>
<b>Cash Operating Expenses</b>	<b>\$110 - 115</b>
<b>Net</b>	<b>~\$90</b>

Over 24 Months of  
Cash Based on  
2019 Guidance

Financial guidance confirmed on May 9, 2019 earnings call

# Upcoming Milestones

Continue to Conduct  
**GALACTIC-HF** through 2019;  
Expect Second Interim  
Analyses in Q1 2020

Continue Enrollment  
in **METEORIC-HF**  
through 2019

Expect to Initiate  
**REDWOOD-HCM**  
in Q4 2019

Continue to Evaluate Results  
of **FORTITUDE-ALS**  
& to Prepare for Potential  
Phase 3 Clinical Trial

Continue to Conduct  
Phase 1 Study of **AMG 594**  
through 2019



  
Cytokinetics

**THANK  
YOU**