BASELINE CHARACTERISTICS FROM THE CARDIOVASCULAR OUTCOMES TRIAL OF OMECAMTIV MECARBIL (GALACTIC-HF)

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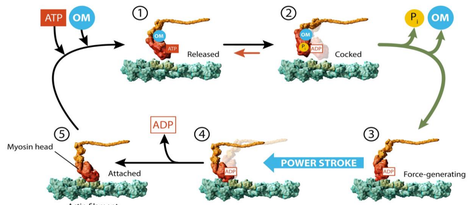
BACKGROUND

Omecamtiv mecarbil (OM) is a novel, selective cardiac myosin activator that improves cardiac function, ventricular volumes, and NT-proBNP in patients with HFrEF.



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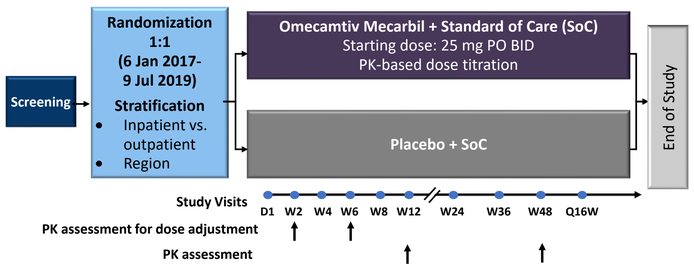
Omecamtiv mecarbil binds with highest affinity to the pre-powerstroke state of myosin, increasing the force produced during each cycle of cardiac contraction.

METHODS

GALACTIC-HF (NCT02929329) is assessing the effect of OM on CV death, HF events, and patient-reported outcomes, as well as its safety profile.

Multinational, double-blind, placebo-controlled, event-driven trial



Key inclusion criteria:

- Age ≥ 18 to ≤ 85 years
- Chronic HF, LVEF ≤ 35%, NYHA Class II to IV, managed with GDMT
- Current hospitalization ("inpatient") OR recent HF hospitalization/ED visit (within 1 year, "outpatient")
- BNP ≥ 125 pg/mL or NT-proBNP level ≥ 400 pg/mL (with atrial fibrillation/flutter: BNP ≥ 375 pg/mL or NT-proBNP ≥ 1200 pg/mL)

Key exclusion criteria:

- ACS event or major cardiac surgery/intervention within 3 months
- SBP >140 or <85 mmHg; HR >110 bpm or <50 bpm
- GFR <20 mL/min/1.72m^2 or on dialysis

Primary efficacy outcome:

- Time to CV death or first HF event, whichever occurs first

GALACTIC-HF

GALACTIC-HF

CV Outcomes Trial for Omecamtiv Mecarbil Enrolls 8,256 Patients With HFrEF

GALACTIC-HF is testing the hypothesis that omecamtiv mecarbil improves clinical outcomes in patients with HFrEF enrolled from both inpatient and outpatient settings.

Results are anticipated Q4 of 2020.

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BASELINE CHARACTERISTICS

	Overall (N=8,256)	Inpatient (N=2,083)	Outpatient (N=6,173)
Time from most recent HF hospitalization/ ED visit (months), median (Q1-Q3)	2 (1-5)	-	3 (2-6)
Region NA/LA/(WE,SA,OCE)/EE/Asia, %	17/ 19/ 23/ 33/ 8	9/ 16/ 23/ 44/ 9	20/ 20/ 23/ 29/ 8
Age (years), mean (SD)	65 (11)	65 (11)	64 (11)
Male, %	79	80	78
White, %	78	82	76
LVEF (%), mean (SD)	27 (6)	27 (6)	27 (6)
MAGGIC Score, mean (SD)	23 (6)	25 (6)	23 (6)
NYHA Class II/III/IV, %	53/ 44/ 3	37/ 57/ 6	59/ 39/ 2
NT-proBNP (pg/mL), median (Q1-Q3)	1998 (990-4078)	2509 (1240-5133)	1884 (923-3772)
hsTnI (ng/mL), median (Q3)	0.027 (0.051)	0.037 (0.068)	0.024 (0.046)
Ischemic Heart Disease Etiology, %	55	56	54
KCCQ Total Symptom Score, mean (SD)	66 (25)	53 (25)	71 (23)
Coronary Artery Disease, %	62	63	61
Peripheral Artery Disease, %	10	10	10
Stroke, %	9	9	9
Atrial Fibrillation or Flutter History, %	42	48	40
Hypertension, %	70	72	70
Type 2 Diabetes Mellitus, %	40	42	40
Chronic Kidney Disease, %	36	39	35
eGFR (mL/min/1.73m^2), median (Q1-Q3)	59 (44-74)	54 (41-70)	60 (45-75)
SBP (mmHg), mean (SD)	117 (15)	114 (14)	117 (16)
Heart rate (beats/min), mean (SD)	72 (12)	73 (12)	72 (12)
ACEi, ARB or ARNi, %	87	83	88
ARNi, %	19	16	21
BB, %	94	93	95
MRA, %	77	81	76
Diuretics other than MRAs, %	90	92	89
Digitalis Glycosides, %	17	17	17
CRT and/or ICD, %	34	31	35
SGLT2 Inhibitors, %	3	3	3
Ivabradine, %	6	7	6

ACEi indicates angiotensin-converting enzyme inhibitor; ARB, angiotensin receptor blocker; ARNi, angiotensin receptor-neprilysin inhibitor; BB, beta blocker; CRT, cardiac resynchronization therapy; ED, emergency department; EE, Eastern Europe including Russia; eGFR, estimated glomerular filtration rate; hsTnI, high-sensitivity troponin I; ICD, implantable cardioverter-defibrillator; KCCQ, Kansas City Cardiomyopathy Questionnaire; LA, Latin America; LVEF, left ventricular ejection fraction; MAGGIC, Meta-Analysis Global Group in Chronic HF; MRA, mineralocorticoid receptor antagonist; NA, North America; NT-proBNP, N-terminal pro-B-type natriuretic peptide; NYHA, New York Heart Association; OCE, Australasia; SA, South Africa; SBP, systolic blood pressure; SGLT2, sodium-glucose co-transporter 2; WE, Western Europe

ENROLLED PATIENT POPULATION

Overall, 8,256 patients were enrolled

79% Male, 21% Female
78% White, 7% Black or African American
65 yr Mean age

1998 pg/mL Median NT-proBNP

25% Inpatient

27% Mean EF
44% NYHA Class III

87% ACE/ARB/ARNi
94% BB
77% MRA

Those randomized as inpatients had higher prevalence of atrial fibrillation/flutter and NYHA Class III, higher NT-proBNP, and decreased renal function.

CONCLUSION

GALACTIC-HF has enrolled a well-treated population from both inpatient and outpatient settings, which will provide guidance on implementation of this potentially life-saving therapy.