

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**

Washington, DC 20549

FORM 8-K

**Current Report Pursuant
to Section 13 or 15(d) of the
Securities Exchange Act of 1934**

Date of Report (Date of earliest event Reported): **October 26, 2011**

THERAVANCE, INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware

(State or Other Jurisdiction of
Incorporation)

000-30319

(Commission File Number)

94-3265960

(I.R.S. Employer Identification Number)

**901 Gateway Boulevard
South San Francisco, California 94080
(650) 808-6000**

(Addresses, including zip code, and telephone numbers, including area code, of principal executive offices)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 8.01 Other Events.

On October 26, 2011, GlaxoSmithKline (GSK) made an oral presentation entitled "Dose-Related Efficacy of GSK573719 ('719): A Long-Acting Muscarinic Receptor Antagonist (LAMA) With Sustained 24-Hour Activity in chronic obstructive pulmonary disease (COPD)" at CHEST 2011, the annual meeting of the American College of Chest Physicians (ACCP), in Honolulu, Hawaii. '719 is the LAMA component in LAMA/LABA ('719/Vilanterol), an investigational product being developed under the LABA collaboration between GSK and Theravance, Inc. for the treatment of COPD.

The presentation is attached hereto as Exhibits 99.1 and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

- (d) Exhibits

<u>Exhibit</u>	<u>Description</u>
Exhibit 99.1	Dose-Related Efficacy of GSK573719: A Long-Acting Muscarinic Receptor Antagonist (LAMA) With Sustained 24-Hour Activity in COPD

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

THERAVANCE, INC.

Date: October 26, 2011

By: /s/ Michael W. Aguiar
Michael W. Aguiar
Chief Financial Officer

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EXHIBIT INDEX

<u>Exhibit</u>	<u>Description</u>
Exhibit 99.1	Dose-Related Efficacy of GSK573719: A Long-Acting Muscarinic Receptor Antagonist (LAMA) With Sustained 24-Hour Activity in COPD

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Dose-related efficacy of GSK573719, a long-acting muscarinic receptor antagonist (LAMA) with sustained 24-hour activity, in COPD

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CHEST
2011 

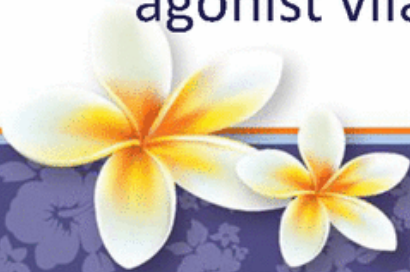
Disclosures

- J.F. Donohue is an advisor, consultant, or member of a DSMB or adjudication committee for Almiral, AstraZeneca, Boehringer Ingelheim, GlaxoSmithKline, Elevation Pharmaceuticals, Forest laboratories, Novartis, Dey, Sunovion, Talecris, Pfizer for which he receives fees
- A. Anzueto is an advisor, consultant, and speaker for Boehringer Ingelheim, GlaxoSmithKline, Pfizer, Merck, Bayer-Schering Pharma, Dey Pharma, Forest laboratories and has investigational grants with the NHLBI, GlaxoSmithKline, Lilly, Pfizer, and Pneuma pharmaceuticals
- G. Crater, C. Kalberg, R. Mehta, and J. Brooks are employees of GlaxoSmithKline
- This study was funded by GlaxoSmithKline



GSK573719

- Competitive muscarinic acetylcholine receptor antagonist
- Long duration of action due to prolonged binding at the M3 muscarinic receptor
- In development for the once-daily treatment of COPD as a monotherapy and in combination with the long-acting beta₂-agonist vilanterol



Study AC4113073

(www.clinicaltrials.gov registration number NCT00950807)

- Primary study objective:
 - Evaluate the dose-response and dosing interval of GSK573719
- Multicenter, randomized, double-blind, double-dummy, placebo-controlled, three-way cross-over, incomplete block study
- Subjects received placebo and 2 of 9 active treatments
- Three 14 day treatment periods



Treatments

- GSK573719
 - 62.5, 125, 250, 500, and 1000mcg once-daily (QD)
 - 62.5, 125, and 250mcg twice-daily (BD)
- Tiotropium 18mcg once-daily (open-label) as active control
- Placebo
- All treatments administered using a novel multidose dry powder inhaler



Key Eligibility Criteria

- COPD patients 40 to 80 years old
- Post-albuterol FEV₁/FVC of ≤ 0.70 and FEV₁ of ≥ 35 and $\leq 70\%$ of predicted normal
- Concurrent use of systemic corticosteroids, long-acting bronchodilators, including theophyllines, and short-acting anticholinergics was not allowed
- Concurrent use of albuterol and stable-dose ICS was allowed



Key Efficacy Measures

- Change from baseline in clinic visit trough FEV₁ at Day 15 (Primary)
- 0–24 hour weighted mean FEV₁ at Day 14
- Serial FEV₁ values at each time point over 28 hours at Day 14
- Rescue albuterol use



Safety Measures

- Adverse events
- Vital signs
- 12-lead ECG
- 24 hour Holter ECG assessments
- Standard clinical laboratory tests
- COPD exacerbations



Baseline Characteristics

	N=176
Age, years ¹	59.7 (8.12)
Male/Female, n (%)	101/75 (57/43)
Race, n (%)	
Caucasian	172 (98)
African American	4 (2)
Body Mass Index (kg/m ²) ¹	26.71 (4.655)
FEV ₁ (L) ^{1,2}	1.65 (0.467)
FEV ₁ % of predicted normal ^{1,2}	52.4 (9.47)
FEV ₁ /FVC % ²	49.6 (9.77)
Smoking history in pack-years ¹	52.2 (27.48)
Concurrent ICS use (%)	28

¹values are mean (SD)

²Post-albuterol



Trough FEV₁ Day 15

LS mean difference from placebo in mL (95% CI)

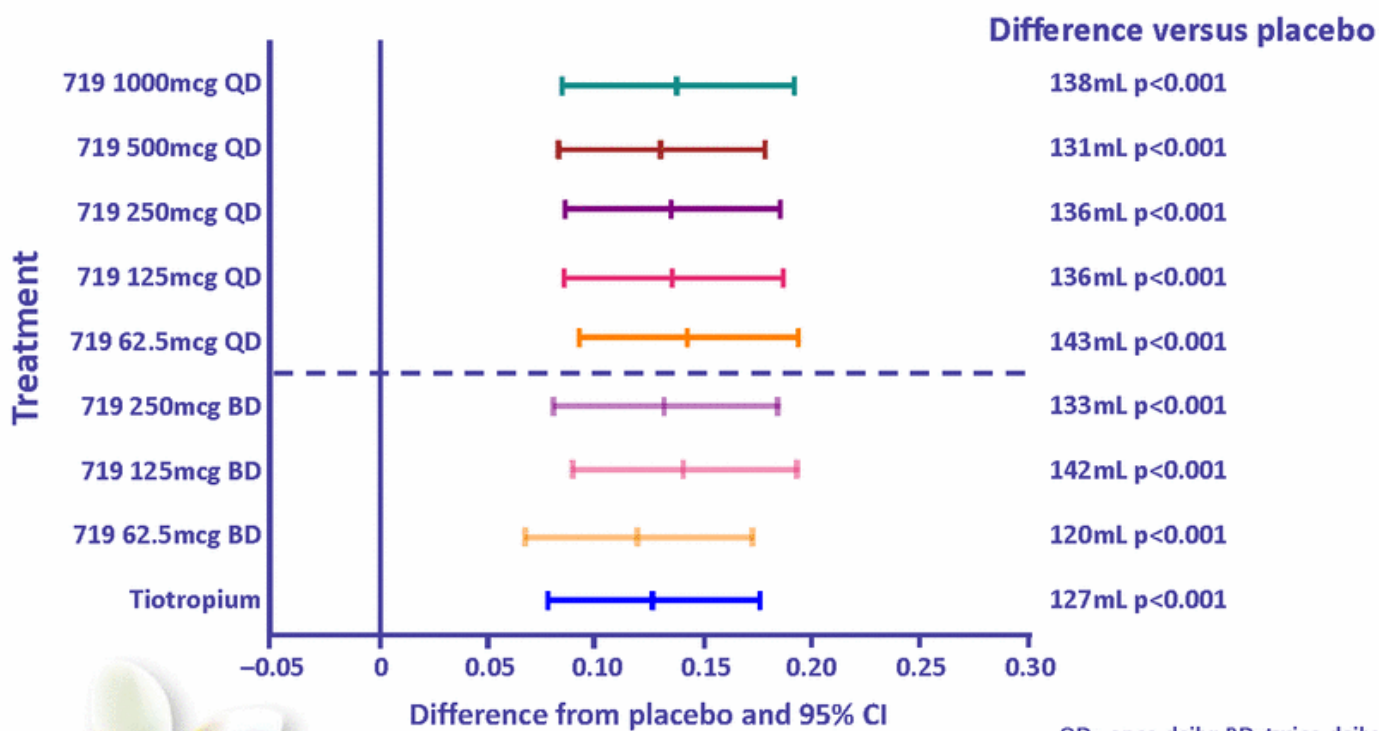
GSK573719 Once-daily					
62.5mcg n=35	125mcg n=34	250mcg n=36	500mcg n=38	1000mcg n=32	Tiotropium n=35
128** (60-196)	147** (77-216)	95* (27-162)	140** (74-205)	186** (113-259)	105* (37-173)

GSK573719 Twice-daily		
62.5mcg n=34	125mcg n=37	250mcg n=33
79† (8-151)	134** (64-204)	172** (101-242)

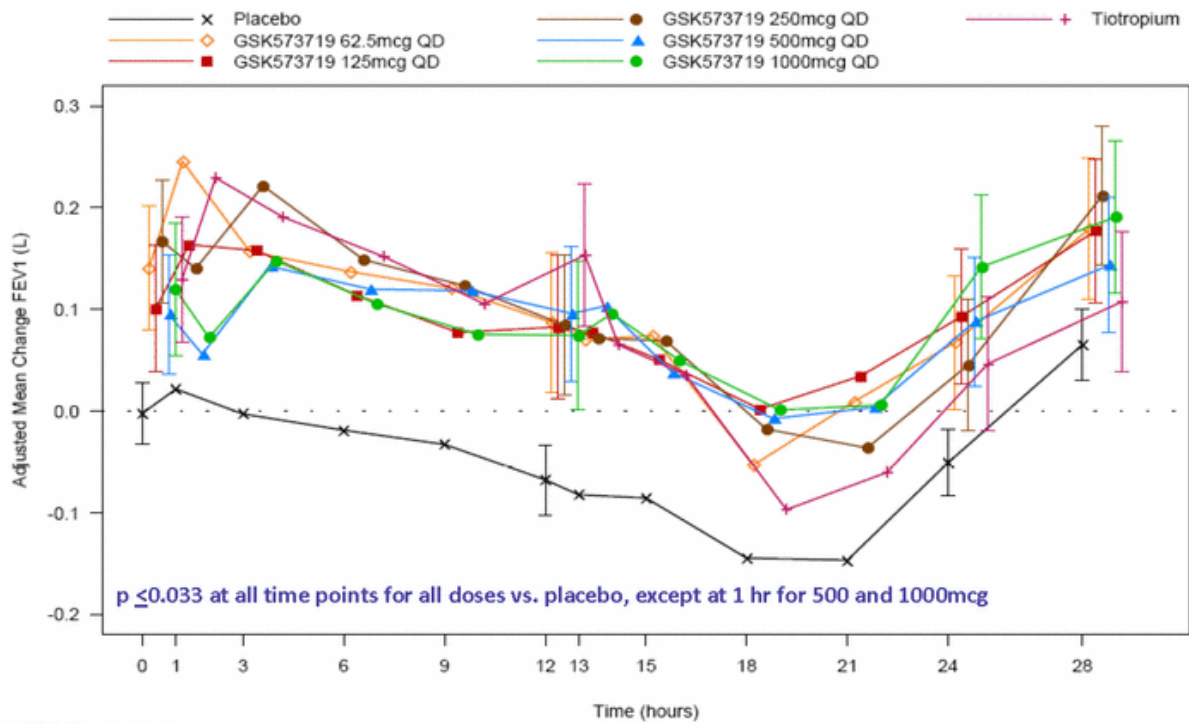
*p<0.01 vs. placebo
**p<0.001 vs. placebo
†p<0.05 vs. placebo



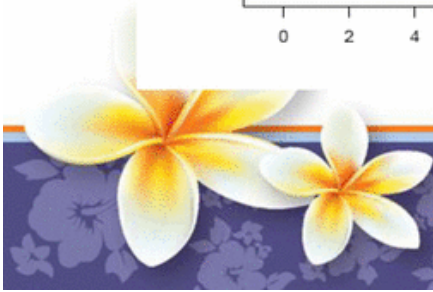
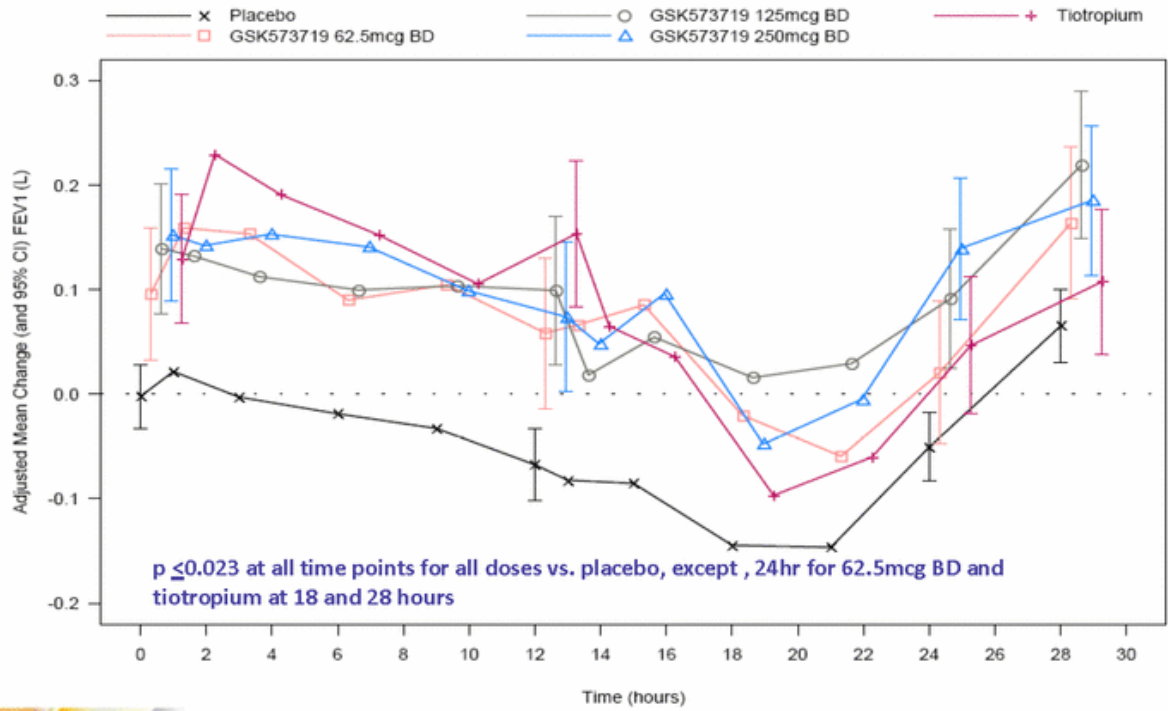
0-24 hour Weighted Mean FEV₁ (Day 14 /15)



Serial FEV₁ at Day 14 to 15 (once-daily doses)



Serial FEV₁ at Day 14 to 15 (twice-daily doses)



Rescue Albuterol Use

LS mean difference from placebo in puffs/day

GSK573719 Once-daily					
62.5mcg n=35	125mcg n=34	250mcg n=36	500mcg n=38	1000mcg n=32	Tiotropium n=35
-0.483	-0.784*	-0.772*	-0.753*	-0.434	-0.888*

GSK573719 Twice-daily		
62.5mcg n=34	125mcg n=37	250mcg n=33
-0.606*	-0.809*	-0.765*

*p<0.05



On-treatment Adverse Events ($\geq 5\%$)¹

	Placebo n=158	GSK573719 once-daily				
		62.5mcg n=35	125mcg n=34	250mcg n=36	500mcg n=38	1000mcg n=32
Any AE, n (%)	25 (16)	8 (23)	6 (18)	14 (39)	14 (37)	13 (41)
Headache	4 (3)	1 (3)	1 (3)	3 (8)	1 (3)	2 (6)
Cough	1 (<1)	1 (3)	0	1 (3)	4 (11)	2 (6)
Dry mouth	1 (<1)	0	0	0	1 (3)	2 (6)
Dysphonia	1 (<1)	0	0	0	0	0
Nasopharyngitis	2 (1)	0	0	2 (6)	0	4 (13)
Oropharyngeal pain	2 (1)	0	0	0	1 (3)	0
Dysgeusia	0	0	0	2 (6)	0	2 (6)
Hypertension	0	0	2 (6)	1 (3)	0	0

¹ $\geq 5\%$ of subjects in any treatment group



On-treatment Adverse Events (≥5%)

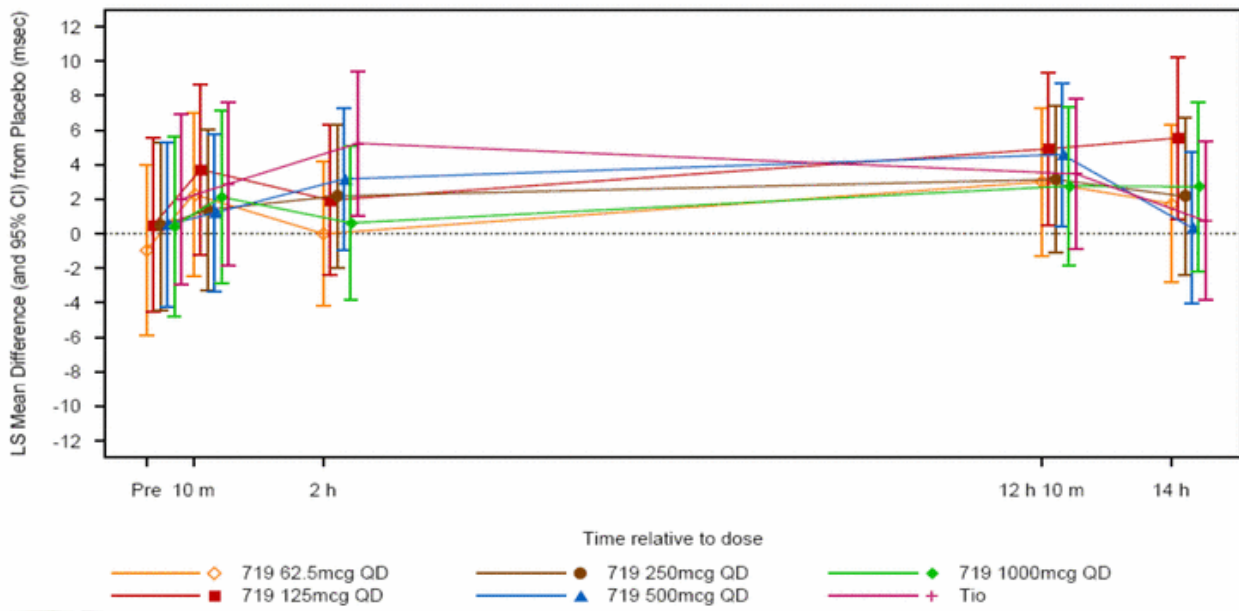
	GSK573719 twice-daily			Tiotropium n=35
	62.5mcg n=34	125mcg n=37	250mcg n=33	
Any AE, n (%)	6 (18)	8 (22)	10 (30)	6 (17)
Headache	0	1 (3)	3 (9)	2 (6)
Cough	0	0	2 (6)	0
Dry mouth	0	1 (3)	3 (9)	1 (3)
Dysphonia	0	2 (5)	0	0
Nasopharyngitis	2 (6)	0	0	0
Oropharyngeal pain	0	1 (3)	2 (6)	0
Dysgeusia	1 (3)	0	2 (6)	0
Hypertension	0	0	0	0

Three serious adverse events were reported:

- COPD exacerbation (250mcg QD and 125mcg BD) and concussion (250mcg QD)
- None were fatal or reported as drug-related



ECG at Day 14: QTc(F) Difference from Placebo (once-daily doses)

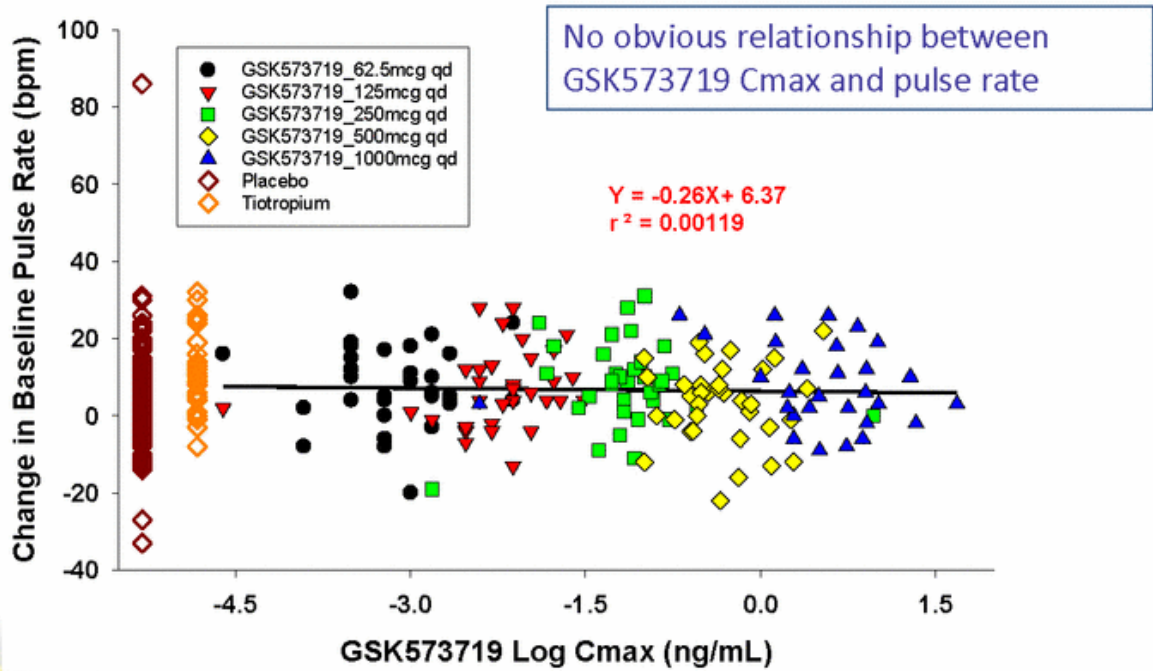


24-hr Holter Findings

- No clear patterns in the rates of single ventricular ectopic beats, couplets or runs were seen across treatments
- Single ventricular ectopics occurred in 81% of placebo-treated patients and 53 to 84% of subjects across all GSK573719 doses
- Couplets occurred in 14% of placebo treated subjects and 3 to 24% of patients across all GSK573719 doses
- The incidence of ventricular ectopic runs was low
 - 2% with placebo and 0 to 3% with GSK573719



Semi-Log Plot of Individual Change from Baseline in Pulse Rate versus GSK573719 Cmax and Pulse Rate (once-daily doses)



AC4113073 Summary

- All doses of GSK573719 significantly improved lung function over 28 hours
- Sustained improvement in lung function over 14 days
- Comparisons of once-daily versus twice-daily dosing and tiotropium confirmed a once-daily profile
- Significant reductions in rescue albuterol use indicate symptomatic improvement
- All doses were well tolerated with no apparent treatment-related changes in vital signs or ECG and 24 hour Holter assessments

