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Effects of Mometasone Furoate/Formoterol Combination Versus Formoterol and Mometasone Furoate Alone in COPD (Study P04229AM4)(COMPLETED)

This study has been completed.

Sponsor:
Merck Sharp & Dohme Corp.

Collaborator:
Novartis

Information provided by (Responsible Party):
Merck Sharp & Dohme Corp.

ClinicalTrials.gov Identifier:
NCT00383435

First received: September 29, 2006
Last updated: September 2, 2015
Last verified: September 2015
History of Changes

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Purpose

This is a randomized, placebo-controlled, parallel-group, multi-site, double-blind study evaluating the efficacy of mometasone furoate/formoterol fumarate (MF/F) metered dose inhaler (MDI) 400/10 mcg twice daily (BID) and MF/F MDI 200/10 mcg BID compared with MF 400 mcg BID and F 10 mcg BID in adults at least 40 years of age, with moderate to severe chronic obstructive pulmonary disease (COPD). All placebo-treated subjects and active-treated

subjects who will not participate in the safety extension will be discontinued

and will have their Final Visit at Week 26. Subjects who continue into the

26-week safety extension will have their Final Visit at Week 52. Efficacy will be measured by the mean change from Baseline to Week 13 in area under the forced expiratory volume in one second concentration time curve from 0 to 12 hours (FEV1 AUC[0-12hr]) and change from Baseline to Week 13 in AM predose FEV1.

Condition	Intervention	Phase
Chronic Obstructive Pulmonary Disease (COPD)	Drug: Mometasone furoate/formoterol (MF/F) combination Drug: Mometasone furoate MDI (MF MDI) Drug: Formoterol MDI Drug: Placebo	Phase 3

Study Type: Interventional
Study Design: Allocation: Randomized
Endpoint Classification: Safety/Efficacy Study
Intervention Model: Parallel Assignment
Masking: Double Blind (Subject, Investigator)
Primary Purpose: Treatment

Official Title: A Randomized, 26-Week, Placebo-Controlled Efficacy and Safety Study With a 26-Week Long-Term Safety Extension, of High- and Medium-Dose Inhaled Mometasone Furoate/Formoterol Fixed-Dose Combination Formulation Compared With Formoterol and High-Dose Inhaled Mometasone Furoate Monotherapy in Subjects With Moderate to Severe COPD

Resource links provided by NLM:

MedlinePlus related topics: COPD Lung Diseases

Drug Information available for: Formoterol fumarate Formoterol Mometasone furoate Mometasone furoate monohydrate Arformoterol Tartrate

U.S. FDA Resources

Further study details as provided by Merck Sharp & Dohme Corp.:

Primary Outcome Measures:

- Mean Area Under the Time Curve From 0 to 12 Hours (AUC(0-12 Hours)) of Change From Baseline to Week 13 in Forced Expiratory Volume (Liters) in 1 Second (FEV1) [Time Frame: Baseline to Endpoint (13 weeks)] [Designated as safety issue: No]

  FEV1 AUC was standardized to liters. Endpoint was the last post-baseline non-missing result through Week 13 carried forward.

- Mean Change From Baseline to Week 13 Endpoint in AM Predose FEV1 [Time Frame: Baseline to Endpoint (13 weeks)] [Designated as safety issue: No]

  Endpoint was the last post-baseline non-missing result through Week 13 carried forward.

Secondary Outcome Measures:

- Change From Baseline to Endpoint in St George's Respiratory Questionaire (SGRQ) Total Score [Time Frame: Baseline to Endpoint (26 weeks)] [Designated as safety issue: No]

  SGRQ consisted of 76 items aggregated into 3 component scores: symptoms (frequency/severity), activity (cause or limited by breathlessness), impact (social functioning, psychological disturbances from airway disease), & total score. Best health scores have a low numeric value. All component scores & total score range from 0-100, with a higher score indicating greater disease burden. A 4-point increase over placebo (and Baseline) was considered the minimum clinically important difference. Endpoint is the last post-baseline non-missing result through the 26 week evaluation carried forward.

- Change From Baseline in Proportion of Chronic Obstructive Pulmonary Disease (COPD) Symptom-Free Nights (AM Diary Symptoms) [Time Frame: Baseline to Endpoint (26 weeks)] [Designated as safety issue: No]

  Prior to the use of study drug rescue medication (in the morning upon awakening) the participant evaluated the COPD symptoms of wheezing, cough, and difficulty breathing. A symptom-free night was defined as a combined score of 0 (no symptoms) across all three COPD symptoms evaluated the following morning. Proportion for Baseline included data from the last week before the first dose. Proportion for Endpoint included data across the entire 26-week treatment period.

- Number of Participants With Partly Stable COPD [Time Frame: Endpoint (26 weeks)] [Designated as safety issue: No]

  Partly stable COPD was a composite measure that included the following COPD outcomes: (1) No oral steroid rescue medication; (2) No AM or PM COPD weekly average symptom score greater than 2 during at least 7 of 8 weeks; (3) No moderate or severe exacerbations; (4) No unscheduled visits due to COPD worsenings; (5) No study discontinuation due to treatment failure or treatment-related adverse event as determined by the investigator.

- Number of Participants With Mild, Moderate, or Severe COPD Exacerbations [Time Frame: Endpoint (26 weeks)] [Designated as safety issue: No]

  Mild = 12 or more inhalations/day of inhaled rescue medication or 2 or more nebulized treatments/day of inhaled rescue medication. Moderate = treatment with antibiotics or oral steroids. Severe = emergency room treatment or hospitalizations of survival curves. If an event was composed of multiple criteria, the most severe criteria was assigned to the event.

Enrollment:	1055
Study Start Date:	October 2006
Study Completion Date:	July 2010
Primary Completion Date:	July 2010 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Experimental: MF/F MDI 400/10 mcg BID	Drug: Mometasone furoate/formoterol (MF/F) combination MF/F 400/10 mcg via a metered dose inhaler (MDI) twice daily for 52 weeks Other Name: SCH 418131
Experimental: MF/F MDI 200/10 mcg BID	Drug: Mometasone furoate/formoterol (MF/F) combination MF/F 200/10 mcg via a metered dose inhaler (MDI) twice daily for 52 weeks Other Name: SCH 418131
Experimental: MF MDI 400 mcg BID	Drug: Mometasone furoate MDI (MF MDI) MF 400 mcg via metered dose inhaler twice daily for 52 weeks Other Name: SCH 32088
Active Comparator: Formoterol MDI 10 mcg BID	Drug: Formoterol MDI Formoterol 10 mcg via metered dose inhaler twice a day for 52 weeks Other Name: Foradil
Placebo Comparator: Placebo MDI BID	Drug: Placebo Placebo MDI twice a day for 26 weeks

Eligibility

Ages Eligible for Study: 40 Years and older
Genders Eligible for Study: Both
Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:

- Moderate to severe COPD based on prebronchodilator FEV1/forced vital capacity (FVC) ratio of <=70%.
- At Screening, postbronchodilator FEV1 must be <=60% predicted normal & >=25% predicted normal.
- COPD symptoms for >=24 months.
- Ex- or current smoker with smoking history >=10 pack years.
- Only albuterol/salbutamol for relief for at least 2 weeks prior to randomization.
- Withdraw from parenteral & oral steroids, anticholinergics, & antibiotics at least 4 weeks prior to Screening.
- No harm in changing current COPD therapy, willing to discontinue his/her anticholinergics, inhaled corticosteroids (ICS) or ICS/long-acting beta agonists (LABA) at Screening, & transferred to albuterol/salbutamol for relief for 2 weeks prior to randomization.
- Lab tests conducted at Screening must be acceptable to investigator. Electrocardiogram (ECG) performed at Screening Visit or within 30 days prior to Screening must be acceptable to investigator. Chest x-ray performed at Screening or within 12 months prior to Screening must be acceptable to investigator.
- Women who have

been surgically sterilized or are at least 1 year postmenopausal are not

considered to be of childbearing potential. A female subject of childbearing

potential must have a negative serum pregnancy test at Screening in order to

be considered eligible for enrollment. Female of childbearing potential must use birth control. Includes: hormonal contraceptives, intra-uterine device (IUD), condom in combination with spermicide, monogamous relationship with male partner who had vasectomy. Started birth control at least 3 months prior to Screening (exception condom), & agree to continue. Female who is not currently sexually active must agree/consent to use a method should she become sexually active. Women surgically sterilized or are at least 1 year postmenopausal are not considered to be of childbearing potential. Female must have negative serum pregnancy test at Screening.

Exclusion Criteria:

- Evidence (upon visual inspection) of oropharyngeal candidiasis at Baseline with or without treatment. If there is evidence at Screening, may be treated as appropriate & visit can be scheduled upon resolution. If there is evidence at Baseline Visit, may be treated as appropriate & visit can be rescheduled upon resolution.
- History of renal, hepatic, cardiovascular, metabolic, neurologic, hematologic, ophthalmological, respiratory, gastrointestinal, cerebrovascular, or other which could interfere with study or require treatment which might interfere with study. Examples include (but are not limited to) hypertension being treated with beta-blockers, active hepatitis, coronary artery disease, arrhythmia, significant QTc prolongation (ie QTcF or

QTcB [Fridericia or Bazett corrections, respectively >500 milliseconds (msecs)]), stroke, severe rheumatoid arthritis, chronic open-angle glaucoma or posterior subcapsular cataracts, acquired immune deficiency syndrome (AIDS), or conditions that may interfere with respiratory function such as asthma, bronchiectasis, cystic fibrosis. Others which are well-controlled & stable (eg hypertension not requiring beta-blockers) will not prohibit participation if deemed appropriate per investigator.

- Allergy/sensitivity to glucocorticosteroids, beta-2 agonists, study drug/excipients.
- Female who is breast-feeding, pregnant, or intends to become pregnant.
- Illicit drug user.
- Human immunodeficiency virus (HIV) positive (testing not conducted).
- Unable to correctly use oral MDI.
- Taking any restricted medications prior to Screening without meeting washout.
- Cannot adhere to permitted concomitant & prohibited medications.
- May not participate in this same study at another investigational site. Cannot participate in different investigational study at any site, during same time of study.
- Not be randomized into study more than once.
- No person directly associated with administration of study may participate.
- Previously participated in MF/F trial.
- Increase in absolute volume of >=400 milliliters (mL) at Screening or prior to Baseline within 30 minutes after administration of 4 inhalations of albuterol/salbutamol (total dose of 360 to 400 mcg), or nebulized 2.5 mg albuterol/salbutamol.
- Asthma.
- Blood eosinophil count greater than 0.57 x 10^3/microliter (uL).
- Lobectomy, pneumonectomy or lung volume reduction surgery.
- Lung cancer.
- Requires long-term administration of oxygen (>15 hours per day).
- A subject who experiences an exacerbation of COPD requiring medical

intervention within 4 weeks prior to randomization, beta-blocking agents, or

treatment with additional excluded medication (other than short-acting beta agonists (SABA)/short-acting

anticholinergic to be used as rescue medication).

- alpha-1-antitrypsin deficiency.
- Cataract extractions on both eyes.
- A history and/or presence of intraocular pressure in either eye >=22 millimeters of mercury (mm Hg), glaucoma, and/or posterior subcapsular cataracts. A subject who has undergone incisional or intraocular surgery in which the natural lens is still present in the eye. A subject with a history of penetrating trauma to both eyes. A subject with one or more of the following Lens Opacities Classification System (LOCS) III grades at screening:

nuclear opalescence (NO): >=3.0,

nuclear color (NC): >=3.0,

cortical cataract (C): >=2.0,

posterior subcapsular (P): >=0.5.

Contacts and Locations

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the Contacts provided below. For general information, see Learn About Clinical Studies.

No Contacts or Locations Provided

More Information

Publications automatically indexed to this study by ClinicalTrials.gov Identifier (NCT Number):

Maspero J, Cherrez I, Doherty DE, Tashkin DP, Kuna P, Kuo WL, Gates D, Nolte H, Chylack LT Jr. Appraisal of lens opacity with mometasone furoate/formoterol fumarate combination in patients with COPD or asthma. Respir Med. 2014 Sep;108(9):1355-62. doi: 10.1016/j.rmed.2014.04.015. Epub 2014 May 2.

Tashkin DP, Doherty DE, Kerwin E, Matiz-Bueno CE, Knorr B, Shekar T, Gates D, Staudinger H. Efficacy and safety characteristics of

mometasone furoate/formoterol fumarate fixed-dose combination in subjects with moderate to very severe COPD: findings from pooled analysis of two randomized, 52-week placebo-controlled trials. Int J Chron Obstruct Pulmon Dis. 2012;7:73-86. doi: 10.2147/COPD.S29444. Epub 2012 Feb 3.

Tashkin DP, Doherty DE, Kerwin E, Matiz-Bueno CE, Knorr B, Shekar T, Banerjee S, Staudinger H. Efficacy and safety of a fixed-dose combination of mometasone furoate and formoterol fumarate in subjects with moderate to very severe COPD: results from a 52-week Phase III trial. Int J Chron Obstruct Pulmon Dis. 2012;7:43-55. doi: 10.2147/COPD.S27319. Epub 2012 Feb 3. Erratum in: Int J Chron Obstruct Pulmon Dis. 2012;7:765.

Responsible Party:	Merck Sharp & Dohme Corp.
ClinicalTrials.gov Identifier:	NCT00383435 History of Changes
Other Study ID Numbers:	P04229 Doc ID: 3227334; Eudract No: 2006-002308-32;
Study First Received:	September 29, 2006
Results First Received:	July 5, 2011
Last Updated:	September 2, 2015
Health Authority:	United States: Food and Drug Administration

Additional relevant MeSH terms:

Lung Diseases, Obstructive	Anti-Asthmatic Agents
Pulmonary Disease, Chronic Obstructive	Anti-Inflammatory Agents
Lung Diseases	Autonomic Agents
Respiratory Tract Diseases	Bronchodilator Agents
Formoterol	Molecular Mechanisms of Pharmacological Action
Mometasone furoate	Neurotransmitter Agents
Adrenergic Agents	Peripheral Nervous System Agents
Adrenergic Agonists	Pharmacologic Actions
Adrenergic beta-2 Receptor Agonists	Physiological Effects of Drugs
Adrenergic beta-Agonists	Respiratory System Agents
Anti-Allergic Agents	Therapeutic Uses

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Effects of Mometasone Furoate/Formoterol Combination Versus Formoterol and Mometasone Furoate Alone in COPD (Study P04229AM4)(COMPLETED)

This study has been completed.

Sponsor:
Merck Sharp & Dohme Corp.

Collaborator:
Novartis

Information provided by (Responsible Party):
Merck Sharp & Dohme Corp.

ClinicalTrials.gov Identifier:
NCT00383435

First received: September 29, 2006
Last updated: September 2, 2015
Last verified: September 2015
History of Changes

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Results First Received: July 5, 2011

Study Type:	Interventional
Study Design:	Allocation: Randomized; Endpoint Classification: Safety/Efficacy Study; Intervention Model: Parallel Assignment; Masking: Double Blind (Subject, Investigator); Primary Purpose: Treatment
Condition:	Chronic Obstructive Pulmonary Disease (COPD)
Interventions:	Drug: Mometasone furoate/formoterol (MF/F) combination Drug: Mometasone furoate MDI (MF MDI) Drug: Formoterol MDI Drug: Placebo

Participant Flow

Hide Participant Flow

Recruitment Details

Key information relevant to the recruitment process for the overall study, such as dates of the recruitment period and locations
No text entered.

Pre-Assignment Details

Significant events and approaches for the overall study following participant enrollment, but prior to group assignment

At Week 26, all participants randomized to placebo were to be discontinued, while 75% of participants randomized to an active treatment were randomly selected to participate in the 26-week Treatment Safety Extension. Several placebo-treated participants continued in error into the Treatment Safety Extension.

Reporting Groups

	Description
MF/F MDI 400/10 mcg BID	Mometasone furoate/formoterol fumarate (MF/F) 400/10 mcg via a metered dose inhaler (MDI) twice daily (BID) for 52 weeks
MF/F MDI 200/10 mcg BID	MF/F 200/10 mcg via a MDI BID for 52 weeks
MF MDI 400 mcg BID	Mometasone furoate (MF) 400 mcg via a MDI BID for 52 weeks
F MDI 10 mcg BID	Formoterol fumarate (F) 10 mcg via a MDI BID for 52 weeks
Placebo	Placebo MDI BID for 26 weeks

Participant Flow for 2 periods

Period 1: 26-Week Double-Blind Treatment Period

	MF/F MDI 400/10 mcg BID	MF/F MDI 200/10 mcg BID	MF MDI 400 mcg BID	F MDI 10 mcg BID	Placebo
STARTED	217	207	210	209	212
COMPLETED	176	169	164	172	159
NOT COMPLETED	41	38	46	37	53
Adverse Event	10	2	8	6	8
Lack of Efficacy	3	2	3	5	8
Lost to Follow-up	3	3	1	2	2
Participant withdrawal unrelated	7	12	14	10	17
Participant withdrawal related	2	3	7	3	7
Non-compliance with protocol	1	5	3	5	4
Did not meet protocol eligibility	10	8	9	5	6
Administrative	5	3	1	1	1

Period 2: 26-Week Treatment Safety Extension

	MF/F MDI 400/10 mcg BID	MF/F MDI 200/10 mcg BID	MF MDI 400 mcg BID	F MDI 10 mcg BID	Placebo
STARTED	131	130	124	131	13
COMPLETED	117	121	108	116	10
NOT COMPLETED	14	9	16	15	3
Adverse Event	4	2	5	5	

					1
Lack of Efficacy	1	1	1	1	0
Lost to Follow-up	0	2	1	0	1
Participant withdrawal unrelated	2	2	6	6	0
Participant withdrawal related	1	0	2	0	1
Non-compliance with protocol	4	1	1	1	0
Did not meet protocol eligibility	1	0	0	1	0
Administrative	1	1	0	1	0

Baseline Characteristics

Hide Baseline Characteristics

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
No text entered.

Reporting Groups

	Description
MF/F MDI 400/10 mcg BID	Mometasone furoate/formoterol fumarate (MF/F) 400/10 mcg via a metered dose inhaler (MDI) twice daily (BID) for 52 weeks
MF/F MDI 200/10 mcg BID	MF/F 200/10 mcg via a MDI BID for 52 weeks
MF MDI 400 mcg BID	Mometasone furoate (MF) 400 mcg via a MDI BID for 52 weeks
F MDI 10 mcg BID	Formoterol fumarate (F) 10 mcg via a MDI BID for 52 weeks
Placebo	Placebo MDI BID for 26 weeks
Total	Total of all reporting groups

Baseline Measures

	MF/F MDI 400/10 mcg BID	**MF/F MDI 200/10 mcg BID**	**MF MDI 400 mcg BID**	**F MDI 10 mcg BID**	**Placebo**	**Total**
Number of Participants [units: participants]	**217**	**207**	**210**	**209**	**212**	**1055**
Age [units: years] Mean (Standard Deviation)	**59.7 (9.1)**	**60.9 (8.1)**	**59.8 (8.9)**	**59.6 (8.5)**	**58.8 (8.7)**	**59.8 (8.7)**
Gender [units: participants]						

Female	**46**	**46**	**46**	**57**	**42**	**237**
Male	**171**	**161**	**164**	**152**	**170**	**818**

Outcome Measures

Hide All Outcome Measures

1. Primary: Mean Area Under the Time Curve From 0 to 12 Hours (AUC(0-12 Hours)) of Change From Baseline to Week 13 in Forced Expiratory Volume (Liters) in 1 Second (FEV1) [Time Frame: Baseline to Endpoint (13 weeks)]

Measure Type	Primary
Measure Title	Mean Area Under the Time Curve From 0 to 12 Hours (AUC(0-12 Hours)) of Change From Baseline to Week 13 in Forced Expiratory Volume (Liters) in 1 Second (FEV1)
Measure Description	FEV1 AUC was standardized to liters. Endpoint was the last post-baseline non-missing result through Week 13 carried forward.
Time Frame	Baseline to Endpoint (13 weeks)
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Intent-to-treat (ITT) population

Reporting Groups

	Description
MF/F MDI 400/10 mcg BID	Mometasone furoate/formoterol fumarate (MF/F) 400/10 mcg via a metered dose inhaler (MDI) twice daily (BID) for 52 weeks
MF/F MDI 200/10 mcg BID	MF/F 200/10 mcg via a MDI BID for 52 weeks
MF MDI 400 mcg BID	Mometasone furoate (MF) 400 mcg via a MDI BID for 52 weeks
F MDI 10 mcg BID	Formoterol fumarate (F) 10 mcg via a MDI BID for 52 weeks
Placebo	Placebo MDI BID for 26 weeks

Measured Values

	MF/F MDI 400/10 mcg BID	**MF/F MDI 200/10 mcg BID**	**MF MDI 400 mcg BID**	**F MDI 10 mcg BID**	**Placebo**
Number of Participants Analyzed [units: participants]	**214**	**207**	**207**	**208**	**207**
Mean Area Under the Time Curve From 0 to 12 Hours (AUC(0-12 Hours)) of Change From Baseline to Week 13 in Forced Expiratory Volume (Liters) in 1 Second (FEV1) [units: Liters] Least Squares Mean (Standard Deviation)					
Baseline	**1.186 (0.418)**	**1.227 (0.418)**	**1.255 (0.418)**	**1.252 (0.418)**	**1.227 (0.418)**
				0.077	**0.003**

Endpoint (Change from Baseline)	**0.166 (0.258)**	**0.126 (0.258)**	**0.057 (0.258)**	**(0.258)**	**(0.258)**

Statistical Analysis 1 for Mean Area Under the Time Curve From 0 to 12 Hours (AUC(0-12 Hours)) of Change From Baseline to Week 13 in Forced Expiratory Volume (Liters) in 1 Second (FEV1)

Groups [1]	MF/F MDI 400/10 mcg BID vs. MF MDI 400 mcg BID
Method [2]	ANCOVA
P Value [3]	<0.001

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.

Statistical Analysis 2 for Mean Area Under the Time Curve From 0 to 12 Hours (AUC(0-12 Hours)) of Change From Baseline to Week 13 in Forced Expiratory Volume (Liters) in 1 Second (FEV1)

Groups [1]	MF/F MDI 200/10 mcg BID vs. MF MDI 400 mcg BID
Method [2]	ANCOVA
P Value [3]	0.007

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.

2. Primary: Mean Change From Baseline to Week 13 Endpoint in AM Predose FEV1 [Time Frame: Baseline to Endpoint (13 weeks)]

Measure Type	Primary
Measure Title	Mean Change From Baseline to Week 13 Endpoint in AM Predose FEV1
Measure Description	Endpoint was the last post-baseline non-missing result through Week 13 carried forward.
Time Frame	Baseline to Endpoint (13 weeks)
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
ITT population

Reporting Groups

	Description
MF/F MDI 400/10 mcg BID	Mometasone furoate/formoterol fumarate (MF/F) 400/10 mcg via a metered dose inhaler (MDI) twice daily (BID) for 52 weeks
MF/F MDI 200/10 mcg BID	MF/F 200/10 mcg via a MDI BID for 52 weeks
MF MDI 400 mcg BID	Mometasone furoate (MF) 400 mcg via a MDI BID for 52 weeks
F MDI 10 mcg BID	Formoterol fumarate (F) 10 mcg via a MDI BID for 52 weeks
Placebo	Placebo MDI BID for 26 weeks

Measured Values

	MF/F MDI 400/10 mcg BID	**MF/F MDI 200/10 mcg BID**	**MF MDI 400 mcg BID**	**F MDI 10 mcg BID**	**Placebo**
Number of Participants Analyzed [units: participants]	**213**	**203**	**206**	**208**	**204**
Mean Change From Baseline to Week 13 Endpoint in AM Predose FEV1 [units: Liters] Least Squares Mean (Standard Deviation)					
Baseline	**1.191 (0.424)**	**1.223 (0.424)**	**1.258 (0.424)**	**1.252 (0.424)**	**1.230 (0.424)**
Endpoint (Change from Baseline)	**0.111 (0.270)**	**0.058 (0.270)**	**0.027 (0.270)**	**0 (0.270)**	**-0.017 (0.270)**

Statistical Analysis 1 for Mean Change From Baseline to Week 13 Endpoint in AM Predose FEV1

Groups [1]	MF/F MDI 400/10 mcg BID vs. F MDI 10 mcg BID
Method [2]	ANCOVA
P Value [3]	<0.001

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.

Statistical Analysis 2 for Mean Change From Baseline to Week 13 Endpoint in AM Predose FEV1

Groups [1]	MF/F MDI 200/10 mcg BID vs. F MDI 10 mcg BID

Method [2]	ANCOVA
P Value [3]	0.029

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.

3. Secondary: Change From Baseline to Endpoint in St George's Respiratory Questionaire (SGRQ) Total Score [Time Frame: Baseline to Endpoint (26 weeks)]

Measure Type	Secondary
Measure Title	Change From Baseline to Endpoint in St George's Respiratory Questionaire (SGRQ) Total Score
Measure Description	SGRQ consisted of 76 items aggregated into 3 component scores: symptoms (frequency/severity), activity (cause or limited by breathlessness), impact (social functioning, psychological disturbances from airway disease), & total score. Best health scores have a low numeric value. All component scores & total score range from 0-100, with a higher score indicating greater disease burden. A 4-point increase over placebo (and Baseline) was considered the minimum clinically important difference. Endpoint is the last post-baseline non-missing result through the 26 week evaluation carried forward.
Time Frame	Baseline to Endpoint (26 weeks)
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
ITT population

Reporting Groups

	Description
MF/F MDI 400/10 mcg BID	Mometasone furoate/formoterol fumarate (MF/F) 400/10 mcg via a metered dose inhaler (MDI) twice daily (BID) for 52 weeks
MF/F MDI 200/10 mcg BID	MF/F 200/10 mcg via a MDI BID for 52 weeks
MF MDI 400 mcg BID	Mometasone furoate (MF) 400 mcg via a MDI BID for 52 weeks
F MDI 10 mcg BID	Formoterol fumarate (F) 10 mcg via a MDI BID for 52 weeks
Placebo	Placebo MDI BID for 26 weeks

Measured Values

	MF/F MDI 400/10 mcg BID	MF/F MDI 200/10 mcg BID	MF MDI 400 mcg BID	F MDI 10 mcg BID	Placebo
Number of Participants Analyzed	**207**	**196**	**193**	**201**	**198**

[units: participants]					
Change From Baseline to Endpoint in St George's Respiratory Questionaire (SGRQ) Total Score [units: Score on a scale] Least Squares Mean (Standard Deviation)					
Baseline	**45.05 (18.48)**	**45.89 (18.48)**	**47.00 (18.48)**	**44.87 (18.48)**	**44.60 (18.48)**
Endpoint (Change from Baseline)	**-7.43 (14.72)**	**-5.69 (14.72)**	**-6.99 (14.72)**	**-6.18 (14.72)**	**-2.87 (14.72)**

Statistical Analysis 1 for Change From Baseline to Endpoint in St George's Respiratory Questionaire (SGRQ) Total Score

Groups [1]	MF/F MDI 400/10 mcg BID vs. Placebo
Method [2]	ANCOVA
P Value [3]	0.002

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.

Statistical Analysis 2 for Change From Baseline to Endpoint in St George's Respiratory Questionaire (SGRQ) Total Score

Groups [1]	MF/F MDI 200/10 mcg BID vs. Placebo
Method [2]	ANCOVA
P Value [3]	0.059

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.

4. Secondary: Change From Baseline in Proportion of Chronic Obstructive Pulmonary Disease (COPD) Symptom-Free Nights (AM Diary Symptoms) [Time Frame: Baseline to Endpoint (26 weeks)]

Measure Type	Secondary
Measure Title	Change From Baseline in Proportion of Chronic Obstructive Pulmonary Disease (COPD) Symptom-Free Nights (AM Diary Symptoms)

Measure Description	Prior to the use of study drug rescue medication (in the morning upon awakening) the participant evaluated the COPD symptoms of wheezing, cough, and difficulty breathing. A symptom-free night was defined as a combined score of 0 (no symptoms) across all three COPD symptoms evaluated the following morning. Proportion for Baseline included data from the last week before the first dose. Proportion for Endpoint included data across the entire 26-week treatment period.
Time Frame	Baseline to Endpoint (26 weeks)
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
ITT population.

Reporting Groups

	Description
MF/F MDI 400/10 mcg BID	Mometasone furoate/formoterol fumarate (MF/F) 400/10 mcg via a metered dose inhaler (MDI) twice daily (BID) for 52 weeks
MF/F MDI 200/10 mcg BID	MF/F 200/10 mcg via a MDI BID for 52 weeks
MF MDI 400 mcg BID	Mometasone furoate (MF) 400 mcg via a MDI BID for 52 weeks
F MDI 10 mcg BID	Formoterol fumarate (F) 10 mcg via a MDI BID for 52 weeks
Placebo	Placebo MDI BID for 26 weeks

Measured Values

	MF/F MDI 400/10 mcg BID	**MF/F MDI 200/10 mcg BID**	**MF MDI 400 mcg BID**	**F MDI 10 mcg BID**	**Placebo**
Number of Participants Analyzed [units: participants]	**213**	**198**	**204**	**206**	**205**
Change From Baseline in Proportion of Chronic Obstructive Pulmonary Disease (COPD) Symptom-Free Nights (AM Diary Symptoms) [units: Proportion of symptom-free nights] Least Squares Mean (Standard Deviation)					
Baseline	**0.31 (0.345)**	**0.29 (0.345)**	**0.33 (0.345)**	**0.35 (0.345)**	**0.31 (0.345)**
Endpoint (Change from Baseline)	**0.15 (0.27)**	**0.07 (0.27)**	**0.11 (0.27)**	**0.14 (0.27)**	**0.06 (0.27)**

No statistical analysis provided for Change From Baseline in Proportion of Chronic Obstructive Pulmonary Disease (COPD) Symptom-Free Nights (AM Diary Symptoms)

5. Secondary: Number of Participants With Partly Stable COPD [Time Frame: Endpoint (26 weeks)]

Measure Type	Secondary
Measure Title	Number of Participants With Partly Stable COPD
Measure Description	Partly stable COPD was a composite measure that included the following COPD

	outcomes: (1) No oral steroid rescue medication; (2) No AM or PM COPD weekly average symptom score greater than 2 during at least 7 of 8 weeks; (3) No moderate or severe exacerbations; (4) No unscheduled visits due to COPD worsenings; (5) No study discontinuation due to treatment failure or treatment-related adverse event as determined by the investigator.
Time Frame	Endpoint (26 weeks)
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
ITT population

Reporting Groups

	Description
MF/F MDI 400/10 mcg BID	Mometasone furoate/formoterol fumarate (MF/F) 400/10 mcg via a metered dose inhaler (MDI) twice daily (BID) for 52 weeks
MF/F MDI 200/10 mcg BID	MF/F 200/10 mcg via a MDI BID for 52 weeks
MF MDI 400 mcg BID	Mometasone furoate (MF) 400 mcg via a MDI BID for 52 weeks
F MDI 10 mcg BID	Formoterol fumarate (F) 10 mcg via a MDI BID for 52 weeks
Placebo	Placebo MDI BID for 26 weeks

Measured Values

	MF/F MDI 400/10 mcg BID	**MF/F MDI 200/10 mcg BID**	**MF MDI 400 mcg BID**	**F MDI 10 mcg BID**	**Placebo**
Number of Participants Analyzed [units: participants]	**217**	**207**	**210**	**209**	**212**
Number of Participants With Partly Stable COPD [units: Participants]	**82**	**95**	**83**	**90**	**85**

No statistical analysis provided for Number of Participants With Partly Stable COPD

6. Secondary: Number of Participants With Mild, Moderate, or Severe COPD Exacerbations [Time Frame: Endpoint (26 weeks)]

Measure Type	Secondary
Measure Title	Number of Participants With Mild, Moderate, or Severe COPD Exacerbations
Measure Description	Mild = 12 or more inhalations/day of inhaled rescue medication or 2 or more nebulized treatments/day of inhaled rescue medication. Moderate = treatment with antibiotics or oral steroids. Severe = emergency room treatment or hospitalizations of survival curves. If an event was composed of multiple criteria, the most severe criteria was assigned to the event.
Time Frame	Endpoint (26 weeks)
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
ITT population

Reporting Groups

	Description
MF/F MDI 400/10 mcg BID	Mometasone furoate/formoterol fumarate (MF/F) 400/10 mcg via a metered dose inhaler (MDI) twice daily (BID) for 52 weeks
MF/F MDI 200/10 mcg BID	MF/F 200/10 mcg via a MDI BID for 52 weeks
MF MDI 400 mcg BID	Mometasone furoate (MF) 400 mcg via a MDI BID for 52 weeks
F MDI 10 mcg BID	Formoterol fumarate (F) 10 mcg via a MDI BID for 52 weeks
Placebo	Placebo MDI BID for 26 weeks

Measured Values

	MF/F MDI 400/10 mcg BID	MF/F MDI 200/10 mcg BID	MF MDI 400 mcg BID	F MDI 10 mcg BID	Placebo
Number of Participants Analyzed [units: participants]	**217**	**207**	**210**	**209**	**212**
Number of Participants With Mild, Moderate, or Severe COPD Exacerbations [units: Participants]					
Mild	**41**	**48**	**41**	**45**	**41**
Moderate	**14**	**23**	**30**	**30**	**25**
Severe	**1**	**0**	**1**	**4**	**3**

No statistical analysis provided for Number of Participants With Mild, Moderate, or Severe COPD Exacerbations

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	No text entered.
Additional Description	Treatment period for adverse events was 52 weeks for MF/F MDI 400/10 mcg BID, MF/F MDI 200/10 mcg BID, MF MDI 400 mcg BID, and F MDI 10 mcg BID and 26 weeks for placebo.

Reporting Groups

	Description
MF/F MDI 200/10 MCG BID	No text entered.
MF/F MDI 400/10 MCG BID	No text entered.
MF MDI 400 MCG BID	No text entered.

F MDI 10 MCG BID	No text entered.
PLACEBO	No text entered.

Serious Adverse Events

	MF/F MDI 200/10 MCG BID	MF/F MDI 400/10 MCG BID	MF MDI 400 MCG BID	F MDI 10 MCG BID	PLACEBO
Total, serious adverse events					
# participants affected / at risk	**13/207 (6.28%)**	**29/217 (13.36%)**	**22/210 (10.48%)**	**29/209 (13.88%)**	**13/212 (6.13%)**
Cardiac disorders					
ACUTE MYOCARDIAL INFARCTION † 1					
# participants affected / at risk	**0/207 (0.00%)**	**0/217 (0.00%)**	**1/210 (0.48%)**	**1/209 (0.48%)**	**0/212 (0.00%)**
# events	**0**	**0**	**1**	**1**	**0**
ANGINA PECTORIS † 1					
# participants affected / at risk	**0/207 (0.00%)**	**2/217 (0.92%)**	**0/210 (0.00%)**	**0/209 (0.00%)**	**0/212 (0.00%)**
# events	**0**	**2**	**0**	**0**	**0**
ANGINA UNSTABLE † 1					
# participants affected / at risk	**0/207 (0.00%)**	**1/217 (0.46%)**	**0/210 (0.00%)**	**1/209 (0.48%)**	**1/212 (0.47%)**
# events	**0**	**1**	**0**	**1**	**1**
ATRIAL FIBRILLATION † 1					
# participants affected / at risk	**0/207 (0.00%)**	**1/217 (0.46%)**	**1/210 (0.48%)**	**0/209 (0.00%)**	**0/212 (0.00%)**
# events	**0**	**1**	**1**	**0**	**0**
BRADYCARDIA † 1					
# participants affected / at risk	**0/207 (0.00%)**	**0/217 (0.00%)**	**1/210 (0.48%)**	**0/209 (0.00%)**	**0/212 (0.00%)**
# events	**0**	**0**	**1**	**0**	**0**
CARDIAC FAILURE CONGESTIVE † 1					
# participants affected / at risk	**0/207 (0.00%)**	**1/217 (0.46%)**	**0/210 (0.00%)**	**0/209 (0.00%)**	**0/212 (0.00%)**
# events	**0**	**1**	**0**	**0**	**0**
COR PULMONALE CHRONIC † 1					
# participants affected / at risk	**0/207 (0.00%)**	**0/217 (0.00%)**	**0/210 (0.00%)**	**1/209 (0.48%)**	**0/212 (0.00%)**
# events	**0**	**0**	**0**	**1**	**0**
CORONARY ARTERY DISEASE † 1					
# participants affected / at risk	**0/207 (0.00%)**	**0/217 (0.00%)**	**1/210 (0.48%)**	**0/209 (0.00%)**	**0/212 (0.00%)**
# events	**0**	**0**	**1**	**0**	**0**
MYOCARDIAL INFARCTION † 1					
# participants affected / at risk	**0/207 (0.00%)**	**0/217 (0.00%)**	**1/210 (0.48%)**	**0/209 (0.00%)**	**1/212 (0.47%)**
# events	**0**	**0**	**1**	**0**	**1**

PALPITATIONS † 1					
# participants affected / at risk	0/207 (0.00%)	0/217 (0.00%)	0/210 (0.00%)	0/209 (0.00%)	1/212 (0.47%)
# events	0	0	0	0	1
Endocrine disorders					
GOITRE † 1					
# participants affected / at risk	1/207 (0.48%)	0/217 (0.00%)	0/210 (0.00%)	0/209 (0.00%)	0/212 (0.00%)
# events	1	0	0	0	0
Eye disorders					
CATARACT † 1					
# participants affected / at risk	1/207 (0.48%)	3/217 (1.38%)	2/210 (0.95%)	0/209 (0.00%)	1/212 (0.47%)
# events	1	4	2	0	1
CATARACT NUCLEAR † 1					
# participants affected / at risk	1/207 (0.48%)	0/217 (0.00%)	1/210 (0.48%)	0/209 (0.00%)	0/212 (0.00%)
# events	1	0	1	0	0
GLAUCOMA † 1					
# participants affected / at risk	0/207 (0.00%)	0/217 (0.00%)	0/210 (0.00%)	1/209 (0.48%)	0/212 (0.00%)
# events	0	0	0	1	0
LENTICULAR OPACITIES † 1					
# participants affected / at risk	1/207 (0.48%)	1/217 (0.46%)	2/210 (0.95%)	1/209 (0.48%)	1/212 (0.47%)
# events	1	1	2	1	1
Gastrointestinal disorders					
DIARRHOEA HAEMORRHAGIC † 1					
# participants affected / at risk	0/207 (0.00%)	0/217 (0.00%)	0/210 (0.00%)	1/209 (0.48%)	0/212 (0.00%)
# events	0	0	0	1	0
EROSIVE OESOPHAGITIS † 1					
# participants affected / at risk	0/207 (0.00%)	0/217 (0.00%)	0/210 (0.00%)	0/209 (0.00%)	1/212 (0.47%)
# events	0	0	0	0	1
GASTRIC ULCER † 1					
# participants affected / at risk	0/207 (0.00%)	0/217 (0.00%)	0/210 (0.00%)	2/209 (0.96%)	0/212 (0.00%)
# events	0	0	0	2	0
GASTRITIS † 1					
# participants affected / at risk	0/207 (0.00%)	1/217 (0.46%)	0/210 (0.00%)	0/209 (0.00%)	0/212 (0.00%)
# events	0	1	0	0	0
GASTROINTESTINAL HAEMORRHAGE † 1					
# participants affected / at risk	0/207 (0.00%)	0/217 (0.00%)	0/210 (0.00%)	1/209 (0.48%)	0/212 (0.00%)
# events	0	0	0	2	0
HERNIAL EVENTRATION † 1					

# participants affected / at risk	1/207 (0.48%)	0/217 (0.00%)	0/210 (0.00%)	0/209 (0.00%)	0/212 (0.00%)
# events	1	0	0	0	0
OESOPHAGEAL FOOD IMPACTION † 1					
# participants affected / at risk	0/207 (0.00%)	1/217 (0.46%)	0/210 (0.00%)	0/209 (0.00%)	0/212 (0.00%)
# events	0	1	0	0	0
OESOPHAGEAL RUPTURE † 1					
# participants affected / at risk	1/207 (0.48%)	0/217 (0.00%)	0/210 (0.00%)	0/209 (0.00%)	0/212 (0.00%)
# events	1	0	0	0	0
PEPTIC ULCER PERFORATION † 1					
# participants affected / at risk	0/207 (0.00%)	1/217 (0.46%)	0/210 (0.00%)	0/209 (0.00%)	0/212 (0.00%)
# events	0	1	0	0	0
VOMITING † 1					
# participants affected / at risk	0/207 (0.00%)	0/217 (0.00%)	0/210 (0.00%)	1/209 (0.48%)	1/212 (0.47%)
# events	0	0	0	1	1
General disorders					
MULTI-ORGAN FAILURE † 1					
# participants affected / at risk	0/207 (0.00%)	1/217 (0.46%)	0/210 (0.00%)	0/209 (0.00%)	0/212 (0.00%)
# events	0	1	0	0	0
SUDDEN DEATH † 1					
# participants affected / at risk	0/207 (0.00%)	0/217 (0.00%)	2/210 (0.95%)	1/209 (0.48%)	0/212 (0.00%)
# events	0	0	2	1	0
Hepatobiliary disorders					
CHOLECYSTITIS † 1					
# participants affected / at risk	1/207 (0.48%)	0/217 (0.00%)	0/210 (0.00%)	0/209 (0.00%)	0/212 (0.00%)
# events	1	0	0	0	0
CHOLELITHIASIS † 1					
# participants affected / at risk	0/207 (0.00%)	0/217 (0.00%)	0/210 (0.00%)	1/209 (0.48%)	0/212 (0.00%)
# events	0	0	0	1	0
CHRONIC HEPATIC FAILURE † 1					
# participants affected / at risk	1/207 (0.48%)	0/217 (0.00%)	0/210 (0.00%)	0/209 (0.00%)	0/212 (0.00%)
# events	1	0	0	0	0
Infections and infestations					
ABSCESS LIMB † 1					
# participants affected / at risk	0/207 (0.00%)	1/217 (0.46%)	0/210 (0.00%)	0/209 (0.00%)	0/212 (0.00%)
# events	0	1	0	0	0
APPENDICITIS † 1					
# participants affected / at risk	0/207 (0.00%)	1/217 (0.46%)	0/210 (0.00%)	0/209 (0.00%)	0/212 (0.00%)

# events	0	1	0	0	0
ARTHRITIS BACTERIAL † 1					
# participants affected / at risk	0/207 (0.00%)	1/217 (0.46%)	0/210 (0.00%)	0/209 (0.00%)	0/212 (0.00%)
# events	0	1	0	0	0
BRONCHITIS † 1					
# participants affected / at risk	0/207 (0.00%)	0/217 (0.00%)	0/210 (0.00%)	0/209 (0.00%)	1/212 (0.47%)
# events	0	0	0	0	1
CELLULITIS † 1					
# participants affected / at risk	0/207 (0.00%)	2/217 (0.92%)	0/210 (0.00%)	0/209 (0.00%)	0/212 (0.00%)
# events	0	2	0	0	0
DIVERTICULITIS † 1					
# participants affected / at risk	0/207 (0.00%)	0/217 (0.00%)	1/210 (0.48%)	0/209 (0.00%)	0/212 (0.00%)
# events	0	0	1	0	0
OESOPHAGEAL CANDIDIASIS † 1					
# participants affected / at risk	0/207 (0.00%)	0/217 (0.00%)	0/210 (0.00%)	0/209 (0.00%)	1/212 (0.47%)
# events	0	0	0	0	1
PNEUMONIA † 1					
# participants affected / at risk	1/207 (0.48%)	3/217 (1.38%)	1/210 (0.48%)	2/209 (0.96%)	1/212 (0.47%)
# events	1	3	1	2	1
PULMONARY TUBERCULOSIS † 1					
# participants affected / at risk	0/207 (0.00%)	1/217 (0.46%)	0/210 (0.00%)	0/209 (0.00%)	0/212 (0.00%)
# events	0	1	0	0	0
VIRAL INFECTION † 1					
# participants affected / at risk	1/207 (0.48%)	0/217 (0.00%)	0/210 (0.00%)	0/209 (0.00%)	1/212 (0.47%)
# events	1	0	0	0	1
Injury, poisoning and procedural complications					
SKIN LACERATION † 1					
# participants affected / at risk	0/207 (0.00%)	1/217 (0.46%)	0/210 (0.00%)	0/209 (0.00%)	0/212 (0.00%)
# events	0	1	0	0	0
SPINAL COMPRESSION FRACTURE † 1					
# participants affected / at risk	0/207 (0.00%)	1/217 (0.46%)	0/210 (0.00%)	0/209 (0.00%)	0/212 (0.00%)
# events	0	1	0	0	0
Metabolism and nutrition disorders					
DEHYDRATION † 1					
# participants affected / at risk	0/207 (0.00%)	0/217 (0.00%)	0/210 (0.00%)	0/209 (0.00%)	1/212 (0.47%)
# events	0	0	0	0	1

Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
ADENOCARCINOMA † 1					
# participants affected / at risk	**0/207 (0.00%)**	**0/217 (0.00%)**	**1/210 (0.48%)**	**0/209 (0.00%)**	**0/212 (0.00%)**
# events	**0**	**0**	**1**	**0**	**0**
COLON NEOPLASM † 1					
# participants affected / at risk	**0/207 (0.00%)**	**0/217 (0.00%)**	**0/210 (0.00%)**	**1/209 (0.48%)**	**0/212 (0.00%)**
# events	**0**	**0**	**0**	**1**	**0**
EXTRANODAL MARGINAL ZONE B-CELL LYMPHOMA (MALT TYPE) † 1					
# participants affected / at risk	**0/207 (0.00%)**	**0/217 (0.00%)**	**0/210 (0.00%)**	**1/209 (0.48%)**	**0/212 (0.00%)**
# events	**0**	**0**	**0**	**1**	**0**
LARYNGEAL CANCER † 1					
# participants affected / at risk	**0/207 (0.00%)**	**0/217 (0.00%)**	**0/210 (0.00%)**	**0/209 (0.00%)**	**1/212 (0.47%)**
# events	**0**	**0**	**0**	**0**	**1**
LUNG CANCER METASTATIC † 1					
# participants affected / at risk	**0/207 (0.00%)**	**1/217 (0.46%)**	**0/210 (0.00%)**	**0/209 (0.00%)**	**0/212 (0.00%)**
# events	**0**	**1**	**0**	**0**	**0**
LUNG NEOPLASM MALIGNANT † 1					
# participants affected / at risk	**0/207 (0.00%)**	**0/217 (0.00%)**	**0/210 (0.00%)**	**1/209 (0.48%)**	**0/212 (0.00%)**
# events	**0**	**0**	**0**	**1**	**0**
MALIGNANT PALATE NEOPLASM † 1					
# participants affected / at risk	**0/207 (0.00%)**	**1/217 (0.46%)**	**0/210 (0.00%)**	**0/209 (0.00%)**	**0/212 (0.00%)**
# events	**0**	**1**	**0**	**0**	**0**
NON-HODGKIN'S LYMPHOMA † 1					
# participants affected / at risk	**0/207 (0.00%)**	**0/217 (0.00%)**	**0/210 (0.00%)**	**1/209 (0.48%)**	**0/212 (0.00%)**
# events	**0**	**0**	**0**	**1**	**0**
Nervous system disorders					
CEREBRAL INFARCTION † 1					
# participants affected / at risk	**0/207 (0.00%)**	**0/217 (0.00%)**	**1/210 (0.48%)**	**0/209 (0.00%)**	**0/212 (0.00%)**
# events	**0**	**0**	**1**	**0**	**0**
CEREBRAL ISCHAEMIA † 1					
# participants affected / at risk	**0/207 (0.00%)**	**0/217 (0.00%)**	**1/210 (0.48%)**	**0/209 (0.00%)**	**0/212 (0.00%)**
# events	**0**	**0**	**1**	**0**	**0**
CEREBROVASCULAR ACCIDENT † 1					
# participants affected / at risk	**0/207 (0.00%)**	**0/217 (0.00%)**	**1/210 (0.48%)**	**0/209 (0.00%)**	**0/212 (0.00%)**
# events	**0**	**0**	**1**	**0**	**0**
CEREBROVASCULAR DISORDER † 1					

# participants affected / at risk	0/207 (0.00%)	0/217 (0.00%)	0/210 (0.00%)	2/209 (0.96%)	0/212 (0.00%)
# events	0	0	0	2	0
SUBARACHNOID HAEMORRHAGE † 1					
# participants affected / at risk	0/207 (0.00%)	0/217 (0.00%)	1/210 (0.48%)	0/209 (0.00%)	0/212 (0.00%)
# events	0	0	1	0	0
TREMOR † 1					
# participants affected / at risk	0/207 (0.00%)	0/217 (0.00%)	0/210 (0.00%)	0/209 (0.00%)	1/212 (0.47%)
# events	0	0	0	0	1
VASCULAR HEADACHE † 1					
# participants affected / at risk	0/207 (0.00%)	0/217 (0.00%)	0/210 (0.00%)	1/209 (0.48%)	0/212 (0.00%)
# events	0	0	0	1	0
Renal and urinary disorders					
RENAL FAILURE ACUTE † 1					
# participants affected / at risk	0/207 (0.00%)	1/217 (0.46%)	0/210 (0.00%)	0/209 (0.00%)	1/212 (0.47%)
# events	0	1	0	0	1
Respiratory, thoracic and mediastinal disorders					
ACUTE RESPIRATORY FAILURE † 1					
# participants affected / at risk	0/207 (0.00%)	2/217 (0.92%)	0/210 (0.00%)	0/209 (0.00%)	2/212 (0.94%)
# events	0	2	0	0	2
CHRONIC OBSTRUCTIVE PULMONARY DISEASE † 1					
# participants affected / at risk	4/207 (1.93%)	13/217 (5.99%)	6/210 (2.86%)	10/209 (4.78%)	7/212 (3.30%)
# events	4	14	6	10	8
COUGH † 1					
# participants affected / at risk	0/207 (0.00%)	0/217 (0.00%)	0/210 (0.00%)	0/209 (0.00%)	1/212 (0.47%)
# events	0	0	0	0	1
DYSPNOEA † 1					
# participants affected / at risk	0/207 (0.00%)	1/217 (0.46%)	0/210 (0.00%)	0/209 (0.00%)	0/212 (0.00%)
# events	0	1	0	0	0
HICCUPS † 1					
# participants affected / at risk	0/207 (0.00%)	0/217 (0.00%)	0/210 (0.00%)	0/209 (0.00%)	1/212 (0.47%)
# events	0	0	0	0	1
HYPOXIA † 1					
# participants affected / at risk	0/207 (0.00%)	0/217 (0.00%)	0/210 (0.00%)	0/209 (0.00%)	1/212 (0.47%)
# events	0	0	0	0	1
PNEUMOMEDIASTINUM † 1					
# participants affected / at risk	1/207 (0.48%)	0/217 (0.00%)	0/210 (0.00%)	0/209 (0.00%)	0/212 (0.00%)

# events	1	0	0	0	0
PNEUMOTHORAX † 1					
# participants affected / at risk	0/207 (0.00%)	0/217 (0.00%)	0/210 (0.00%)	1/209 (0.48%)	0/212 (0.00%)
# events	0	0	0	2	0
PULMONARY AMYLOIDOSIS † 1					
# participants affected / at risk	0/207 (0.00%)	1/217 (0.46%)	0/210 (0.00%)	0/209 (0.00%)	0/212 (0.00%)
# events	0	1	0	0	0
PULMONARY EMBOLISM † 1					
# participants affected / at risk	0/207 (0.00%)	2/217 (0.92%)	0/210 (0.00%)	1/209 (0.48%)	0/212 (0.00%)
# events	0	2	0	1	0
RESPIRATORY FAILURE † 1					
# participants affected / at risk	1/207 (0.48%)	0/217 (0.00%)	0/210 (0.00%)	1/209 (0.48%)	0/212 (0.00%)
# events	1	0	0	1	0
Surgical and medical procedures					
CAROTID ENDARTERECTOMY † 1					
# participants affected / at risk	1/207 (0.48%)	0/217 (0.00%)	0/210 (0.00%)	0/209 (0.00%)	0/212 (0.00%)
# events	1	0	0	0	0
INCISIONAL HERNIA REPAIR † 1					
# participants affected / at risk	0/207 (0.00%)	1/217 (0.46%)	0/210 (0.00%)	0/209 (0.00%)	0/212 (0.00%)
# events	0	1	0	0	0
Vascular disorders					
FEMORAL ARTERIAL STENOSIS † 1					
# participants affected / at risk	0/207 (0.00%)	0/217 (0.00%)	0/210 (0.00%)	1/209 (0.48%)	0/212 (0.00%)
# events	0	0	0	1	0
PERIPHERAL ARTERY ANEURYSM † 1					
# participants affected / at risk	0/207 (0.00%)	0/217 (0.00%)	0/210 (0.00%)	1/209 (0.48%)	0/212 (0.00%)
# events	0	0	0	1	0
POOR PERIPHERAL CIRCULATION † 1					
# participants affected / at risk	1/207 (0.48%)	0/217 (0.00%)	0/210 (0.00%)	0/209 (0.00%)	0/212 (0.00%)
# events	1	0	0	0	0

† Events were collected by systematic assessment
1 Term from vocabulary, MedDRA 13.0

Other Adverse Events

Hide Other Adverse Events

Time Frame	No text entered.

Additional Description	Treatment period for adverse events was 52 weeks for MF/F MDI 400/10 mcg BID, MF/F MDI 200/10 mcg BID, MF MDI 400 mcg BID, and F MDI 10 mcg BID and 26 weeks for placebo.

Frequency Threshold

Threshold above which other adverse events are reported	5%

Reporting Groups

	Description
MF/F MDI 200/10 MCG BID	No text entered.
MF/F MDI 400/10 MCG BID	No text entered.
MF MDI 400 MCG BID	No text entered.
F MDI 10 MCG BID	No text entered.
PLACEBO	No text entered.

Other Adverse Events

	MF/F MDI 200/10 MCG BID	MF/F MDI 400/10 MCG BID	MF MDI 400 MCG BID	F MDI 10 MCG BID	PLACEBO
Total, other (not including serious) adverse events					
# participants affected / at risk	**8/207 (3.86%)**	**10/217 (4.61%)**	**9/210 (4.29%)**	**11/209 (5.26%)**	**11/212 (5.19%)**
Nervous system disorders					
HEADACHE † 1					
# participants affected / at risk	**8/207 (3.86%)**	**10/217 (4.61%)**	**9/210 (4.29%)**	**11/209 (5.26%)**	**11/212 (5.19%)**
# events	**11**	**15**	**21**	**18**	**22**

† Events were collected by systematic assessment
1 Term from vocabulary, MedDRA 13.0

Limitations and Caveats

Hide Limitations and Caveats

Limitations of the study, such as early termination leading to small numbers of participants analyzed and technical problems with measurement leading to unreliable or uninterpretable data
No text entered.

More Information

Hide More Information

Certain Agreements:

Principal Investigators are **NOT** employed by the organization sponsoring the study.

There **IS** an agreement between Principal Investigators and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.

The agreement is:

☐ The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **less than or equal to 60 days**. The sponsor cannot require changes to the communication and cannot extend the embargo.

☐ The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **more than 60 days but less than or equal to 180 days**. The sponsor cannot require changes to the communication and cannot extend the embargo.

Other disclosure agreement that restricts the right of the PI to discuss or publish trial results after the trial is completed.

☑ **Restriction Description:** The investigator has the right to publish or publicly present results. The investigator agrees not to publish or publicly present any interim results without prior written consent of the sponsor. The investigator agrees to provide to the sponsor 45 days before submission for publication that report results of the study. The sponsor shall have the right to review & comment with respect to publications, abstracts, slides, & manuscripts & the right to review & comment on the data & presentation.

Results Point of Contact:

Name/Title: Senior Vice President, Global Clinical Development
Organization: Merck Sharp & Dohme Corp.
e-mail: ClinicalTrialsDisclosure@merck.com

Publications automatically indexed to this study by ClinicalTrials.gov Identifier (NCT Number):

Maspero J, Cherrez I, Doherty DE, Tashkin DP, Kuna P, Kuo WL, Gates D, Nolte H, Chylack LT Jr. Appraisal of lens opacity with mometasone furoate/formoterol fumarate combination in patients with COPD or asthma. Respir Med. 2014 Sep;108(9):1355-62. doi: 10.1016/j.rmed.2014.04.015. Epub 2014 May 2.

Tashkin DP, Doherty DE, Kerwin E, Matiz-Bueno CE, Knorr B, Shekar T, Gates D, Staudinger H. Efficacy and safety characteristics of mometasone furoate/formoterol fumarate fixed-dose combination in subjects with moderate to very severe COPD: findings from pooled analysis of two randomized, 52-week placebo-controlled trials. Int J Chron Obstruct Pulmon Dis. 2012;7:73-86. doi: 10.2147/COPD.S29444. Epub 2012 Feb 3.

Tashkin DP, Doherty DE, Kerwin E, Matiz-Bueno CE, Knorr B, Shekar T, Banerjee S, Staudinger H. Efficacy and safety of a fixed-dose combination of mometasone furoate and formoterol fumarate in subjects with moderate to very severe COPD: results from a 52-week Phase III trial. Int J Chron Obstruct Pulmon Dis. 2012;7:43-55. doi: 10.2147/COPD.S27319. Epub 2012 Feb 3. Erratum in: Int J Chron Obstruct Pulmon Dis. 2012;7:765.

Responsible Party:	Merck Sharp & Dohme Corp.
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Study First Received:	September 29, 2006
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