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Efficacy And Safety Of GW642444M Comparing Placebo In Adolescent And Adult Subjects With Persistent Asthma.

This study has been completed.

Sponsor:	GlaxoSmithKline
Collaborators:	
Information provided by (Responsible Party):	GlaxoSmithKline
ClinicalTrials.gov Identifier:	NCT00600171

Purpose

This study is designed to determine if the investigational drug is effective and safe in individuals with asthma

Condition	Intervention	Phase
Asthma	Drug: GW642444M Drug: Placebo	Phase 2

Study Type: Interventional
Study Design: Treatment, Parallel Assignment, Double Blind (Subject, Investigator), Randomized, Safety/Efficacy Study
Official Title: A Randomised, Double-blind, Placebo Controlled, Parallel Group, Dose Ranging Study Evaluating the Efficacy and Safety of GW642444M Administered Once Daily Compared With Placebo for 28 Days in Adolescent and Adult Subjects With Persistent Asthma

Further study details as provided by GlaxoSmithKline:

Primary Outcome Measure:

- Mean Change From Baseline in Clinic Visit Trough FEV1 at Day 28 (Last Observation Carried Forward [LOCF]) [Time Frame: Baseline and Day 28] [Designated as safety issue: No]

  Pulmonary function was measured by forced expiratory volume in one second (FEV1), defined as the maximal amount of air that can be forcefully exhaled in one second. Trough FEV1 is defined as the clinic visit (pre-bronchodilator and pre-dose) FEV1 at the end of the 28-day treatment period,

with the trough FEV1 defined as the mean of the 23 hour and 24 hour post-dose assessments on Day 28. Change from Baseline was calculated as the post-Baseline value minus the Baseline value. Analysis was performed using Analysis of Covariance (ANCOVA) using LOCF with covariates of Baseline (pre-dose on Day 1), country, sex, age, stratum, and treatment.

Secondary Outcome Measures:

- Mean Change From Baseline in Clinic Visit Trough FEV1 at Day 28 Per Stratum (LOCF) [Time Frame: Baseline and Day 28] [Designated as safety issue: No]

  Pulmonary function was measured by forced expiratory volume in one second (FEV1), defined as the maximal amount of air that can be forcefully exhaled in one second. Trough FEV1 is defined as the clinic visit (pre-bronchodilator and pre-dose) FEV1 at the end of the 28-day treatment period, with the trough FEV1 defined as the mean of the 23 hour and 24 hour post-dose assessments on Day 28. Change from Baseline in trough FEV1 at the end of the treatment period (23 hours and 24 hours after dosing on Day 28) was analyzed for each stratum (Lower stratum: FEV1 percent predicted, >=40% to <=65%; Upper stratum: FEV1 percent predicted, >=65% to <=90%). Change from Baseline was calculated as the post-Baseline value minus the Baseline value. Analysis was performed using ANCOVA using LOCF with covariates of Baseline (pre-dose on Day 1), country, sex, age, stratum, treatment, and treatment by stratum interaction.
- Change From Baseline in Weighted Mean 24-hour Serial FEV1 at Day 1 and Day 28 [Time Frame: Baseline; Day 1 and Day 28 (mean post-dose FEV1 after 15, 30, and 60 minutes and 2, 3, 4, 6, 12, 16, 20, 22, 23, and 24 hours)] [Designated as safety issue: No]

  Pulmonary function was measured by FEV1, defined as the maximal amount of air that can be forcefully exhaled in one second. Change from Baseline in weighted mean for 24-hour serial FEV1 on Days 1 and Day 28 was assessed. Change from Baseline was calculated as the post-Baseline value minus the Baseline value. Analysis was performed using ANCOVA with covariates of Baseline (pre-dose on Day 1), country, sex, age, stratum, and treatment.
- Mean Change From Baseline in Trough (Pre-dose and Pre-bronchodilator) Daily Evening (PM) Peak Expiratory Flow (PEF) Averaged Over the 28-day Treatment Period [Time Frame: Baseline and Days 1-28] [Designated as safety issue: No]

  Peak Expiratory Flow (PEF) is defined as the maximum airflow during a forced expiration beginning with the lungs fully inflated. Change from Baseline was calculated as the value of the averaged PEF daily PM over the 28-day treatment period (at Day 28) minus the Baseline value (defined as the last 7 days prior to randomization of the participants). Analysis was performed using ANCOVA with covariates of Baseline, country, sex, age, stratum, and treatment.
- Mean Change From Baseline in Daily Morning (AM) PEF Averaged Over the 28-day Treatment Period [Time Frame: Baseline and Days 1-28] [Designated as safety issue: No]

  Peak Expiratory Flow (PEF) is defined as the maximum airflow during a forced expiration beginning with the lungs fully inflated. Change from Baseline was calculated as the value of the averaged PEF daily AM over the 28-day treatment period (at Day 28) minus the Baseline value (defined as the last 7 days prior to randomization of the participants). Analysis was performed using ANCOVA with covariates of Baseline, country, sex, age, stratum, and treatment.
- Mean Change From Baseline in the Percentage of Symptom-free 24-hour (hr) Periods Averaged Over the 28-day Treatment Period [Time Frame: Baseline and Days 1-28] [Designated as safety issue: No]

  Participants who were symptom free for 24 hours were assessed. Change from Baseline was calculated as the value at Day 28 minus the value at Baseline (defined as the last 7 days prior to randomization of the participants). Analysis was performed using ANCOVA with covariates of Baseline, country, sex, age, stratum, and treatment.
- Change From Baseline in the Percentage of Rescue-free 24-hour (hr) Periods Averaged Over the 28-day Treatment Period [Time Frame: Baseline and Days 1-28] [Designated as safety issue: No]

  The time span during which the participants did not have to take any rescue medication (medication intended to relieve symptoms immediately) was considered to be a rescue-free period. Change from Baseline is calculated as the value at Day 28 minus the value at Baseline (defined as the last 7 days prior to randomization of the participants). Analysis was performed using ANCOVA with covariates of Baseline, country, sex, age, stratum, and treatment.

- Difference in Post Salbutamol/Albuterol FEV1 (FEV1 30 Minutes After a Single Dose of 400 µg Salbutamol/Albuterol) Between the Following Time Points: 24 Hours After Dosing on Day 1 and Day 28 [Time Frame: 24 hours after dosing on Day 1 (Visit 2) and on Day 28 (Visit 5)] [Designated as safety issue: No]

  Assessment at Visit 2/2a was made prior to the evening dose of study medication on Day 2. Participants were administered a single 400 µg dose of salbutamol/albuterol, and FEV1 was measured 30 minutes after this administration. The highest of three technically acceptable measurements was recorded. These assessments were performed as follows: between 5 PM and 10 PM, >=6 hours after the last use of salbutamol/albuterol, >=6 hours after the last caffeine consumption, >=2 hours after exercise (or strenuous activity), >=24 hours after the first dose (Visit 2) or last dose (Visit 5) of study medication. Analysis was performed using ANCOVA with covariates of Baseline (pre-salbutamol measurement at Screening), country, sex, age, stratum, and treatment. Analysis is of the differences in absolute FEV1 measurements taken post-salbutamol/albuterol.
- Difference in Post Salbutamol/Albuterol FEV1 (FEV1 30minutes After a Single Dose of 400 µg Salbutamol/Albuterol) Between the Following Time Points: Screening and 24 Hours After Dosing on Day 1 [Time Frame: Screening (Visit 1) and 24 hours after dosing on Day 1 (Visit 2)] [Designated as safety issue: No]

  Assessment at Visit 2/2a was made prior to the evening dose of study medication on Day 2. Participants were administered a single 400 µg dose of salbutamol/albuterol, and FEV1 was measured 30 minutes after this administration. The highest of three technically acceptable measurements was recorded. These assessments were performed as follows: between 5 PM and 10 PM, >=6 hours after the last use of salbutamol/albuterol, >=6 hours after the last caffeine consumption, >=2 hours after exercise (or strenuous activity), Screening and >=24 hours after the first dose (Visit 2) of study medication. Analysis was performed using ANCOVA with covariates of Baseline (pre-salbutamol measurement at Screening), country, sex, age, stratum, and treatment. Analysis is of the differences in absolute FEV1 measurements taken post-salbutamol/albuterol.
- Difference in Post Salbutamol/Albuterol FEV1 (FEV1 30 Minutes After a Single Dose of 400 µg Salbutamol/Albuterol) Between the Following Time Points: Screening and 24 Hours After Dosing on Day 28 [Time Frame: Screening (Visit 1) and 24 hours after dosing on Day 28 (Visit 5)] [Designated as safety issue: No]

  Assessment at Visit 2/2a was made prior to the evening dose of study medication on Day 2. Participants were administered a single 400 µg dose of salbutamol/albuterol, and FEV1 was measured 30 minutes after this administration. The highest of three technically acceptable measurements was recorded. These assessments were performed as follows: between 5 PM and 10 PM, >=6 hours after the last use of salbutamol/albuterol, >=6 hours after the last caffeine consumption, >=2 hours after exercise (or strenuous activity), Screening and >=24 hours after the first dose (Visit 2) of study medication. Analysis was performed using ANCOVA with covariates of Baseline (pre-salbutamol measurement at Screening), country, sex, age, stratum, and treatment. Analysis is of the differences in absolute FEV1 measurements taken post-salbutamol/albuterol.

Enrollment: 614
Study Start Date: December 2007
Primary Completion Date: September 2008
Study Completion Date: September 2008

Arms	Assigned Interventions
Placebo Comparator: Placebo Placebo Multi dose dry powder inhlaer	Drug: Placebo Placebo mulit-dose dry powder inhaler
Experimental: GW642444M GW642444M	Drug: GW642444M GW642444M

Eligibility

Ages Eligible for Study: 12 Years and older
Genders Eligible for Study: Both

Accepts Healthy Volunteers: No

Criteria

Inclusion criteria:

- Aged 12 years of age or older at Visit 1 For sites in the following countries, subjects recruited will be ³ 18 years of age: Germany, Hungary and the Russian Federation and any other countries where local regulations or the regulatory status of study medication permit enrolment of adults only.
- Male or eligible female subjects

A female is eligible to enter and participate in the study if she is of:

Non-child bearing potential (i.e. physiologically incapable of becoming pregnant), including any female who is post-menopausal.

Child bearing potential, has a negative pregnancy test at screening, and agrees to one of the following acceptable contraceptive methods used consistently and correctly (i.e. in accordance with the approved product label and the instructions of the physician for the duration of the study - screening to follow-up contact):

- Complete abstinence from intercourse from screening until 2 weeks after the follow-up contact; or
- Sterilisation of male partner (vasectomy with documentation of azoospermia) prior to female subject entry into the study, and this male partner is the sole partner for that subject; or
- Implants of levonorgestral inserted for at least 1 month prior to the study medication administration but not beyond the third successive year following insertion; or
- Injectable progestogen administered for at least 1 month prior to study medication administration and administered for 1 month following study completion; or
- Oral contraceptive (combined or progestogen only) administered for at least one monthly cycle prior to study medication administration; or
- Double barrier method: condom or occlusive cap (diaphragm or cervical/vault caps) plus spermicidal agent (foam/gel/film/cream/suppository) N.B. For German sites female subjects must use a method of birth control other than the double barrier method
- An intrauterine device (IUD), inserted by a qualified physician, with published data showing that the highest expected failure rate is less than 1% per year; or
- Estrogenic vaginal ring inserted for at least 1 month prior to study medication administration; or
- Percutaneous contraceptive patches in place for at least 1 month prior to study medication administration Female subjects should not be enrolled if they are pregnant, or lactating, or plan to become pregnant during the time of study participation.
- Documented clinical history of persistent asthma, as defined by the National Institutes of Health [NIH, 2007] first diagnosed at least 6 months prior to Visit 1.
- Subjects with current reversible airways disease as demonstrated at Visit 1 by an increase in FEV1 of ≥ 12% and ≥ 200ml over the pre-salbutamol/albuterol FEV1 at approximately 30 minutes after the inhalation of 400mcg of salbutamol/albuterol via MDI (spacer permitted for reversibility testing only if required) or one nebulised salbutamol/albuterol solution.
- Subjects must be using an inhaled corticosteroid and have been maintained on a stable dose for 4 weeks prior to Visit 1 at one of the following doses:

Maximum Allowable Concurrent Inhaled Corticosteroid Doses

Asthma Therapy(Maximum Daily Dose (mcg/day)) fluticasone propionate MDI CFC/HFA (≤ 880mcg1/ ≤1000mcg2) fluticasone propionate DPI(≤ 1000mcg) beclomethasone dipropionate(≤ 1680mcg1/ ≤ 2000mcg2) beclomethasone dipropionate HFA (QVAR)(≤ 640mcg1/ ≤ 800mcg2) budesonide DPI/MDI(≤ 2000mcg) Flunisolide(≤ 2000mcg) triamcinolone acetonide(≤ 2000mcg) mometasone furoate(≤ 880mcg) Ciclesonide(≤ 320mcg1/ ≤ 400mcg2)

CFC=chlorofluorocarbon HFA=hydrofluoroalkane

1. Ex-actuator dose
2. Ex-valve dose

    - Pre-bronchodilator FEV1 between ≥ 40 - ≤ 90% predicted at Visit 1. NHANES III predicted values will be used for subjects aged ≥ 12 years and adjustments to predicted values will be made for African American subjects [Hankinson, 1999].

- Appropriately signed and dated informed consent has been obtained.
- Capable of withholding salbutamol/albuterol use for ≥ 6 hours prior to clinic visits.
- In France, a subject will be eligible for inclusion in this study only if either affiliated to or a beneficiary of a social security category.

Exclusion criteria:

- An exacerbation of asthma within 4 weeks of Visit 1, or a culture documented or suspected bacterial or viral infection of the upper or lower respiratory tract, sinus or middle ear within 4 weeks of Visit 1 that led to a change in asthma management, or in the opinion of the Investigator is expected to affect the subjects asthma status or the subjects ability to participate in the study.
- History of life-threatening asthma, defined as an asthma episode that required intubation and/or was associated with hypercapnoea, respiratory arrest or hypoxia seizures.
- Asthma exacerbation requiring treatment with oral corticosteroids within 3 months prior to Visit 1.
- Hospitalised for an asthma exacerbation within 6 months of Visit 1. Hospitalisation is defined as an overnight stay in a hospital.
- Previously enrolled in this study, or has participated in any study using an investigational drug during the previous 30 days or will participate simultaneously in another clinical trial.
- A subject must not have any clinically significant, uncontrolled condition or disease state that, in the opinion of the investigator, would put the subject's safety at risk through study participation or would confound the interpretation of the efficacy results if the condition/disease exacerbated during the study.

The list of additional excluded conditions/diseases includes, but is not limited to the following:

congestive heart failure, known aortic aneurysm clinically significant coronary heart disease, clinically significant cardiac arrhythmia stroke within 3 months of Visit 1, uncontrolled hypertension1 poorly controlled peptic ulcer, haematologic, hepatic, or renal disease immunologic compromise, current malignancy2 tuberculosis (current or untreated3), Cushing's disease Addison's disease, uncontrolled diabetes mellitus uncontrolled thyroid disorder, recent history of drug or alcohol abuse neurological disease, pulmonary disease4

1. systolic blood pressure 160, or diastolic blood pressure >100
2. history of malignancy is acceptable only if subject has been in remission for one year prior to Visit 1 (remission = no current evidence of malignancy and no treatment for the malignancy in the 12 months prior to Visit 1)
3. Subjects with a history of tuberculosis who have received an approved prophylactic treatment regimen or an approved active treatment regimen and who have no evidence of active disease for a minimum of 2 years may be enrolled [American Thoracic Society Documents, 2005] [American Thoracic Society (ATS), 2003]
4. Including but not limited to chronic bronchitis, emphysema, bronchiectasis with the need of treatment, cystic fibrosis, bronchopulmonary dysplasia, and chronic obstructive pulmonary disease.

    - Any adverse reaction including immediate or delayed hypersensitivity to any ß2-agonist or sympathomimetic drug, or known (i.e., patients with a history of severe milk protein allergy) or suspected sensitivity to the constituents of GW642444M inhalation powder (e.g., lactose or magnesium stearate).
    - Subjects who are likely to be non-compliant with study medication and other study-related requirements (e.g. attendance at clinic visits or completion of Daily Diary).
    - Neurological or psychiatric disease or history of drug or alcohol abuse which would interfere with the subject's proper completion of the protocol requirements.

Abuse of alcohol is defined as an average weekly intake of greater than 21 units or an average daily intake of greater than 3 units (males) or defined as an average weekly intake of greater than 14 units or an average daily intake of greater than 2 units (females). The number of units of alcohol in a drink can be determined by multiplying the volume of the drink (in millilitres) by its percentage ABV and dividing by 1000

- Current smoker or a smoking history of 10 pack years or more (e.g. 20 cigarettes/day for 10 years). A subject may not have used tobacco products within the past one year (i.e., cigarettes, cigars, or pipe tobacco).

- Administration of systemic, oral or depot corticosteroids or administration of anti-IgE (e.g. omalizumab [Xolair]) within 12 weeks of Visit 1.
- Administration of the following asthma medications within 14 days of Visit 1:
- Theophyllines
- Oral β2-agonists (e.g. bambuterol)
- Slow-release bronchodilators
- Anticholinergics - short or long-acting
- Oral long acting antihistamines
- Oral leukotriene receptor antagonists (e.g. montelukast)

Contacts and Locations

Locations

United States, Arizona

GSK Investigational Site
Phoenix, Arizona, United States, 85006

GSK Investigational Site
Phoenix, Arizona, United States, 85050

United States, California

GSK Investigational Site
Fresno, California, United States, 93720

GSK Investigational Site
Huntington Beach, California, United States, 92647

GSK Investigational Site
Huntington Beach, California, United States, 92647

GSK Investigational Site
Long Beach, California, United States, 90806

GSK Investigational Site
Long Beach, California, United States, 90808

GSK Investigational Site
Rolling Hills Estates, California, United States, 90274

GSK Investigational Site
San Diego, California, United States, 92123

United States, Colorado

GSK Investigational Site
Denver, Colorado, United States, 80230

United States, Florida

GSK Investigational Site
Tallahassee, Florida, United States, 32308

GSK Investigational Site
Valrico, Florida, United States, 33596

United States, Idaho

GSK Investigational Site
Coeur D'Alene, Idaho, United States, 83814

United States, Illinois

GSK Investigational Site
River Forest, Illinois, United States, 60305
United States, Louisiana
GSK Investigational Site
Metairie, Louisiana, United States, 70006
GSK Investigational Site
Sunset, Louisiana, United States, 70584
United States, Maryland
GSK Investigational Site
Bethesda, Maryland, United States, 20814
United States, Massachusetts
GSK Investigational Site
North Dartmouth, Massachusetts, United States, 02747
United States, Missouri
GSK Investigational Site
Columbia, Missouri, United States, 65203
GSK Investigational Site
Rolla, Missouri, United States, 65401
GSK Investigational Site
St. Louis, Missouri, United States, 63141
United States, New Jersey
GSK Investigational Site
Skillman, New Jersey, United States, 08558
United States, New York
GSK Investigational Site
Bronx, New York, United States, 10461
United States, North Carolina
GSK Investigational Site
Raleigh, North Carolina, United States, 27607
United States, Ohio
GSK Investigational Site
Canton, Ohio, United States, 44718
GSK Investigational Site
Cincinnati, Ohio, United States, 45231
United States, Oklahoma
GSK Investigational Site
Oklahoma City, Oklahoma, United States, 73120
United States, Oregon
GSK Investigational Site
Medford, Oregon, United States, 97504
United States, Rhode Island
GSK Investigational Site
Providence, Rhode Island, United States, 02909
United States, South Carolina
GSK Investigational Site

Orangeburg, South Carolina, United States, 29118
United States, Tennessee
GSK Investigational Site
Knoxville, Tennessee, United States, 37909
Argentina
GSK Investigational Site
Tucuman, Argentina, 4000
GSK Investigational Site
Buenos Aires, Buenos Aires, Argentina, 1437
GSK Investigational Site
Buenos Aires, Buenos Aires, Argentina, 1425
GSK Investigational Site
La Plata, Buenos Aires, Argentina, CP1900
GSK Investigational Site
Mendoza, Mendoza, Argentina, M5500CCG
Belgium
GSK Investigational Site
Edegem, Belgium, 2650
GSK Investigational Site
Liège, Belgium, 4000
Canada, Ontario
GSK Investigational Site
Brampton, Ontario, Canada, L6T 3T1
GSK Investigational Site
Mississauga, Ontario, Canada, L4W 1N2
GSK Investigational Site
Mississauga, Ontario, Canada, L5A 3V4
Canada, Quebec
GSK Investigational Site
Montreal, Quebec, Canada, H4W 1S7
GSK Investigational Site
Montreal, Quebec, Canada, H3H 2R9
GSK Investigational Site
Quebec City, Quebec, Canada, G1V 4M6
GSK Investigational Site
Sainte-Foy, Quebec, Canada, G1V 4G5
GSK Investigational Site
Trois Rivières, Quebec, Canada, G8T 7A1
Chile
GSK Investigational Site
Santiago, Chile, 8380453
GSK Investigational Site
Santiago, Región Metro De Santiago, Chile, 7500551
France
GSK Investigational Site

Montpellier, France, 34295
GSK Investigational Site
Paris, France, 75018
GSK Investigational Site
Toulouse cedex 9, France, 31059
Germany
GSK Investigational Site
Mannheim, Baden-Wuerttemberg, Germany, 68161
GSK Investigational Site
Wiesloch, Baden-Wuerttemberg, Germany, 69168
GSK Investigational Site
Berlin, Berlin, Germany, 14057
GSK Investigational Site
Ruedersdorf, Brandenburg, Germany, 15562
GSK Investigational Site
Wiesbaden, Hessen, Germany, 65187
GSK Investigational Site
Hannover, Niedersachsen, Germany, 30159
GSK Investigational Site
Magdeburg, Sachsen-Anhalt, Germany, 39112
GSK Investigational Site
Geesthacht, Schleswig-Holstein, Germany, 21502
Korea, Republic of
GSK Investigational Site
Cheongju, Chungcheongbuk-do, Korea, Republic of, 361-711
GSK Investigational Site
Suwon-Si, Korea, Republic of, 443-721
Netherlands
GSK Investigational Site
Harderwijk, Netherlands, 3844 DG
GSK Investigational Site
Heerlen, Netherlands, 6419 PC
GSK Investigational Site
Utrecht, Netherlands, 3584 CJ
Peru
GSK Investigational Site
Lima, Peru, Lima 11
GSK Investigational Site
Lima, Lima, Peru, Lima 27
GSK Investigational Site
Lima, Lima, Peru, Lima 1
Philippines
GSK Investigational Site
Cavite, Philippines, 4114
GSK Investigational Site

Manila, Philippines, 1000

Poland

GSK Investigational Site
Bialystok, Poland, 15-025

GSK Investigational Site
Bydgoszcz, Poland, 85-168

GSK Investigational Site
Krakow, Poland, 31-023

GSK Investigational Site
Lodz, Poland, 93-504

GSK Investigational Site
Lodz, Poland, 91-348

Russian Federation

GSK Investigational Site
Kazan, Russian Federation, 420015

GSK Investigational Site
Moscow, Russian Federation, 115446

GSK Investigational Site
Moscow, Russian Federation, 117292

GSK Investigational Site
Ryazan, Russian Federation, 390039

GSK Investigational Site
Saratov, Russian Federation, 410002

GSK Investigational Site
St.Petersburg, Russian Federation

GSK Investigational Site
Yaroslavl, Russian Federation, 150003

South Africa

GSK Investigational Site
Amanzimtoti, South Africa, 4126

GSK Investigational Site
Cape Town, South Africa, 7500

GSK Investigational Site
Claremont, South Africa, 7708

GSK Investigational Site
Mowbray, South Africa, 7700

GSK Investigational Site
Cape Town, Gauteng, South Africa, 7505

Sweden

GSK Investigational Site
Göteborg, Sweden, SE-413 45

GSK Investigational Site
Lund, Sweden, SE-221 85

Thailand

GSK Investigational Site

Chiangmai, Thailand, 50200
GSK Investigational Site
Khon Kaen, Thailand, 40002

Investigators

Study Director:	GSK Clinical Trials	GlaxoSmithKline

More Information

Publications:

Lötvall J, Bateman ED, Bleecker ER, Busse WW, Woodcock A, Follows R, Lim J, Stone S, Jacques L, Haumann B. 24h duration of the novel LABA vilanterol trifenatate in asthma patients treated with ICSs. [Eur Respir J]. 2012;40(3):570-579.

Responsible Party:	GlaxoSmithKline
Study ID Numbers:	B2C109575
Health Authority:	Germany: Federal Institute for Drugs and Medical Devices United States: Food and Drug Administration

Study Results

Participant Flow

Recruitment Details	614 participants were randomized to study drug; however, 7 of these participants were randomized in error and did not receive any study drug. 607 participants comprised the Intent-to-Treat Population (all participants randomized to treatment and who received at least one dose of study medication).
Pre-Assignment Details	Participants were screened (Visit 1), for eligibility, which included the inhaled albuterol/salbutamol reversibility test. Following screening and a 14-day Run-in period, participants meeting eligibility criteria were stratified in an approximately 1:1 ratio according to their Baseline Forced Expiratory Volume per one second (FEV1).

Reporting Groups

	Description
Placebo	Particpants received placebo at the clinic on Days 1 7, 14, and 28, and self-administered placebo on non-clinic study days, once daily in the evening via the Dry Powder Inhaler (DPI). Participants remained on their current ICS therapy (at fixed doses) throughout the study (screening to follow-up inclusive).
GW642444M 3 µg	Particpants received GW642444M 3 micrograms (µg) at the clinic on Days 1, 7, 14, and 28, and self administered GW642444M 3 µg on non-clinic study days, once daily in the evening via the DPI. Participants remained on their current ICS therapy (at fixed doses) throughout the study (screening to follow-up inclusive).

	Description
GW642444M 6.25 µg	Particpants received GW642444M 6.25 µg at the clinic on Days 1, 7, 14, and 28, and self administered GW642444M 6.25 µg on non-clinic study days, once daily in the evening via the DPI. Participants remained on their current ICS therapy (at fixed doses) throughout the study (screening to follow-up inclusive).
GW642444M 12.5 µg	Particpants received GW642444M 12.5 µg at the clinic on Days 1, 7, 14, and 28, and self administered GW642444M 12.5 µg on non-clinic study days, once daily in the evening via the DPI. Participants remained on their current ICS therapy (at fixed doses) throughout the study (screening to follow-up inclusive).
GW642444M 25 µg	Particpants received GW642444M 25 µg at the clinic on Days 1, 7, 14, and 28, and self administered GW642444M 25 µg on non-clinic study days, once daily in the evening via the DPI. Participants remained on their current ICS therapy (at fixed doses) throughout the study (screening to follow-up inclusive).
GW642444M 50 µg	Particpants received GW642444M 50 µg at the clinic on Days 1, 7, 14, and 28, and self administered GW642444M 50 µg on non-clinic study days, once daily in the evening via the DPI. Participants remained on their current ICS therapy (at fixed doses) throughout the study (screening to follow-up inclusive).

Overall Study

	Placebo	GW642444M 3 µg	GW642444M 6.25 µg	GW642444M 12.5 µg	GW642444M 25 µg	GW642444M 50 µg
Started	102	101	101	100	101	102
Completed	86	84	91	88	93	97
Not Completed	16	17	10	12	8	5
Adverse Event	0	1	0	0	1	0
Lack of Efficacy	9	12	3	5	4	0
Protocol Violation	1	2	0	1	0	0
Met Protocol-defined Stopping Criteria	3	1	7	3	2	2
Withdrawal by Subject	3	0	0	1	1	1
Physician Decision	0	1	0	1	0	2
Lost to Follow-up	0	0	0	1	0	0

Baseline Characteristics

Reporting Groups

	Description
Placebo	Particpants received placebo at the clinic on Days 1 7, 14, and 28, and self-administered placebo on non-clinic study days, once daily in the evening via the Dry Powder Inhaler (DPI). Participants remained on their current ICS therapy (at fixed doses) throughout the study (screening to follow-up inclusive).
GW642444M 3 µg	Particpants received GW642444M 3 micrograms (µg) at the clinic on Days 1, 7, 14, and 28, and self administered GW642444M 3 µg on non-clinic study days, once daily in the evening via the DPI. Participants remained on their current ICS therapy (at fixed doses) throughout the study (screening to follow-up inclusive).
GW642444M 6.25 µg	Particpants received GW642444M 6.25 µg at the clinic on Days 1, 7, 14, and 28, and self administered GW642444M 6.25 µg on non-clinic study days, once daily in the evening via the DPI. Participants remained on their current ICS therapy (at fixed doses) throughout the study (screening to follow-up inclusive).
GW642444M 12.5 µg	Particpants received GW642444M 12.5 µg at the clinic on Days 1, 7, 14, and 28, and self administered GW642444M 12.5 µg on non-clinic study days, once daily in the evening via the DPI. Participants remained on their current ICS therapy (at fixed doses) throughout the study (screening to follow-up inclusive).
GW642444M 25 µg	Particpants received GW642444M 25 µg at the clinic on Days 1, 7, 14, and 28, and self administered GW642444M 25 µg on non-clinic study days, once daily in the evening via the DPI. Participants remained on their current ICS therapy (at fixed doses) throughout the study (screening to follow-up inclusive).
GW642444M 50 µg	Particpants received GW642444M 50 µg at the clinic on Days 1, 7, 14, and 28, and self administered GW642444M 50 µg on non-clinic study days, once daily in the evening via the DPI. Participants remained on their current ICS therapy (at fixed doses) throughout the study (screening to follow-up inclusive).

Baseline Measures

	Placebo	GW642444M 3 µg	GW642444M 6.25 µg	GW642444M 12.5 µg	GW642444M 25 µg	GW642444M 50 µg	Total
Number of Participants	102	101	101	100	101	102	607
Age, Continuous [units: Years] Mean (Standard Deviation)	39.9 (15.60)	44.4 (13.50)	42.4 (14.13)	41.3 (15.33)	42.2 (14.27)	44.0 (15.22)	42.4 (14.72)
Gender, Male/Female [units: Participants]							
Female	61	52	51	56	61	57	338
Male	41	49	50	44	40	45	269
Race/Ethnicity, Customized [units: participants]							

	Placebo	GW642444M 3 µg	GW642444M 6.25 µg	GW642444M 12.5 µg	GW642444M 25 µg	GW642444M 50 µg	Total
African American (AfAm)/ African Heritage (AfH)	4	11	8	12	14	8	57
American Indian (AmIn) or Alaska Native (AN)	3	2	3	2	2	1	13
Central/South Asian Heritage (Her)	1	0	0	0	1	0	2
Japanese/East Asian (EA) Her/ South EA Her	10	13	11	8	8	9	59
Native Hawaiian or other Pacific Islander	0	0	1	0	0	0	1
White	81	74	77	75	75	83	465
AfAm/AfH & AmIn or AN	0	1	0	0	0	0	1
AfAm/AfH & White	2	0	0	0	0	0	2
AmIn or AN & White	1	0	1	2	1	1	6
Asian & White	0	0	0	1	0	0	1

Outcome Measures

1. Primary Outcome Measure:

Measure Title	Mean Change From Baseline in Clinic Visit Trough FEV1 at Day 28 (Last Observation Carried Forward [LOCF])
Measure Description	Pulmonary function was measured by forced expiratory volume in one second (FEV1), defined as the maximal amount of air that can be forcefully exhaled in one second. Trough FEV1 is defined as the clinic visit (pre-bronchodilator and pre-dose) FEV1 at the end of the 28-day treatment period, with the trough FEV1 defined as the mean of the 23 hour and 24 hour post-dose assessments on Day 28. Change from Baseline was calculated as the post-Baseline value minus the Baseline value. Analysis was performed using Analysis of Covariance (ANCOVA) using LOCF with covariates of Baseline (pre-dose on Day 1), country, sex, age, stratum, and treatment.
Time Frame	Baseline and Day 28
Safety Issue?	No

Analysis Population Description

ITT Population: all participants who were randomized to treatment and received at least one dose of study medication. The LOCF method was used to impute missing data. When the endpoint was missing, the last valid non-missing on-treatment, post-Baseline trough assessment was used instead. Only measurements from scheduled visits were used.

Reporting Groups

	Description
Placebo	Particpants received placebo at the clinic on Days 1 7, 14, and 28, and self-administered placebo on non-clinic study days, once daily in the evening via the Dry Powder Inhaler (DPI). Participants remained on their current ICS therapy (at fixed doses) throughout the study (screening to follow-up inclusive).
GW642444M 3 µg	Particpants received GW642444M 3 micrograms (µg) at the clinic on Days 1, 7, 14, and 28, and self administered GW642444M 3 µg on non-clinic study days, once daily in the evening via the DPI. Participants remained on their current ICS therapy (at fixed doses) throughout the study (screening to follow-up inclusive).
GW642444M 6.25 µg	Particpants received GW642444M 6.25 µg at the clinic on Days 1, 7, 14, and 28, and self administered GW642444M 6.25 µg on non-clinic study days, once daily in the evening via the DPI. Participants remained on their current ICS therapy (at fixed doses) throughout the study (screening to follow-up inclusive).
GW642444M 12.5 µg	Particpants received GW642444M 12.5 µg at the clinic on Days 1, 7, 14, and 28, and self administered GW642444M 12.5 µg on non-clinic study days, once daily in the evening via the DPI. Participants remained on their current ICS therapy (at fixed doses) throughout the study (screening to follow-up inclusive).
GW642444M 25 µg	Particpants received GW642444M 25 µg at the clinic on Days 1, 7, 14, and 28, and self administered GW642444M 25 µg on non-clinic study days, once daily in the evening via the DPI. Participants remained on their current ICS therapy (at fixed doses) throughout the study (screening to follow-up inclusive).
GW642444M 50 µg	Particpants received GW642444M 50 µg at the clinic on Days 1, 7, 14, and 28, and self administered GW642444M 50 µg on non-clinic study days, once daily in the evening via the DPI. Participants remained on their current ICS therapy (at fixed doses) throughout the study (screening to follow-up inclusive).

Measured Values

	Placebo	GW642444M 3 µg	GW642444M 6.25 µg	GW642444M 12.5 µg	GW642444M 25 µg	GW642444M 50 µg
Number of Participants Analyzed	95	98	99	97	99	100
Mean Change From Baseline in Clinic Visit Trough FEV1 at Day 28 (Last Observation Carried Forward [LOCF]) [units: Liters] Least Squares Mean (Standard Error)	0.147 (0.036)	0.212 (0.036)	0.217 (0.035)	0.278 (0.036)	0.269 (0.035)	0.309 (0.035)

Statistical Analysis 1 for Mean Change From Baseline in Clinic Visit Trough FEV1 at Day 28 (Last Observation Carried Forward [LOCF])

Statistical Analysis Overview	Comparison Groups	Placebo, GW642444M 3 µg
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No

	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.208
	Comments	[Not specified]
	Method	ANCOVA
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Mean Difference (Final Values)
	Estimated Value	0.064
	Confidence Interval	(2-Sided) 95% -0.036 to 0.164
	Estimation Comments	[Not specified]

Statistical Analysis 2 for Mean Change From Baseline in Clinic Visit Trough FEV1 at Day 28 (Last Observation Carried Forward [LOCF])

Statistical Analysis Overview	Comparison Groups	Placebo, GW642444M 6.25 µg
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.169
	Comments	[Not specified]
	Method	ANCOVA
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Mean Difference (Final Values)
	Estimated Value	0.069
	Confidence Interval	(2-Sided) 95% -0.029 to 0.168
	Estimation Comments	[Not specified]

Statistical Analysis 3 for Mean Change From Baseline in Clinic Visit Trough FEV1 at Day 28 (Last Observation Carried Forward [LOCF])

Statistical Analysis Overview	Comparison Groups	Placebo, GW642444M 12.5 µg
	Comments	[Not specified]

	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.011
	Comments	[Not specified]
	Method	ANCOVA
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Mean Difference (Final Values)
	Estimated Value	0.130
	Confidence Interval	(2-Sided) 95% 0.030 to 0.230
	Estimation Comments	[Not specified]

Statistical Analysis 4 for Mean Change From Baseline in Clinic Visit Trough FEV1 at Day 28 (Last Observation Carried Forward [LOCF])

Statistical Analysis Overview	Comparison Groups	Placebo, GW642444M 25 µg
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.016
	Comments	[Not specified]
	Method	ANCOVA
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Median Difference (Final Values)
	Estimated Value	0.121
	Confidence Interval	(2-Sided) 95% 0.023 to 0.220
	Estimation Comments	[Not specified]

Statistical Analysis 5 for Mean Change From Baseline in Clinic Visit Trough FEV1 at Day 28 (Last Observation Carried Forward [LOCF])

Statistical Analysis Overview	Comparison Groups	Placebo, GW642444M 50 µg
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	0.001
	Comments	[Not specified]
	Method	ANCOVA
	Comments	[Not specified]
Method of Estimation	Estimation Parameter	Mean Difference (Final Values)
	Estimated Value	0.162
	Confidence Interval	(2-Sided) 95% 0.062 to 0.261
	Estimation Comments	[Not specified]

2. Secondary Outcome Measure:

Measure Title	Mean Change From Baseline in Clinic Visit Trough FEV1 at Day 28 Per Stratum (LOCF)
Measure Description	Pulmonary function was measured by forced expiratory volume in one second (FEV1), defined as the maximal amount of air that can be forcefully exhaled in one second. Trough FEV1 is defined as the clinic visit (pre-bronchodilator and pre-dose) FEV1 at the end of the 28-day treatment period, with the trough FEV1 defined as the mean of the 23 hour and 24 hour post-dose assessments on Day 28. Change from Baseline in trough FEV1 at the end of the treatment period (23 hours and 24 hours after dosing on Day 28) was analyzed for each stratum (Lower stratum: FEV1 percent predicted, >=40% to <=65%; Upper stratum: FEV1 percent predicted, >=65% to <=90%). Change from Baseline was calculated as the post-Baseline value minus the Baseline value. Analysis was performed using ANCOVA using LOCF with covariates of Baseline (pre-dose on Day 1), country, sex, age, stratum, treatment, and treatment by stratum interaction.
Time Frame	Baseline and Day 28
Safety Issue?	No

Analysis Population Description

ITT Population. The LOCF method was used to impute missing data. When the endpoint was missing, the last valid non-missing on-treatment, post-Baseline trough assessment was used instead. Only measurements from scheduled visits were used. Only those participants with available data (using LOCF) at the indicated time point were analyzed.

Reporting Groups

	Description
Placebo	Particpants received placebo at the clinic on Days 1 7, 14, and 28, and self-administered placebo on non-clinic study days, once daily in the evening via the Dry Powder Inhaler (DPI). Participants remained on their current ICS therapy (at fixed doses) throughout the study (screening to follow-up inclusive).
GW642444M 3 µg	Particpants received GW642444M 3 micrograms (µg) at the clinic on Days 1, 7, 14, and 28, and self administered GW642444M 3 µg on non-clinic study days, once daily in the evening via the DPI. Participants remained on their current ICS therapy (at fixed doses) throughout the study (screening to follow-up inclusive).
GW642444M 6.25 µg	Particpants received GW642444M 6.25 µg at the clinic on Days 1, 7, 14, and 28, and self administered GW642444M 6.25 µg on non-clinic study days, once daily in the evening via the DPI. Participants remained on their current ICS therapy (at fixed doses) throughout the study (screening to follow-up inclusive).
GW642444M 12.5 µg	Particpants received GW642444M 12.5 µg at the clinic on Days 1, 7, 14, and 28, and self administered GW642444M 12.5 µgon non-clinic study days, once daily in the evening via the DPI. Participants remained on their current ICS therapy (at fixed doses) throughout the study (screening to follow-up inclusive).
GW642444M 25 µg	Particpants received GW642444M 25 µg at the clinic on Days 1, 7, 14, and 28, and self administered GW642444M 25 µg on non-clinic study days, once daily in the evening via the DPI. Participants remained on their current ICS therapy (at fixed doses) throughout the study (screening to follow-up inclusive).
GW642444M 50 µg	Particpants received GW642444M 50 µg at the clinic on Days 1, 7, 14, and 28, and self administered GW642444M 50 µg on non-clinic study days, once daily in the evening via the DPI. Participants remained on their current ICS therapy (at fixed doses) throughout the study (screening to follow-up inclusive).

Measured Values

	Placebo	GW642444M 3 µg	GW642444M 6.25 µg	GW642444M 12.5 µg	GW642444M 25 µg	GW642444M 50 µg
Number of Participants Analyzed	95	98	99	97	99	100
Mean Change From Baseline in Clinic Visit Trough FEV1 at Day 28 Per Stratum (LOCF) [units: Liters] Least Squares Mean (Standard Error)						
Lower stratum, n=43, 44, 41, 40, 46, 45	0.210 (0.057)	0.161 (0.056)	0.247 (0.057)	0.319 (0.057)	0.281 (0.054)	0.349 (0.055)
Upper stratum, n=52, 54, 58, 57, 53, 55	0.098 (0.049)	0.254 (0.051)	0.194 (0.048)	0.247 (0.049)	0.259 (0.049)	0.276 (0.049)

3. Secondary Outcome Measure:

Measure Title	Change From Baseline in Weighted Mean 24-hour Serial FEV1 at Day 1 and Day 28

Measure Description	Pulmonary function was measured by FEV1, defined as the maximal amount of air that can be forcefully exhaled in one second. Change from Baseline in weighted mean for 24-hour serial FEV1 on Days 1 and Day 28 was assessed. Change from Baseline was calculated as the post-Baseline value minus the Baseline value. Analysis was performed using ANCOVA with covariates of Baseline (pre-dose on Day 1), country, sex, age, stratum, and treatment.
Time Frame	Baseline; Day 1 and Day 28 (mean post-dose FEV1 after 15, 30, and 60 minutes and 2, 3, 4, 6, 12, 16, 20, 22, 23, and 24 hours)
Safety Issue?	No

Analysis Population Description

ITT Population. Only those participants available at the indicated time points were analyzed.

Reporting Groups

	Description
Placebo	Particpants received placebo at the clinic on Days 1 7, 14, and 28, and self-administered placebo on non-clinic study days, once daily in the evening via the Dry Powder Inhaler (DPI). Participants remained on their current ICS therapy (at fixed doses) throughout the study (screening to follow-up inclusive).
GW642444M 3 µg	Particpants received GW642444M 3 micrograms (µg) at the clinic on Days 1, 7, 14, and 28, and self administered GW642444M 3 µg on non-clinic study days, once daily in the evening via the DPI. Participants remained on their current ICS therapy (at fixed doses) throughout the study (screening to follow-up inclusive).
GW642444M 6.25 µg	Particpants received GW642444M 6.25 µg at the clinic on Days 1, 7, 14, and 28, and self administered GW642444M 6.25 µg on non-clinic study days, once daily in the evening via the DPI. Participants remained on their current ICS therapy (at fixed doses) throughout the study (screening to follow-up inclusive).
GW642444M 12.5 µg	Particpants received GW642444M 12.5 µg at the clinic on Days 1, 7, 14, and 28, and self administered GW642444M 12.5 µg on non-clinic study days, once daily in the evening via the DPI. Participants remained on their current ICS therapy (at fixed doses) throughout the study (screening to follow-up inclusive).
GW642444M 25 µg	Particpants received GW642444M 25 µg at the clinic on Days 1, 7, 14, and 28, and self administered GW642444M 25 µg on non-clinic study days, once daily in the evening via the DPI. Participants remained on their current ICS therapy (at fixed doses) throughout the study (screening to follow-up inclusive).
GW642444M 50 µg	Particpants received GW642444M 50 µg at the clinic on Days 1, 7, 14, and 28, and self administered GW642444M 50 µg on non-clinic study days, once daily in the evening via the DPI. Participants remained on their current ICS therapy (at fixed doses) throughout the study (screening to follow-up inclusive).

Measured Values

	Placebo	GW642444M 3 µg	GW642444M 6.25 µg	GW642444M 12.5 µg	GW642444M 25 µg	GW642444M 50 µg
Number of Participants Analyzed	101	100	101	99	100	100
Change From Baseline in Weighted Mean 24-hour Serial FEV1 at Day 1 and Day 28						

	Placebo	GW642444M 3 µg	GW642444M 6.25 µg	GW642444M 12.5 µg	GW642444M 25 µg	GW642444M 50 µg
[units: Liters] Least Squares Mean (Standard Error)						
Day 1, n=101, 100, 101, 99, 100, 100	0.137 (0.029)	0.239 (0.029)	0.215 (0.029)	0.267 (0.029)	0.330 (0.029)	0.352 (0.029)
Day 28, n=87, 83, 91, 88, 93, 97	0.149 (0.032)	0.300 (0.033)	0.253 (0.031)	0.292 (0.032)	0.315 (0.031)	0.321 (0.031)

4. Secondary Outcome Measure:

Measure Title	Mean Change From Baseline in Trough (Pre-dose and Pre-bronchodilator) Daily Evening (PM) Peak Expiratory Flow (PEF) Averaged Over the 28-day Treatment Period
Measure Description	Peak Expiratory Flow (PEF) is defined as the maximum airflow during a forced expiration beginning with the lungs fully inflated. Change from Baseline was calculated as the value of the averaged PEF daily PM over the 28-day treatment period (at Day 28) minus the Baseline value (defined as the last 7 days prior to randomization of the participants). Analysis was performed using ANCOVA with covariates of Baseline, country, sex, age, stratum, and treatment.
Time Frame	Baseline and Days 1-28
Safety Issue?	No

Analysis Population Description

ITT Population. Only those participants available at the indicated time points were analyzed.

Reporting Groups

	Description
Placebo	Particpants received placebo at the clinic on Days 1 7, 14, and 28, and self-administered placebo on non-clinic study days, once daily in the evening via the Dry Powder Inhaler (DPI). Participants remained on their current ICS therapy (at fixed doses) throughout the study (screening to follow-up inclusive).
GW642444M 3 µg	Particpants received GW642444M 3 micrograms (µg) at the clinic on Days 1, 7, 14, and 28, and self administered GW642444M 3 µg on non-clinic study days, once daily in the evening via the DPI. Participants remained on their current ICS therapy (at fixed doses) throughout the study (screening to follow-up inclusive).
GW642444M 6.25 µg	Particpants received GW642444M 6.25 µg at the clinic on Days 1, 7, 14, and 28, and self administered GW642444M 6.25 µg on non-clinic study days, once daily in the evening via the DPI. Participants remained on their current ICS therapy (at fixed doses) throughout the study (screening to follow-up inclusive).
GW642444M 12.5 µg	Particpants received GW642444M 12.5 µg at the clinic on Days 1, 7, 14, and 28, and self administered GW642444M 12.5 µg on non-clinic study days, once daily in the evening via the DPI. Participants remained on their current ICS therapy (at fixed doses) throughout the study (screening to follow-up inclusive).

	Description
GW642444M 25 µg	Particpants received GW642444M 25 µg at the clinic on Days 1, 7, 14, and 28, and self administered GW642444M 25 µg on non-clinic study days, once daily in the evening via the DPI. Participants remained on their current ICS therapy (at fixed doses) throughout the study (screening to follow-up inclusive).
GW642444M 50 µg	Particpants received GW642444M 50 µg at the clinic on Days 1, 7, 14, and 28, and self administered GW642444M 50 µg on non-clinic study days, once daily in the evening via the DPI. Participants remained on their current ICS therapy (at fixed doses) throughout the study (screening to follow-up inclusive).

Measured Values

	Placebo	GW642444M 3 µg	GW642444M 6.25 µg	GW642444M 12.5 µg	GW642444M 25 µg	GW642444M 50 µg
Number of Participants Analyzed	99	99	101	98	101	102
Mean Change From Baseline in Trough (Pre-dose and Pre-bronchodilator) Daily Evening (PM) Peak Expiratory Flow (PEF) Averaged Over the 28-day Treatment Period [units: Liters per minute] Least Squares Mean (Standard Error)	0.4 (3.87)	14.0 (3.87)	24.5 (3.82)	28.9 (3.87)	34.0 (3.81)	38.4 (3.82)

5. Secondary Outcome Measure:

Measure Title	Mean Change From Baseline in Daily Morning (AM) PEF Averaged Over the 28-day Treatment Period
Measure Description	Peak Expiratory Flow (PEF) is defined as the maximum airflow during a forced expiration beginning with the lungs fully inflated. Change from Baseline was calculated as the value of the averaged PEF daily AM over the 28-day treatment period (at Day 28) minus the Baseline value (defined as the last 7 days prior to randomization of the participants). Analysis was performed using ANCOVA with covariates of Baseline, country, sex, age, stratum, and treatment.
Time Frame	Baseline and Days 1-28
Safety Issue?	No

Analysis Population Description

ITT Population. Only those participants available at the indicated time points were analyzed.

Reporting Groups

	Description
Placebo	Particpants received placebo at the clinic on Days 1 7, 14, and 28, and self-administered placebo on non-clinic study days, once daily in the evening via the Dry Powder Inhaler (DPI). Participants remained on their current ICS therapy (at fixed doses) throughout the study (screening to follow-up inclusive).

	Description
GW642444M 3 µg	Particpants received GW642444M 3 micrograms (µg) at the clinic on Days 1, 7, 14, and 28, and self administered GW642444M 3 µg on non-clinic study days, once daily in the evening via the DPI. Participants remained on their current ICS therapy (at fixed doses) throughout the study (screening to follow-up inclusive).
GW642444M 6.25 µg	Particpants received GW642444M 6.25 µg at the clinic on Days 1, 7, 14, and 28, and self administered GW642444M 6.25 µg µgon non-clinic study days, once daily in the evening via the DPI. Participants remained on their current ICS therapy (at fixed doses) throughout the study (screening to follow-up inclusive).
GW642444M 12.5 µg	Particpants received GW642444M 12.5 µg at the clinic on Days 1, 7, 14, and 28, and self administered GW642444M 12.5 µg on non-clinic study days, once daily in the evening via the DPI. Participants remained on their current ICS therapy (at fixed doses) throughout the study (screening to follow-up inclusive).
GW642444M 25 µg	Particpants received GW642444M 25 µg at the clinic on Days 1, 7, 14, and 28, and self administered GW642444M 25 µg on non-clinic study days, once daily in the evening via the DPI. Participants remained on their current ICS therapy (at fixed doses) throughout the study (screening to follow-up inclusive).
GW642444M 50 µg	Particpants received GW642444M 50 µg at the clinic on Days 1, 7, 14, and 28, and self administered GW642444M 50 µg on non-clinic study days, once daily in the evening via the DPI. Participants remained on their current ICS therapy (at fixed doses) throughout the study (screening to follow-up inclusive).

Measured Values

	Placebo	GW642444M 3 µg	GW642444M 6.25 µg	GW642444M 12.5 µg	GW642444M 25 µg	GW642444M 50 µg
Number of Participants Analyzed	98	99	101	98	101	102
Mean Change From Baseline in Daily Morning (AM) PEF Averaged Over the 28-day Treatment Period [units: Liters per minute] Least Squares Mean (Standard Error)	1.9 (3.69)	18.7 (3.67)	26.8 (3.63)	34.2 (3.68)	38.1 (3.61)	44.0 (3.63)

6. Secondary Outcome Measure:

Measure Title	Mean Change From Baseline in the Percentage of Symptom-free 24-hour (hr) Periods Averaged Over the 28-day Treatment Period
Measure Description	Participants who were symptom free for 24 hours were assessed. Change from Baseline was calculated as the value at Day 28 minus the value at Baseline (defined as the last 7 days prior to randomization of the participants). Analysis was performed using ANCOVA with covariates of Baseline, country, sex, age, stratum, and treatment.
Time Frame	Baseline and Days 1-28
Safety Issue?	No

Analysis Population Description

ITT Population. Only those participants available at the indicated time points were analyzed.

Reporting Groups

	Description
Placebo	Particpants received placebo at the clinic on Days 1 7, 14, and 28, and self-administered placebo on non-clinic study days, once daily in the evening via the Dry Powder Inhaler (DPI). Participants remained on their current ICS therapy (at fixed doses) throughout the study (screening to follow-up inclusive).
GW642444M 3 µg	Particpants received GW642444M 3 micrograms (µg) at the clinic on Days 1, 7, 14, and 28, and self administered GW642444M 3 µg on non-clinic study days, once daily in the evening via the DPI. Participants remained on their current ICS therapy (at fixed doses) throughout the study (screening to follow-up inclusive).
GW642444M 6.25 µg	Particpants received GW642444M 6.25 µg at the clinic on Days 1, 7, 14, and 28, and self administered GW642444M 6.25 µg on non-clinic study days, once daily in the evening via the DPI. Participants remained on their current ICS therapy (at fixed doses) throughout the study (screening to follow-up inclusive).
GW642444M 12.5 µg	Particpants received GW642444M 12.5 µg at the clinic on Days 1, 7, 14, and 28, and self administered GW642444M 12.5 µg on non-clinic study days, once daily in the evening via the DPI. Participants remained on their current ICS therapy (at fixed doses) throughout the study (screening to follow-up inclusive).
GW642444M 25 µg	Particpants received GW642444M 25 µg at the clinic on Days 1, 7, 14, and 28, and self administered GW642444M 25 µg on non-clinic study days, once daily in the evening via the DPI. Participants remained on their current ICS therapy (at fixed doses) throughout the study (screening to follow-up inclusive).
GW642444M 50 µg	Particpants received GW642444M 50 µg at the clinic on Days 1, 7, 14, and 28, and self administered GW642444M 50 µg on non-clinic study days, once daily in the evening via the DPI. Participants remained on their current ICS therapy (at fixed doses) throughout the study (screening to follow-up inclusive).

Measured Values

	Placebo	GW642444M 3 µg	GW642444M 6.25 µg	GW642444M 12.5 µg	GW642444M 25 µg	GW642444M 50 µg
Number of Participants Analyzed	98	99	101	98	101	102
Mean Change From Baseline in the Percentage of Symptom-free 24-hour (hr) Periods Averaged Over the 28-day Treatment Period [units: Percentage of symptom-free 24-hr periods] Least Squares Mean (Standard Error)	14.2 (3.27)	22.6 (3.25)	23.6 (3.21)	26.8 (3.26)	36.4 (3.21)	32.3 (3.21)

7. Secondary Outcome Measure:

Measure Title	Change From Baseline in the Percentage of Rescue-free 24-hour (hr) Periods Averaged Over the 28-day Treatment Period
Measure Description	The time span during which the participants did not have to take any rescue medication (medication intended to relieve symptoms immediately) was considered to be a rescue-free period. Change from Baseline is calculated as the value at Day 28 minus the value at Baseline (defined as the last 7 days prior to randomization of the participants). Analysis was performed using ANCOVA with covariates of Baseline, country, sex, age, stratum, and treatment.
Time Frame	Baseline and Days 1-28
Safety Issue?	No

Analysis Population Description

ITT Population. Only those participants available at the indicated time points were analyzed.

Reporting Groups

	Description
Placebo	Particpants received placebo at the clinic on Days 1 7, 14, and 28, and self-administered placebo on non-clinic study days, once daily in the evening via the Dry Powder Inhaler (DPI). Participants remained on their current ICS therapy (at fixed doses) throughout the study (screening to follow-up inclusive).
GW642444M 3 µg	Particpants received GW642444M 3 micrograms (µg) at the clinic on Days 1, 7, 14, and 28, and self administered GW642444M 3 µg on non-clinic study days, once daily in the evening via the DPI. Participants remained on their current ICS therapy (at fixed doses) throughout the study (screening to follow-up inclusive).
GW642444M 6.25 µg	Particpants received GW642444M 6.25 µg at the clinic on Days 1, 7, 14, and 28, and self administered GW642444M 6.25 µg on non-clinic study days, once daily in the evening via the DPI. Participants remained on their current ICS therapy (at fixed doses) throughout the study (screening to follow-up inclusive).
GW642444M 12.5 µg	Particpants received GW642444M 12.5 µg at the clinic on Days 1, 7, 14, and 28, and self administered GW642444M 12.5 µg on non-clinic study days, once daily in the evening via the DPI. Participants remained on their current ICS therapy (at fixed doses) throughout the study (screening to follow-up inclusive).
GW642444M 25 µg	Particpants received GW642444M 25 µg at the clinic on Days 1, 7, 14, and 28, and self administered GW642444M 25 µg on non-clinic study days, once daily in the evening via the DPI. Participants remained on their current ICS therapy (at fixed doses) throughout the study (screening to follow-up inclusive).
GW642444M 50 µg	Particpants received GW642444M 50 µg at the clinic on Days 1, 7, 14, and 28, and self administered GW642444M 50 µg on non-clinic study days, once daily in the evening via the DPI. Participants remained on their current ICS therapy (at fixed doses) throughout the study (screening to follow-up inclusive).

Measured Values

	Placebo	GW642444M 3 µg	GW642444M 6.25 µg	GW642444M 12.5 µg	GW642444M 25 µg	GW642444M 50 µg
Number of Participants Analyzed	99	99	101	98	101	102

	Placebo	GW642444M 3 µg	GW642444M 6.25 µg	GW642444M 12.5 µg	GW642444M 25 µg	GW642444M 50 µg
Change From Baseline in the Percentage of Rescue-free 24-hour (hr) Periods Averaged Over the 28-day Treatment Period [units: Percentage of rescue-free 24-hr periods] Least Squares Mean (Standard Error)	15.0 (3.33)	25.8 (3.33)	27.3 (3.28)	29.6 (3.34)	43.4 (3.28)	34.0 (3.28)

8. Secondary Outcome Measure:

Measure Title	Difference in Post Salbutamol/Albuterol FEV1 (FEV1 30 Minutes After a Single Dose of 400 µg Salbutamol/Albuterol) Between the Following Time Points: 24 Hours After Dosing on Day 1 and Day 28
Measure Description	Assessment at Visit 2/2a was made prior to the evening dose of study medication on Day 2. Participants were administered a single 400 µg dose of salbutamol/albuterol, and FEV1 was measured 30 minutes after this administration. The highest of three technically acceptable measurements was recorded. These assessments were performed as follows: between 5 PM and 10 PM, >=6 hours after the last use of salbutamol/albuterol, >=6 hours after the last caffeine consumption, >=2 hours after exercise (or strenuous activity), >=24 hours after the first dose (Visit 2) or last dose (Visit 5) of study medication. Analysis was performed using ANCOVA with covariates of Baseline (pre-salbutamol measurement at Screening), country, sex, age, stratum, and treatment. Analysis is of the differences in absolute FEV1 measurements taken post-salbutamol/albuterol.
Time Frame	24 hours after dosing on Day 1 (Visit 2) and on Day 28 (Visit 5)
Safety Issue?	No

Analysis Population Description

ITT Population. Only those participants available at the indicated time points were analyzed.

Reporting Groups

	Description
Placebo	Particpants received placebo at the clinic on Days 1 7, 14, and 28, and self-administered placebo on non-clinic study days, once daily in the evening via the Dry Powder Inhaler (DPI). Participants remained on their current ICS therapy (at fixed doses) throughout the study (screening to follow-up inclusive).
GW642444M 3 µg	Particpants received GW642444M 3 micrograms (µg) at the clinic on Days 1, 7, 14, and 28, and self administered GW642444M 3 µg on non-clinic study days, once daily in the evening via the DPI. Participants remained on their current ICS therapy (at fixed doses) throughout the study (screening to follow-up inclusive).
GW642444M 6.25 µg	Particpants received GW642444M 6.25 µg at the clinic on Days 1, 7, 14, and 28, and self administered GW642444M 6.25 µg on non-clinic study days, once daily in the evening via the DPI. Participants remained on their current ICS therapy (at fixed doses) throughout the study (screening to follow-up inclusive).

	Description
GW642444M 12.5 µg	Particpants received GW642444M 12.5 µg at the clinic on Days 1, 7, 14, and 28, and self administered GW642444M 12.5 µg on non-clinic study days, once daily in the evening via the DPI. Participants remained on their current ICS therapy (at fixed doses) throughout the study (screening to follow-up inclusive).
GW642444M 25 µg	Particpants received GW642444M 25 µg at the clinic on Days 1, 7, 14, and 28, and self administered GW642444M 25 µg on non-clinic study days, once daily in the evening via the DPI. Participants remained on their current ICS therapy (at fixed doses) throughout the study (screening to follow-up inclusive).
GW642444M 50 µg	Particpants received GW642444M 50 µg at the clinic on Days 1, 7, 14, and 28, and self administered GW642444M 50 µg on non-clinic study days, once daily in the evening via the DPI. Participants remained on their current ICS therapy (at fixed doses) throughout the study (screening to follow-up inclusive).

Measured Values

	Placebo	GW642444M 3 µg	GW642444M 6.25 µg	GW642444M 12.5 µg	GW642444M 25 µg	GW642444M 50 µg
Number of Participants Analyzed	83	80	87	86	86	92
Difference in Post Salbutamol/Albuterol FEV1 (FEV1 30 Minutes After a Single Dose of 400 µg Salbutamol/ Albuterol) Between the Following Time Points: 24 Hours After Dosing on Day 1 and Day 28 [units: Liters] Least Squares Mean (Standard Error)	-0.039 (0.023)	-0.035 (0.024)	-0.012 (0.023)	-0.017 (0.023)	-0.062 (0.023)	-0.049 (0.022)

9. Secondary Outcome Measure:

Measure Title	Difference in Post Salbutamol/Albuterol FEV1 (FEV1 30minutes After a Single Dose of 400 µg Salbutamol/Albuterol) Between the Following Time Points: Screening and 24 Hours After Dosing on Day 1
Measure Description	Assessment at Visit 2/2a was made prior to the evening dose of study medication on Day 2. Participants were administered a single 400 µg dose of salbutamol/albuterol, and FEV1 was measured 30 minutes after this administration. The highest of three technically acceptable measurements was recorded. These assessments were performed as follows: between 5 PM and 10 PM, >=6 hours after the last use of salbutamol/albuterol, >=6 hours after the last caffeine consumption, >=2 hours after exercise (or strenuous activity), Screening and >=24 hours after the first dose (Visit 2) of study medication. Analysis was performed using ANCOVA with covariates of Baseline (pre-salbutamol measurement at Screening), country, sex, age, stratum, and treatment. Analysis is of the differences in absolute FEV1 measurements taken post-salbutamol/albuterol.
Time Frame	Screening (Visit 1) and 24 hours after dosing on Day 1 (Visit 2)
Safety Issue?	No

Analysis Population Description

ITT Population. Only those participants available at the indicated time points were analyzed.

Reporting Groups

	Description
Placebo	Particpants received placebo at the clinic on Days 1 7, 14, and 28, and self-administered placebo on non-clinic study days, once daily in the evening via the Dry Powder Inhaler (DPI). Participants remained on their current ICS therapy (at fixed doses) throughout the study (screening to follow-up inclusive).
GW642444M 3 µg	Particpants received GW642444M 3 micrograms (µg) at the clinic on Days 1, 7, 14, and 28, and self administered GW642444M 3 µg on non-clinic study days, once daily in the evening via the DPI. Participants remained on their current ICS therapy (at fixed doses) throughout the study (screening to follow-up inclusive).
GW642444M 6.25 µg	Particpants received GW642444M 6.25 µg at the clinic on Days 1, 7, 14, and 28, and self administered GW642444M 6.25 µg on non-clinic study days, once daily in the evening via the DPI. Participants remained on their current ICS therapy (at fixed doses) throughout the study (screening to follow-up inclusive).
GW642444M 12.5 µg	Particpants received GW642444M 12.5 µg at the clinic on Days 1, 7, 14, and 28, and self administered GW642444M 12.5 µg on non-clinic study days, once daily in the evening via the DPI. Participants remained on their current ICS therapy (at fixed doses) throughout the study (screening to follow-up inclusive).
GW642444M 25 µg	Particpants received GW642444M 25 µg at the clinic on Days 1, 7, 14, and 28, and self administered GW642444M 25 µg on non-clinic study days, once daily in the evening via the DPI. Participants remained on their current ICS therapy (at fixed doses) throughout the study (screening to follow-up inclusive).
GW642444M 50 µg	Particpants received GW642444M 50 µg at the clinic on Days 1, 7, 14, and 28, and self administered GW642444M 50 µg on non-clinic study days, once daily in the evening via the DPI. Participants remained on their current ICS therapy (at fixed doses) throughout the study (screening to follow-up inclusive).

Measured Values

	Placebo	GW642444M 3 µg	GW642444M 6.25 µg	GW642444M 12.5 µg	GW642444M 25 µg	GW642444M 50 µg
Number of Participants Analyzed	97	97	98	99	96	98
Difference in Post Salbutamol/Albuterol FEV1 (FEV1 30minutes After a Single Dose of 400 µg Salbutamol/ Albuterol) Between the Following Time Points: Screening and 24 Hours After Dosing on Day 1 [units: Liters] Least Squares Mean (Standard Error)	-0.040 (0.028)	0.008 (0.028)	-0.061 (0.028)	-0.029 (0.028)	-0.020 (0.028)	-0.060 (0.028)

10. Secondary Outcome Measure:

Measure Title	Difference in Post Salbutamol/Albuterol FEV1 (FEV1 30 Minutes After a Single Dose of 400 µg Salbutamol/Albuterol) Between the Following Time Points: Screening and 24 Hours After Dosing on Day 28
Measure Description	Assessment at Visit 2/2a was made prior to the evening dose of study medication on Day 2. Participants were administered a single 400 µg dose of salbutamol/albuterol, and FEV1 was measured 30 minutes after this administration. The highest of three technically acceptable measurements was recorded. These assessments were performed as follows: between 5 PM and 10 PM, >=6 hours after the last use of salbutamol/albuterol, >=6 hours after the last caffeine consumption, >=2 hours after exercise (or strenuous activity), Screening and >=24 hours after the first dose (Visit 2) of study medication. Analysis was performed using ANCOVA with covariates of Baseline (pre-salbutamol measurement at Screening), country, sex, age, stratum, and treatment. Analysis is of the differences in absolute FEV1 measurements taken post-salbutamol/albuterol.
Time Frame	Screening (Visit 1) and 24 hours after dosing on Day 28 (Visit 5)
Safety Issue?	No

Analysis Population Description

ITT Population. Only those participants available at the indicated time points were analyzed.

Reporting Groups

	Description
Placebo	Particpants received placebo at the clinic on Days 1 7, 14, and 28, and self-administered placebo on non-clinic study days, once daily in the evening via the Dry Powder Inhaler (DPI). Participants remained on their current ICS therapy (at fixed doses) throughout the study (screening to follow-up inclusive).
GW642444M 3 µg	Particpants received GW642444M 3 micrograms (µg) at the clinic on Days 1, 7, 14, and 28, and self administered GW642444M 3 µg on non-clinic study days, once daily in the evening via the DPI. Participants remained on their current ICS therapy (at fixed doses) throughout the study (screening to follow-up inclusive).
GW642444M 6.25 µg	Particpants received GW642444M 6.25 µg at the clinic on Days 1, 7, 14, and 28, and self administered GW642444M 6.25 µg on non-clinic study days, once daily in the evening via the DPI. Participants remained on their current ICS therapy (at fixed doses) throughout the study (screening to follow-up inclusive).
GW642444M 12.5 µg	Particpants received GW642444M 12.5 µg at the clinic on Days 1, 7, 14, and 28, and self administered GW642444M 12.5 µg on non-clinic study days, once daily in the evening via the DPI. Participants remained on their current ICS therapy (at fixed doses) throughout the study (screening to follow-up inclusive).
GW642444M 25 µg	Particpants received GW642444M 25 µg at the clinic on Days 1, 7, 14, and 28, and self administered GW642444M 25 µg on non-clinic study days, once daily in the evening via the DPI. Participants remained on their current ICS therapy (at fixed doses) throughout the study (screening to follow-up inclusive).
GW642444M 50 µg	Particpants received GW642444M 50 µg at the clinic on Days 1, 7, 14, and 28, and self administered GW642444M 50 µg on non-clinic study days, once daily in the evening via the DPI. Participants remained on their current ICS therapy (at fixed doses) throughout the study (screening to follow-up inclusive).

Measured Values

	Placebo	GW642444M 3 µg	GW642444M 6.25 µg	GW642444M 12.5 µg	GW642444M 25 µg	GW642444M 50 µg
Number of Participants Analyzed	84	80	89	86	88	93
Difference in Post Salbutamol/Albuterol FEV1 (FEV1 30 Minutes After a Single Dose of 400 µg Salbutamol/ Albuterol) Between the Following Time Points: Screening and 24 Hours After Dosing on Day 28 [units: Liters] Least Squares Mean (Standard Error)	-0.076 (0.031)	-0.022 (0.031)	-0.055 (0.030)	-0.048 (0.030)	-0.086 (0.030)	-0.104 (0.029)

Reported Adverse Events

Time Frame	On-treatment adverse events (AEs), defined as those events occurring while participants were on treatment, up to and including the day after the last dose in each treatment period (up to Day 28), are reported.
Additional Description	Serious adverse events (SAEs) and non-serious AEs were collected in the Intent-to-Treat (ITT) Population, comprised of all participants randomized to treatment who received at least one dose of study medication.

Reporting Groups

	Description
Placebo	Particpants received placebo at the clinic on Days 1 7, 14, and 28, and self-administered placebo on non-clinic study days, once daily in the evening via the Dry Powder Inhaler (DPI). Participants remained on their current ICS therapy (at fixed doses) throughout the study (screening to follow-up inclusive).
GW642444M 3 µg	Particpants received GW642444M 3 micrograms (µg) at the clinic on Days 1, 7, 14, and 28, and self administered GW642444M 3 µg on non-clinic study days, once daily in the evening via the DPI. Participants remained on their current ICS therapy (at fixed doses) throughout the study (screening to follow-up inclusive).
GW642444M 6.25 µg	Particpants received GW642444M 6.25 µg at the clinic on Days 1, 7, 14, and 28, and self administered GW642444M 6.25 µg on non-clinic study days, once daily in the evening via the DPI. Participants remained on their current ICS therapy (at fixed doses) throughout the study (screening to follow-up inclusive).
GW642444M 12.5 µg	Particpants received GW642444M 12.5 µg at the clinic on Days 1, 7, 14, and 28, and self administered GW642444M 12.5 µg on non-clinic study days, once daily in the evening via the DPI. Participants remained on their current ICS therapy (at fixed doses) throughout the study (screening to follow-up inclusive).

	Description
GW642444M 25 µg	Particpants received GW642444M 25 µg at the clinic on Days 1, 7, 14, and 28, and self administered GW642444M 25 µg on non-clinic study days, once daily in the evening via the DPI. Participants remained on their current ICS therapy (at fixed doses) throughout the study (screening to follow-up inclusive).
GW642444M 50 µg	Particpants received GW642444M 50 µg at the clinic on Days 1, 7, 14, and 28, and self administered GW642444M 50 µg on non-clinic study days, once daily in the evening via the DPI. Participants remained on their current ICS therapy (at fixed doses) throughout the study (screening to follow-up inclusive).

Serious Adverse Events

	Placebo	GW642444M 3 µg	GW642444M 6.25 µg	GW642444M 12.5 µg	GW642444M 25 µg	GW642444M 50 µg
	Affected/ At Risk (%)	Affected/ At Risk (%)	Affected/ At Risk (%)	Affected/ At Risk (%)	Affected/ At Risk (%)	Affected/ At Risk (%)
Total	0/102 (0%)	0/101 (0%)	0/101 (0%)	0/100 (0%)	0/101 (0%)	0/102 (0%)

Other Adverse Events

Frequency Threshold Above Which Other Adverse Events are Reported: 3%

	Placebo	GW642444M 3 µg	GW642444M 6.25 µg	GW642444M 12.5 µg	GW642444M 25 µg	GW642444M 50 µg
	Affected/ At Risk (%)	Affected/ At Risk (%)	Affected/ At Risk (%)	Affected/ At Risk (%)	Affected/ At Risk (%)	Affected/ At Risk (%)
Total	14/102 (13.73%)	15/101 (14.85%)	9/101 (8.91%)	12/100 (12%)	9/101 (8.91%)	11/102 (10.78%)
Infections and infestations						
Nasopharyngitis [A] †	4/102 (3.92%)	2/101 (1.98%)	2/101 (1.98%)	0/100 (0%)	0/101 (0%)	2/102 (1.96%)
Upper respiratory tract infection [A] †	2/102 (1.96%)	2/101 (1.98%)	1/101 (0.99%)	3/100 (3%)	2/101 (1.98%)	2/102 (1.96%)
Nervous system disorders						
Headache [A] †	8/102 (7.84%)	12/101 (11.88%)	7/101 (6.93%)	9/100 (9%)	7/101 (6.93%)	8/102 (7.84%)

† Indicates events were collected by systematic assessment.

A Term from vocabulary, MedDRA

Limitations and Caveats

[Not specified]

More Information

Certain Agreements:

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

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

GSK agreements may vary with individual investigators, but will not prohibit any investigator from publishing. GSK supports the publication of results from all centers of a multi-center trial but requests that reports based on single-site data not precede the primary publication of the entire clinical trial.

Results Point of Contact:

Name/Official Title: GSK Response Center
Organization: GlaxoSmithKline
Phone: 866-435-7343
Email: