ClinicalTrials.gov Protocol Registration and Results System (PRS) Receipt
Release Date: 12/05/2013

ClinicalTrials.gov ID: NCT00519376

Study Identification

Unique Protocol ID:	B2C110165
Brief Title:	A Study To Investigate The Effect Of Inhaling A Single Dose Of GW642444M In COPD Patients.
Official Title:	A Randomised, Single-dose, Dose Ascending, Double-blind, Placebo Controlled, Four-way, Incomplete Block Crossover Study to Investigate the Safety, Tolerability, Pharmacokinetics and Pharmacodynamics of Inhaled Doses of GW642444M With Magnesium Stearate in COPD Patients.
Secondary IDs:	

Study Status

Record Verification:	September 2013
Overall Status:	Completed
Study Start:	August 2007
Primary Completion:	November 2007 [Actual]
Study Completion:	November 2007 [Actual]

Sponsor/Collaborators

Sponsor:	GlaxoSmithKline
Responsible Party:	Sponsor
Collaborators:	

Oversight

FDA Regulated?:	Yes

Applicable Trial?:	Section 801 Clinical Trial? Yes Delayed Posting? No
IND/IDE Protocol?:	No
Review Board:	Approval Status: Approved Approval Number: EK5 240/07 Board Name: Land Authority for Health and Social Issues Board Affiliation: Ethics Committee of the Land Berlin Phone: +493090127638 Email: susan-isabelle.gutsche@lageso.verwalt-berlin.de
Data Monitoring?:	No
Plan to Share Data?:	
Oversight Authorities:	Germany: Federal Institute for Drugs and Medical Devices

Study Description

Brief Summary:	This study will involve the use of a new compound, GW642444 that is being developed for the treatment of asthma and chronic obstructive pulmonary disease (COPD). It works by acting on cells in the lungs, causing some of the muscles around the lungs to relax and open up better (bronchodilation), making breathing easier. When a medicine is made into a form ready to be given to patients, the active ingredient is often prepared in the form of a salt, and inactive ingredients (excipients) are often added. Inactive ingredients might be used to help a medicine work better, to make it easier to produce the medicine, or to make it easier to get an accurate dose of medicine. In previous studies the study drug has been given as a dry powder in the form of either the ‘H’ salt (with the excipient lactose), or in the form of the ‘M’ salt (with the excipients lactose and cellobiose octaacetate). In this study the ‘M’ salt form of the study drug has been prepared with lactose and a new excipient called magnesium stearate (instead of cellobiose octaacetate). Participants in this study will receive both the ‘H’ salt (GW642444H) and the new ‘M’ salt (GW642444M) containing magnesium stearate. This study will be the first time the new ‘M’ salt form of the study drug will be given to COPD patients.
Detailed Description:	

Conditions

Conditions:	Pulmonary Disease, Chronic Obstructive
Keywords:	pharmacodynamics, Chronic Obstructive Pulmonary Disease (COPD) safety, COPD patients pharmacokinetics, tolerability, GW642444,

Study Design

Study Type:	Interventional
Primary Purpose:	Treatment
Study Phase:	Phase 2
Intervention Model:	Crossover Assignment
Number of Arms:	5
Masking:	Double Blind (Subject, Investigator)
Allocation:	Randomized
Endpoint Classification:	Safety Study
Enrollment:	20 [Actual]

Arms and Interventions

Arms	Assigned Interventions
Experimental: GW642444M 25mcg	Drug: GW642444M drug Drug: placebo
Experimental: GW642444M 50mcg	Drug: GW642444M drug
Experimental: GW642444M 100mcg	Drug: GW642444M drug Drug: placebo
Experimental: GW642444H 100mcg	Drug: GW642444H drug Drug: placebo
Experimental: placebo	Drug: placebo

Outcome Measures

[See Results Section.]

Eligibility

Minimum Age:	40 Years
Maximum Age:	

Gender: Both

Accepts Healthy Volunteers?: No

Criteria: Inclusion criteria:

- Male or female (of non-childbearing potential) > or = 40 years
- History of COPD
- Smoker or ex-smoker
- Body weight > or = 50 kg with BMI 18-32 kg/m2

Exclusion criteria:

- History of significant disease
- Subjects with a primary asthma diagnosis
- Alpha-1 antitrypsin deficiency as underlying cause of COPD
- Recent respiratory tract infection
- Poorly controlled COPD
- Blood potassium level < 3.5mmol/L
- Short-term or long tern oxygen therapy
- Recent participation in another trial
- History of drug or alcohol abuse
- Known allergies
- Recent blood donation
- ECG abnormalities

Contacts/Locations

Study Officials: GSK Clinical Trials
Study Director
GlaxoSmithKline

Locations: Germany
GSK Investigational Site
Berlin, Berlin, Germany, 14057

GSK Investigational Site
Mainz, Rheinland-Pfalz, Germany, 55131

GSK Investigational Site
Berlin, Berlin, Germany, 14050

GSK Investigational Site
Wiesbaden, Hessen, Germany, 65187

References

Citations: Kempsford R, Norris V, Siederer S. Vilanterol trifenatate, a novel inhaled long-acting beta2 adrenoceptor agonist, is well tolerated in healthy subjects and demonstrates prolonged bronchodilation in subjects with asthma and COPD. Pulm Pharmacol Ther. 2013;26(2):256-64.

Links:

Study Data/Documents:

Study Results

Participant Flow

Pre-Assignment Details	Participants meeting eligibility criteria at screening were randomized and entered a treatment period. Participants were then randomized to 4 treatment periods in one of 16 sequences (seq) each lasting 1 day and separated by a 7 - 14 day washout period.

Reporting Groups

	Description
Seq 1: PB, GW642444M 25 µg, GW642444M 50 µg, GW642444M 100 µg	Participants were administered single dose of the following treatments: Placebo (PB), GW642444M 25 µg, GW642444M 50 µg, GW642444M 100 µg. Each participants received doses in an ascending dose manner as per randomization from the dry powder inhaler (DPI) from the DISKUS/ACCUHALER (one inhalation in the morning).
Seq 2: GW642444M 25 µg, PB, GW642444M 50 µg, GW642444M 100 µg	Participants were administered single dose of the following treatments: GW642444M 25 µg, Placebo, GW642444M 50 µg, GW642444M 100 µg. Each participant received doses in an ascending dose manner as per randomization from the dry powder inhaler (DPI) from the DISKUS/ACCUHALER (one inhalation in the morning).
Seq 3: GW642444M 25 µg, GW642444M 50 µg, PB, GW642444M 100 µg	Participants were administered single dose of the following treatments: GW642444M 25 µg, GW642444M 50 µg, Placebo, GW642444M 100 µg. Each participant received doses in an ascending dose manner as per randomization from the dry powder inhaler (DPI) from the DISKUS/ACCUHALER (one inhalation in the morning).
Seq 4: GW642444M 25 µg, GW642444M 50 µg, GW642444M 100 µg, PB	Participants were administered single dose of the following treatments: GW642444M 25 µg, GW642444M 50 µg, GW642444M 100 µg, Placebo. Each participant received doses in an ascending dose manner as per randomization from the dry powder inhaler (DPI) from the DISKUS/ACCUHALER (one inhalation in the morning).

	Description
Seq 5: PB, GW642444M 25 µg, GW642444M 50 µg, GW642444H 100 µg	Participants were administered single dose of the following treatments: Placebo, GW642444M 25 µg, GW642444M 50 µg, GW642444H 100 µg. Each participant received doses in an ascending dose manner as per randomization from the dry powder inhaler (DPI) from the DISKUS/ACCUHALER (one inhalation in the morning).
Seq 6: GW642444M 25 µg, PB, GW642444M 50 µg, GW642444H 100 µg	Participants were administered single dose of the following treatments: GW642444M 25 µg, Placebo, GW642444M 50 µg, GW642444H 100 µg. Each participant received doses in an ascending dose manner as per randomization from the dry powder inhaler (DPI) from the DISKUS/ACCUHALER (one inhalation in the morning).
Seq 7: GW642444M 25 µg, GW642444M 50 µg, PB, GW642444H 100 µg	Participants were administered single dose of the following treatments: GW642444M 25 µg, GW642444M 50 µg, Placebo, GW642444H 100 µg. Each participant received doses in an ascending dose manner as per randomization from the dry powder inhaler (DPI) from the DISKUS/ACCUHALER (one inhalation in the morning).
Seq 8: PB, GW642444M 25 µg, GW642444H 100 µg, GW642444M 50 µg	Participants were administered single dose of the following treatments: Placebo, GW642444M 25 µg, GW642444H 100 µg, GW642444M 50 µg. Each participant received doses in an ascending dose manner as per randomization from the dry powder inhaler (DPI) from the DISKUS/ACCUHALER (one inhalation in the morning).
Seq 9: GW642444M 25 µg, PB, GW642444H 100 µg, GW642444M 50 µg	Participants were administered single dose of the following treatments: GW642444M 25 µg, Placebo, GW642444H 100 µg, GW642444M 50 µg. Each participant received doses in an ascending dose manner as per randomization from the dry powder inhaler (DPI) from the DISKUS/ACCUHALER (one inhalation in the morning).
Seq 10: GW642444M 25 µg, GW642444M 50 µg, GW642444H 100 µg, PB	Participants were administered single dose of the following treatments: GW642444M 25 µg, GW642444M 50 µg, GW642444H 100 µg, Placebo. Each participant received doses in an ascending dose manner as per randomization from the dry powder inhaler (DPI) from the DISKUS/ACCUHALER (one inhalation in the morning).
Seq 11: PB, GW642444H 100 µg, GW642444M 25 µg, GW642444M 50 µg	Participants were administered single dose of the following treatments: Placebo, GW642444H 100 µg, GW642444M 25 µg, GW642444M 50 µg. Each participant received doses in an ascending dose manner as per randomization from the dry powder inhaler (DPI) from the DISKUS/ACCUHALER (one inhalation in the morning).
Seq 12: GW642444M 25 µg, GW642444H 100 µg, PB, GW642444M 50 µg	Participants were administered single dose of the following treatments: GW642444M 25 µg, GW642444H 100 µg, Placebo, GW642444M 50 µg. Each participant received doses in an ascending dose manner as per randomization from the dry powder inhaler (DPI) from the DISKUS/ACCUHALER (one inhalation in the morning).
Seq 13: GW642444M 25 µg, GW642444H 100 µg, GW642444M 50 µg, PB	Participants were administered single dose of the following treatments: GW642444M 25 µg, GW642444H 100 µg, GW642444M 50 µg, Placebo. Each participant received doses in an ascending dose manner as per randomization from the dry powder inhaler (DPI) from the DISKUS/ACCUHALER (one inhalation in the morning).

	Description
Seq 14: GW642444H 100 µg, PB, GW642444M 25 µg, GW642444M 50 µg	Participants were administered single dose of the following treatments: GW642444H 100 µg, Placebo, GW642444M 25 µg, GW642444M 50 µg. Each participant received doses in an ascending dose manner as per randomization from the dry powder inhaler (DPI) from the DISKUS/ACCUHALER (one inhalation in the morning).
Seq 15: GW642444H 100 µg, GW642444M 25 µg, PB, GW642444M 50 µg	Participants were administered single dose of the following treatments: GW642444H 100 µg, GW642444M 25 µg, Placebo, GW642444M 50 µg. Each participant received doses in an ascending dose manner as per randomization from the dry powder inhaler (DPI) from the DISKUS/ACCUHALER (one inhalation in the morning).
Seq 16: GW642444H 100 µg, GW642444M 25 µg, GW642444M 50 µg, PB	Participants were administered single dose of the following treatments: GW642444H 100 µg, GW642444M 25µg, GW642444M 50 µg, Placebo. Each participant received doses in an ascending dose manner as per randomization from the dry powder inhaler (DPI) from the DISKUS/ACCUHALER (one inhalation in the morning).

Treatment Period 1

	Seq 1: PB, GW642444M 25 µg, GW642444M 50 µg, GW642444M 100 µg	Seq 2: GW642444M 25 µg, PB, GW642444M 50 µg, GW642444M 100 µg	Seq 3: GW642444M 25 µg, GW642444M 50 µg, PB, GW642444M 100 µg	Seq 4: GW642444M 25 µg, GW642444M 50 µg, GW642444M 100 µg, PB	Seq 5: PB, GW642444M 25 µg, GW642444M 50 µg, GW642444H 100 µg	Seq 6: GW642444M 25 µg, PB, GW642444M 50 µg, GW642444H 100 µg
Started	2	2	2	2	1	1
Completed	2	2	2	2	1	1
Not Completed	0	0	0	0	0	0

	Seq 7: GW642444M 25 µg, GW642444M 50 µg, PB, GW642444H 100 µg	Seq 8: PB, GW642444M 25 µg, GW642444H 100 µg, GW642444M 50 µg	Seq 9: GW642444M 25 µg, PB, GW642444H 100 µg, GW642444M 50 µg	Seq 10: GW642444M 25 µg, GW642444M 50 µg, GW642444H 100 µg, PB	Seq 11: PB, GW642444H 100 µg, GW642444M 25 µg, GW642444M 50 µg	Seq 12: GW642444M 25 µg, GW642444H 100 µg, PB, GW642444M 50 µg
Started	1	1	1	1	1	1
Completed	1	1	1	1	1	1
Not Completed	0	0	0	0	0	0

	Seq 13: GW642444M 25 µg, GW642444H 100 µg, GW642444M 50 µg, PB	Seq 14: GW642444H 100 µg, PB, GW642444M 25 µg, GW642444M 50 µg	Seq 15: GW642444H 100 µg, GW642444M 25 µg, PB, GW642444M 50 µg	Seq 16: GW642444H 100 µg, GW642444M 25 µg, GW642444M 50 µg, PB
Started	1	1	1	1
Completed	1	1	1	1
Not Completed	0	0	0	0

Washout Period 1

	Seq 1: PB, GW642444M 25 µg, GW642444M 50 µg, GW642444M 100 µg	Seq 2: GW642444M 25 µg, PB, GW642444M 50 µg, GW642444M 100 µg	Seq 3: GW642444M 25 µg, GW642444M 50 µg, PB, GW642444M 100 µg	Seq 4: GW642444M 25 µg, GW642444M 50 µg, GW642444M 100 µg, PB	Seq 5: PB, GW642444M 25 µg, GW642444M 50 µg, GW642444H 100 µg	Seq 6: GW642444M 25 µg, PB, GW642444M 50 µg, GW642444H 100 µg
Started	2	2	2	2	1	1
Completed	2	2	2	2	1	1
Not Completed	0	0	0	0	0	0

	Seq 7: GW642444M 25 µg, GW642444M 50 µg, PB, GW642444H 100 µg	Seq 8: PB, GW642444M 25 µg, GW642444H 100 µg, GW642444M 50 µg	Seq 9: GW642444M 25 µg, PB, GW642444H 100 µg, GW642444M 50 µg	Seq 10: GW642444M 25 µg, GW642444M 50 µg, GW642444H 100 µg, PB	Seq 11: PB, GW642444H 100 µg, GW642444M 25 µg, GW642444M 50 µg	Seq 12: GW642444M 25 µg, GW642444H 100 µg, PB, GW642444M 50 µg
Started	1	1	1	1	1	1
Completed	1	1	1	1	1	1
Not Completed	0	0	0	0	0	0

	Seq 13: GW642444M 25 µg, GW642444H 100 µg, GW642444M 50 µg, PB	Seq 14: GW642444H 100 µg, PB, GW642444M 25 µg, GW642444M 50 µg	Seq 15: GW642444H 100 µg, GW642444M 25 µg, PB, GW642444M 50 µg	Seq 16: GW642444H 100 µg, GW642444M 25 µg, GW642444M 50 µg, PB
Started	1	1	1	1
Completed	1	1	1	1
Not Completed	0	0	0	0

Treatment Period 2

	Seq 1: PB, GW642444M 25 µg, GW642444M 50 µg, GW642444M 100 µg	Seq 2: GW642444M 25 µg, PB, GW642444M 50 µg, GW642444M 100 µg	Seq 3: GW642444M 25 µg, GW642444M 50 µg, PB, GW642444M 100 µg	Seq 4: GW642444M 25 µg, GW642444M 50 µg, GW642444M 100 µg, PB	Seq 5: PB, GW642444M 25 µg, GW642444M 50 µg, GW642444H 100 µg	Seq 6: GW642444M 25 µg, PB, GW642444M 50 µg, GW642444H 100 µg
Started	2	2	2	2	1	1
Completed	2	2	2	2	1	1
Not Completed	0	0	0	0	0	0
Unable Evaluate Cardiovascular Endpoints	0	0	0	0	0	0

	Seq 7: GW642444M 25 µg, GW642444M 50 µg, PB, GW642444H 100 µg	Seq 8: PB, GW642444M 25 µg, GW642444H 100 µg, GW642444M 50 µg	Seq 9: GW642444M 25 µg, PB, GW642444H 100 µg, GW642444M 50 µg	Seq 10: GW642444M 25 µg, GW642444M 50 µg, GW642444H 100 µg, PB	Seq 11: PB, GW642444H 100 µg, GW642444M 25 µg, GW642444M 50 µg	Seq 12: GW642444M 25 µg, GW642444H 100 µg, PB, GW642444M 50 µg
Started	1	1	1	1	1	1
Completed	1	1	1	1	1	1
Not Completed	0	0	0	0	0	0
Unable Evaluate Cardiovascular Endpoints	0	0	0	0	0	0

	Seq 13: GW642444M 25 µg, GW642444H 100 µg, GW642444M 50 µg, PB	Seq 14: GW642444H 100 µg, PB, GW642444M 25 µg, GW642444M 50 µg	Seq 15: GW642444H 100 µg, GW642444M 25 µg, PB, GW642444M 50 µg	Seq 16: GW642444H 100 µg, GW642444M 25 µg, GW642444M 50 µg, PB
Started	1	1	1	1
Completed	0	1	1	1
Not Completed	1	0	0	0
Unable Evaluate Cardiovascular Endpoints	1	0	0	0

Washout Period 2

	Seq 1: PB, GW642444M 25 µg, GW642444M 50 µg, GW642444M 100 µg	Seq 2: GW642444M 25 µg, PB, GW642444M 50 µg, GW642444M 100 µg	Seq 3: GW642444M 25 µg, GW642444M 50 µg, PB, GW642444M 100 µg	Seq 4: GW642444M 25 µg, GW642444M 50 µg, GW642444M 100 µg, PB	Seq 5: PB, GW642444M 25 µg, GW642444M 50 µg, GW642444H 100 µg	Seq 6: GW642444M 25 µg, PB, GW642444M 50 µg, GW642444H 100 µg
Started	2	2	2	2	1	1
Completed	2	2	2	2	1	1
Not Completed	0	0	0	0	0	0

	Seq 7: GW642444M 25 µg, GW642444M 50 µg, PB, GW642444H 100 µg	Seq 8: PB, GW642444M 25 µg, GW642444H 100 µg, GW642444M 50 µg	Seq 9: GW642444M 25 µg, PB, GW642444H 100 µg, GW642444M 50 µg	Seq 10: GW642444M 25 µg, GW642444M 50 µg, GW642444H 100 µg, PB	Seq 11: PB, GW642444H 100 µg, GW642444M 25 µg, GW642444M 50 µg	Seq 12: GW642444M 25 µg, GW642444H 100 µg, PB, GW642444M 50 µg
Started	1	1	1	1	1	1
Completed	1	1	1	1	1	1
Not Completed	0	0	0	0	0	0

	Seq 13: GW642444M 25 µg, GW642444H 100 µg, GW642444M 50 µg, PB	Seq 14: GW642444H 100 µg, PB, GW642444M 25 µg, GW642444M 50 µg	Seq 15: GW642444H 100 µg, GW642444M 25 µg, PB, GW642444M 50 µg	Seq 16: GW642444H 100 µg, GW642444M 25 µg, GW642444M 50 µg, PB
Started	0	1	1	1
Completed	0	1	1	1
Not Completed	0	0	0	0

Treatment Period 3

	Seq 1: PB, GW642444M 25 µg, GW642444M 50 µg, GW642444M 100 µg	Seq 2: GW642444M 25 µg, PB, GW642444M 50 µg, GW642444M 100 µg	Seq 3: GW642444M 25 µg, GW642444M 50 µg, PB, GW642444M 100 µg	Seq 4: GW642444M 25 µg, GW642444M 50 µg, GW642444M 100 µg, PB	Seq 5: PB, GW642444M 25 µg, GW642444M 50 µg, GW642444H 100 µg	Seq 6: GW642444M 25 µg, PB, GW642444M 50 µg, GW642444H 100 µg
Started	2	2	2	2	1	1
Completed	2	2	2	2	1	1
Not Completed	0	0	0	0	0	0

	Seq 7: GW642444M 25 µg, GW642444M 50 µg, PB, GW642444H 100 µg	Seq 8: PB, GW642444M 25 µg, GW642444H 100 µg, GW642444M 50 µg	Seq 9: GW642444M 25 µg, PB, GW642444H 100 µg, GW642444M 50 µg	Seq 10: GW642444M 25 µg, GW642444M 50 µg, GW642444H 100 µg, PB	Seq 11: PB, GW642444H 100 µg, GW642444M 25 µg, GW642444M 50 µg	Seq 12: GW642444M 25 µg, GW642444H 100 µg, PB, GW642444M 50 µg
Started	1	1	1	1	1	1
Completed	1	1	1	1	1	1
Not Completed	0	0	0	0	0	0

	Seq 13: GW642444M 25 µg, GW642444H 100 µg, GW642444M 50 µg, PB	Seq 14: GW642444H 100 µg, PB, GW642444M 25 µg, GW642444M 50 µg	Seq 15: GW642444H 100 µg, GW642444M 25 µg, PB, GW642444M 50 µg	Seq 16: GW642444H 100 µg, GW642444M 25 µg, GW642444M 50 µg, PB
Started	0	1	1	1
Completed	0	1	1	1
Not Completed	0	0	0	0

Washout Period 3

	Seq 1: PB, GW642444M 25 µg, GW642444M 50 µg, GW642444M 100 µg	Seq 2: GW642444M 25 µg, PB, GW642444M 50 µg, GW642444M 100 µg	Seq 3: GW642444M 25 µg, GW642444M 50 µg, PB, GW642444M 100 µg	Seq 4: GW642444M 25 µg, GW642444M 50 µg, GW642444M 100 µg, PB	Seq 5: PB, GW642444M 25 µg, GW642444M 50 µg, GW642444H 100 µg	Seq 6: GW642444M 25 µg, PB, GW642444M 50 µg, GW642444H 100 µg
Started	2	2	2	2	1	1
Completed	2	2	2	2	1	1
Not Completed	0	0	0	0	0	0

	Seq 7: GW642444M 25 µg, GW642444M 50 µg, PB, GW642444H 100 µg	Seq 8: PB, GW642444M 25 µg, GW642444H 100 µg, GW642444M 50 µg	Seq 9: GW642444M 25 µg, PB, GW642444H 100 µg, GW642444M 50 µg	Seq 10: GW642444M 25 µg, GW642444M 50 µg, GW642444H 100 µg, PB	Seq 11: PB, GW642444H 100 µg, GW642444M 25 µg, GW642444M 50 µg	Seq 12: GW642444M 25 µg, GW642444H 100 µg, PB, GW642444M 50 µg
Started	1	1	1	1	1	1
Completed	1	1	1	1	1	1
Not Completed	0	0	0	0	0	0

	Seq 13: GW642444M 25 µg, GW642444H 100 µg, GW642444M 50 µg, PB	Seq 14: GW642444H 100 µg, PB, GW642444M 25 µg, GW642444M 50 µg	Seq 15: GW642444H 100 µg, GW642444M 25 µg, PB, GW642444M 50 µg	Seq 16: GW642444H 100 µg, GW642444M 25 µg, GW642444M 50 µg, PB
Started	0	1	1	1
Completed	0	1	1	1
Not Completed	0	0	0	0

Treatment Period 4

	Seq 1: PB, GW642444M 25 µg, GW642444M 50 µg, GW642444M 100 µg	Seq 2: GW642444M 25 µg, PB, GW642444M 50 µg, GW642444M 100 µg	Seq 3: GW642444M 25 µg, GW642444M 50 µg, PB, GW642444M 100 µg	Seq 4: GW642444M 25 µg, GW642444M 50 µg, GW642444M 100 µg, PB	Seq 5: PB, GW642444M 25 µg, GW642444M 50 µg, GW642444H 100 µg	Seq 6: GW642444M 25 µg, PB, GW642444M 50 µg, GW642444H 100 µg
Started	2	2	2	2	1	1
Completed	2	2	1	2	1	1
Not Completed	0	0	1	0	0	0
Lost to Follow-up	0	0	1	0	0	0

	Seq 7: GW642444M 25 µg, GW642444M 50 µg, PB, GW642444H 100 µg	Seq 8: PB, GW642444M 25 µg, GW642444H 100 µg, GW642444M 50 µg	Seq 9: GW642444M 25 µg, PB, GW642444H 100 µg, GW642444M 50 µg	Seq 10: GW642444M 25 µg, GW642444M 50 µg, GW642444H 100 µg, PB	Seq 11: PB, GW642444H 100 µg, GW642444M 25 µg, GW642444M 50 µg	Seq 12: GW642444M 25 µg, GW642444H 100 µg, PB, GW642444M 50 µg
Started	1	1	1	1	1	1
Completed	1	1	1	1	1	1
Not Completed	0	0	0	0	0	0
Lost to Follow-up	0	0	0	0	0	0

	Seq 13: GW642444M 25 µg, GW642444H 100 µg, GW642444M 50 µg, PB	Seq 14: GW642444H 100 µg, PB, GW642444M 25 µg, GW642444M 50 µg	Seq 15: GW642444H 100 µg, GW642444M 25 µg, PB, GW642444M 50 µg	Seq 16: GW642444H 100 µg, GW642444M 25 µg, GW642444M 50 µg, PB
Started	0	1	1	1
Completed	0	1	1	1
Not Completed	0	0	0	0
Lost to Follow-up	0	0	0	0

Baseline Characteristics

Reporting Groups

	Description
GW642444M(25,50 and 100 µg),GW642444H(100 µg), PB in 1-16 Seq	Participants were administered single dose of four of the five following treatments: GW642444M (25, 50 and 100 µg), GW642444H (100 µg) or placebo. Each participant received doses of GW642444M in an ascending dose manner with GW642444H and placebo randomly interspersed as per randomization from the dry powder inhaler (DPI) from the DISKUS/ACCUHALER (one inhalation in the morning).

Baseline Measures

	GW642444M(25,50 and 100 µg),GW642444H(100 µg), PB in 1-16 Seq
Number of Participants	20
Age, Continuous [units: Years] Mean (Standard Deviation)	62.3 (7.57)
Gender, Male/Female [units: Participants]	
Female	3
Male	17

	GW642444M(25,50 and 100 µg),GW642444H(100 µg), PB in 1-16 Seq
Race/Ethnicity, Customized White/Caucasian/European Heritage [units: Participants]	20

Outcome Measures

1. Primary Outcome Measure:

Measure Title	Number of Participants With Any Adverse Event (AE) or Any Serious Adverse Event (SAE) During the Treatment Period
Measure Description	An AE is defined as any untoward medical occurrence in a participant or clinical investigation participant, temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product. A serious adverse event (SAE) is defined as any untoward medical occurrence that, at any dose, results in death, is life threatening, requires hospitalization or prolongation of existing hospitalization, results in disability/incapacity, or is a congenital anomaly/birth defect. Medical or scientific judgment should be exercised in deciding whether reporting is appropriate in other situations. Refer to the General Adverse AE/SAE module for a complete list of AEs and SAEs.
Time Frame	From the first dose of the study medication until the Follow-up Visit (up to Study Day 60)
Safety Issue?	No

Analysis Population Description

All Subjects Population: all participants who received at least one dose of study medication

Reporting Groups

	Description
Placebo	Participants received placebo single dose in the morning from the dry powder inhaler (DPI) from the DISKUS/ ACCUHALER (one inhalation in the morning).
GW642444M 25 µg	Participants received GW642444M 25 µg single dose in the morning from the dry powder inhaler (DPI) from the DISKUS/ACCUHALER (one inhalation in the morning).
GW642444M 50 µg	Participants received GW642444M 50 µg single dose in the morning from the dry powder inhaler (DPI) from the DISKUS/ACCUHALER (one inhalation in the morning).
GW642444M 100 µg	Participants received GW642444M 100 µg single dose in the morning from the dry powder inhaler (DPI) from the DISKUS/ACCUHALER (one inhalation in the morning).
GW642444H 100 µg	Participants received GW642444H 100 µg single dose in the morning from the dry powder inhaler (DPI) from the DISKUS/ACCUHALER (one inhalation in the morning).

Measured Values

	Placebo	GW642444M 25 µg	GW642444M 50 µg	GW642444M 100 µg	GW642444H 100 µg
Number of Participants Analyzed	19	20	19	8	12
Number of Participants With Any Adverse Event (AE) or Any Serious Adverse Event (SAE) During the Treatment Period [units: Participants]					
Any AE	2	1	2	0	0
Any SAE	0	0	0	0	0

2. Primary Outcome Measure:

Measure Title	Change From Baseline in Basophils, Eosinophils, Lymphocytes, Monocytes, Total Neutrophils, Platelet Count, and White Blood Cell Count at 24 Hours Post-dose on Day 1 of Each Treatment Period
Measure Description	Blood samples were collected for the measurement of basophils, eosinophils, lymphocytes, monocytes, total neutrophils, platelet count, and white blood cell (WBC) count at Baseline and 24 hours post-dose on Day 1of each treatment period. Baseline is defined as the measurement at Screening (Day -28 to Day -1). Change from Baseline was calculated as the value at the post-Baseline time point minus the value at Baseline.
Time Frame	Baseline and Day 1 of each treatment period (up to Study Day 54)
Safety Issue?	No

Analysis Population Description

All Subjects Population. Only those participants available at the specified time points were analyzed (represented by n=X, X in the category titles). Different participants may have been analyzed for different parameters, so the overall number of participants analyzed reflects everyone in the All Subjects Population.

Reporting Groups

	Description
Placebo	Participants received placebo single dose in the morning from the dry powder inhaler (DPI) from the DISKUS/ ACCUHALER (one inhalation in the morning).
GW642444M 25 µg	Participants received GW642444M 25 µg single dose in the morning from the dry powder inhaler (DPI) from the DISKUS/ACCUHALER (one inhalation in the morning).
GW642444M 50 µg	Participants received GW642444M 50 µg single dose in the morning from the dry powder inhaler (DPI) from the DISKUS/ACCUHALER (one inhalation in the morning).

	Description
GW642444M 100 µg	Participants received GW642444M 100 µg single dose in the morning from the dry powder inhaler (DPI) from the DISKUS/ACCUHALER (one inhalation in the morning).
GW642444H 100 µg	Participants received GW642444H 100 µg single dose in the morning from the dry powder inhaler (DPI) from the DISKUS/ACCUHALER (one inhalation in the morning).

Measured Values

	Placebo	GW642444M 25 µg	GW642444M 50 µg	GW642444M 100 µg	GW642444H 100 µg
Number of Participants Analyzed	19	20	19	8	11
Change From Baseline in Basophils, Eosinophils, Lymphocytes, Monocytes, Total Neutrophils, Platelet Count, and White Blood Cell Count at 24 Hours Post-dose on Day 1 of Each Treatment Period [units: 10^9 cells per liter (GI/L)] Mean (Standard Deviation)					
Basophils, n=19, 20, 19, 8, 11	0.004 (0.0154)	0.001 (0.0168)	0.001 (0.0133)	0.004 (0.0185)	-0.004 (0.0211)
Eosinophils, n=19, 20, 19, 8, 11	0.003 (0.1771)	-0.045 (0.0707)	-0.023 (0.0921)	-0.031 (0.0895)	-0.002 (0.0637)
Lymphocytes, n=19, 20, 19, 8, 11	0.068 (0.4094)	0.021 (0.3719)	-0.126 (0.2608)	-0.146 (0.4055)	-0.116 (0.3261)
Monocytes, n=19, 20, 19, 8, 11	0.006 (0.1323)	-0.027 (0.1390)	0.007 (0.0917)	-0.018 (0.1331)	0.025 (0.1347)
Total Neutrophils, n=19, 20, 19, 8, 11	-0.100 (0.6174)	0.188 (0.9814)	0.343 (0.9674)	0.201 (0.6165)	-0.021 (0.7415)
Platelet count, n=19, 20, 19, 8, 11	5.0 (16.16)	8.2 (18.38)	8.5 (15.33)	9.5 (13.72)	-1.1 (10.82)
WBC, n=19, 20, 19, 8, 11	-0.02 (0.807)	0.14 (1.215)	0.20 (1.029)	0.04 (1.094)	-0.12 (0.774)

3. Primary Outcome Measure:

Measure Title	Change From Baseline in Hemoglobin and Mean Corpuscle Hemoglobin Concentration (MCHC) at 24 Hours Post-dose on Day 1 of Each Treatment Period
Measure Description	Blood samples were collected for the measurement of hemoglobin and MCHC at Baseline and 24 hours post-dose on Day 1of each treatment period. Baseline is defined as the measurement at Screening (Day -28 to Day -1). Change from Baseline was calculated as the value at the post-Baseline time point minus the value at Baseline.
Time Frame	Baseline and Day 1 of each treatment period (up to Study Day 54)
Safety Issue?	No

Analysis Population Description

All Subjects Population. Only those participants available at the specified time points were analyzed (represented by n=X, X in the category titles). Different participants may have been analyzed for different parameters, so the overall number of participants analyzed reflects everyone in the All Subjects Population.

Reporting Groups

	Description
Placebo	Participants received placebo single dose in the morning from the dry powder inhaler (DPI) from the DISKUS/ ACCUHALER (one inhalation in the morning).
GW642444M 25 µg	Participants received GW642444M 25 µg single dose in the morning from the dry powder inhaler (DPI) from the DISKUS/ACCUHALER (one inhalation in the morning).
GW642444M 50 µg	Participants received GW642444M 50 µg single dose in the morning from the dry powder inhaler (DPI) from the DISKUS/ACCUHALER (one inhalation in the morning).
GW642444M 100 µg	Participants received GW642444M 100 µg single dose in the morning from the dry powder inhaler (DPI) from the DISKUS/ACCUHALER (one inhalation in the morning).
GW642444H 100 µg	Participants received GW642444H 100 µg single dose in the morning from the dry powder inhaler (DPI) from the DISKUS/ACCUHALER (one inhalation in the morning).

Measured Values

	Placebo	GW642444M 25 µg	GW642444M 50 µg	GW642444M 100 µg	GW642444H 100 µg
Number of Participants Analyzed	19	20	19	8	11
Change From Baseline in Hemoglobin and Mean Corpuscle Hemoglobin Concentration (MCHC) at 24 Hours Post-dose on Day 1 of Each Treatment Period [units: Grams per liter (g/L)] Mean (Standard Deviation)					
Hemoglobin, n=19, 20, 19, 8, 11	-0.4 (6.21)	-1.2 (6.41)	-0.5 (4.02)	-3.0 (4.21)	0.8 (5.47)
MCHC, n=19, 20, 19, 8, 11	-3.5 (5.23)	-5.8 (22.66)	1.7 (5.58)	5.3 (3.65)	-0.8 (6.27)

4. Primary Outcome Measure:

Measure Title	Change From Baseline in Reticulocyte and Red Blood Cell (RBC) Count at 24 Hours Post-dose on Day 1 of Each Treatment Period

Measure Description	Blood samples were collected for the measurement of reticulocyte and RBCs at Baseline and 24 hours post-dose on Day 1of each treatment period. Baseline is defined as the measurement at Screening (Day -28 to Day -1). Change from Baseline was calculated as the value at the post-Baseline time point minus the value at Baseline.
Time Frame	Baseline and Day 1 of each treatment period (up to Study Day 54)
Safety Issue?	No

Analysis Population Description

All Subjects Population. Only those participants available at the specified time points were analyzed (represented by n=X, X in the category titles). Different participants may have been analyzed for different parameters, so the overall number of participants analyzed reflects everyone in the All Subjects Population.

Reporting Groups

	Description
Placebo	Participants received placebo single dose in the morning from the dry powder inhaler (DPI) from the DISKUS/ ACCUHALER (one inhalation in the morning).
GW642444M 25 µg	Participants received GW642444M 25 µg single dose in the morning from the dry powder inhaler (DPI) from the DISKUS/ACCUHALER (one inhalation in the morning).
GW642444M 50 µg	Participants received GW642444M 50 µg single dose in the morning from the dry powder inhaler (DPI) from the DISKUS/ACCUHALER (one inhalation in the morning).
GW642444M 100 µg	Participants received GW642444M 100 µg single dose in the morning from the dry powder inhaler (DPI) from the DISKUS/ACCUHALER (one inhalation in the morning).
GW642444H 100 µg	Participants received GW642444H 100 µg single dose in the morning from the dry powder inhaler (DPI) from the DISKUS/ACCUHALER (one inhalation in the morning).

Measured Values

	Placebo	GW642444M 25 µg	GW642444M 50 µg	GW642444M 100 µg	GW642444H 100 µg
Number of Participants Analyzed	19	20	19	8	11
Change From Baseline in Reticulocyte and Red Blood Cell (RBC) Count at 24 Hours Post-dose on Day 1 of Each Treatment Period [units: 10^12 cells per liter (TI/L)] Mean (Standard Deviation)					
Reticulocytes, n=19, 19, 19, 8, 11	-0.00714 (0.021416)	-0.00065 (0.019905)	0.00208 (0.017391)	0.00905 (0.016387)	0.00094 (0.012676)
RBC, n=19, 20, 19, 8, 11	0.00 (0.194)	0.01 (0.193)	-0.01 (0.137)	-0.11 (0.173)	0.05 (0.186)

5. Primary Outcome Measure:

Measure Title	Change From Baseline in Hematocrit at 24 Hours Post-dose on Day 1 of Each Treatment Period
Measure Description	Blood samples were collected for the measurement of hematocrit at Baseline and 24 hours post-dose on Day 1of each treatment period. Baseline is defined as the measurement at Screening (Day -28 to Day -1). Change from Baseline was calculated as the value at the post-Baseline time point minus the value at Baseline.
Time Frame	Baseline and Day 1 of each treatment period (up to Study Day 54)
Safety Issue?	No

Analysis Population Description

All Subjects Population. Only those participants available at the specified time points were analyzed (represented by n=X, X in the category titles). Different participants may have been analyzed for different parameters, so the overall number of participants analyzed reflects everyone in the All Subjects Population.

Reporting Groups

	Description
Placebo	Participants received placebo single dose in the morning from the dry powder inhaler (DPI) from the DISKUS/ ACCUHALER (one inhalation in the morning).
GW642444M 25 µg	Participants received GW642444M 25 µg single dose in the morning from the dry powder inhaler (DPI) from the DISKUS/ACCUHALER (one inhalation in the morning).
GW642444M 50 µg	Participants received GW642444M 50 µg single dose in the morning from the dry powder inhaler (DPI) from the DISKUS/ACCUHALER (one inhalation in the morning).
GW642444M 100 µg	Participants received GW642444M 100 µg single dose in the morning from the dry powder inhaler (DPI) from the DISKUS/ACCUHALER (one inhalation in the morning).
GW642444H 100 µg	Participants received GW642444H 100 µg single dose in the morning from the dry powder inhaler (DPI) from the DISKUS/ACCUHALER (one inhalation in the morning).

Measured Values

	Placebo	GW642444M 25 µg	GW642444M 50 µg	GW642444M 100 µg	GW642444H 100 µg
Number of Participants Analyzed	19	20	19	8	11
Change From Baseline in Hematocrit at 24 Hours Post-dose on Day 1 of Each Treatment Period [units: Proportion of 1.0] Mean (Standard Deviation)	0.0044 (0.02025)	-0.0024 (0.02132)	-0.0018 (0.01674)	-0.0161 (0.01408)	0.0036 (0.02025)

6. Primary Outcome Measure:

Measure Title	Change From Baseline in Mean Corpuscle Volume (MCV) at 24 Hours Post-dose on Day 1 of Each Treatment Period
Measure Description	Blood samples were collected for the measurement of MCV at Baseline and 24 hours post-dose on Day 1of each treatment period. Baseline is defined as the measurement at Screening (Day -28 to Day -1). Change from Baseline was calculated as the value at the post-Baseline time point minus the value at Baseline.
Time Frame	Baseline and Day 1 of each treatment period (up to Study Day 54)
Safety Issue?	No

Analysis Population Description

Blood samples were collected for the measurement of MCV at Baseline and 24 hours post-dose on Day 1of each treatment period. Baseline is defined as the measurement at Screening (Day -28 to Day -1). Change from Baseline was calculated as the value at the post-Baseline time point minus the value at Baseline.

Reporting Groups

	Description
Placebo	Participants received placebo single dose in the morning from the dry powder inhaler (DPI) from the DISKUS/ ACCUHALER (one inhalation in the morning).
GW642444M 25 µg	Participants received GW642444M 25 µg single dose in the morning from the dry powder inhaler (DPI) from the DISKUS/ACCUHALER (one inhalation in the morning).
GW642444M 50 µg	Participants received GW642444M 50 µg single dose in the morning from the dry powder inhaler (DPI) from the DISKUS/ACCUHALER (one inhalation in the morning).
GW642444M 100 µg	Participants received GW642444M 100 µg single dose in the morning from the dry powder inhaler (DPI) from the DISKUS/ACCUHALER (one inhalation in the morning).
GW642444H 100 µg	Participants received GW642444H 100 µg single dose in the morning from the dry powder inhaler (DPI) from the DISKUS/ACCUHALER (one inhalation in the morning).

Measured Values

	Placebo	GW642444M 25 µg	GW642444M 50 µg	GW642444M 100 µg	GW642444H 100 µg
Number of Participants Analyzed	19	20	19	8	11
Change From Baseline in Mean Corpuscle Volume (MCV) at 24 Hours Post-dose on Day 1 of Each Treatment Period [units: 10^15 femtoliters (fL) per cell] Mean (Standard Deviation)	0.6 (1.67)	-0.2 (2.09)	-0.2 (1.96)	-1.0 (0.76)	-0.5 (1.81)

7. Primary Outcome Measure:

Measure Title	Change From Baseline in Mean Corpuscle Hemoglobin (MCH) Values at 24 Hours Post-dose on Day 1 of Each Treatment Period
Measure Description	Blood samples were collected for the measurement of MCH at Baseline and 24 hours post-dose on Day 1of each treatment period. Baseline is defined as the measurement at Screening (Day -28 to Day -1). Change from Baseline was calculated as the value at the post-Baseline time point minus the value at Baseline.
Time Frame	Baseline and Day 1 of each treatment period (up to Study Day 54)
Safety Issue?	No

Analysis Population Description

All Subjects Population. Only those participants available at the specified time points were analyzed (represented by n=X, X in the category titles). Different participants may have been analyzed for different parameters, so the overall number of participants analyzed reflects everyone in the All Subjects Population.

Reporting Groups

	Description
Placebo	Participants received placebo single dose in the morning from the dry powder inhaler (DPI) from the DISKUS/ ACCUHALER (one inhalation in the morning).
GW642444M 25 µg	Participants received GW642444M 25 µg single dose in the morning from the dry powder inhaler (DPI) from the DISKUS/ACCUHALER (one inhalation in the morning).
GW642444M 50 µg	Participants received GW642444M 50 µg single dose in the morning from the dry powder inhaler (DPI) from the DISKUS/ACCUHALER (one inhalation in the morning).
GW642444M 100 µg	Participants received GW642444M 100 µg single dose in the morning from the dry powder inhaler (DPI) from the DISKUS/ACCUHALER (one inhalation in the morning).
GW642444H 100 µg	Participants received GW642444H 100 µg single dose in the morning from the dry powder inhaler (DPI) from the DISKUS/ACCUHALER (one inhalation in the morning).

Measured Values

	Placebo	GW642444M 25 µg	GW642444M 50 µg	GW642444M 100 µg	GW642444H 100 µg
Number of Participants Analyzed	19	20	19	8	11
Change From Baseline in Mean Corpuscle Hemoglobin (MCH) Values at 24 Hours Post-dose on Day 1 of Each Treatment Period	-0.11 (0.403)	-0.22 (0.465)	0.24 (0.581)	0.14 (0.342)	-0.21 (0.528)

	Placebo	GW642444M 25 µg	GW642444M 50 µg	GW642444M 100 µg	GW642444H 100 µg
[units: 10^12 picograms (pg) per cell] Mean (Standard Deviation)					

8. Primary Outcome Measure:

Measure Title	Change From Baseline in Alanine Amino Transferase (ALT), Alkaline Phosphatase (ALP), Aspartate Amino Transferase (AST), Creatine Kinase (CK) and Gamma Glutamyl Transferase (GGT) Values at 24 Hours Post-dose on Day 1 of Each Treatment Period
Measure Description	Blood samples were collected for the measurement of ALT, ALP, AST, and GGT at Baseline and 24 hours post-dose on Day 1of each treatment period. Baseline is defined as the measurement at Screening (Day -28 to Day -1). Change from Baseline was calculated as the value at the post-Baseline time point minus the value at Baseline.
Time Frame	Baseline and Day 1 of each treatment period (up to Study Day 54)
Safety Issue?	No

Analysis Population Description

All Subjects Population, Only those participants available at the specified time points were analyzed (represented by n=X, X in the category titles). Different participants may have been analyzed for different parameters, so the overall number of participants analyzed reflects everyone in the All Subjects Population.

Reporting Groups

	Description
Placebo	Participants received placebo single dose in the morning from the dry powder inhaler (DPI) from the DISKUS/ ACCUHALER (one inhalation in the morning).
GW642444M 25 µg	Participants received GW642444M 25 µg single dose in the morning from the dry powder inhaler (DPI) from the DISKUS/ACCUHALER (one inhalation in the morning).
GW642444M 50 µg	Participants received GW642444M 50 µg single dose in the morning from the dry powder inhaler (DPI) from the DISKUS/ACCUHALER (one inhalation in the morning).
GW642444M 100 µg	Participants received GW642444M 100 µg single dose in the morning from the dry powder inhaler (DPI) from the DISKUS/ACCUHALER (one inhalation in the morning).
GW642444H 100 µg	Participants received GW642444H 100 µg single dose in the morning from the dry powder inhaler (DPI) from the DISKUS/ACCUHALER (one inhalation in the morning).

Measured Values

	Placebo	GW642444M 25 µg	GW642444M 50 µg	GW642444M 100 µg	GW642444H 100 µg
Number of Participants Analyzed	17	15	17	7	10
Change From Baseline in Alanine Amino Transferase (ALT), Alkaline Phosphatase (ALP), Aspartate Amino Transferase (AST), Creatine Kinase (CK) and Gamma Glutamyl Transferase (GGT) Values at 24 Hours Post-dose on Day 1 of Each Treatment Period [units: International units per liter (IU/L)] Mean (Standard Deviation)					
ALT, n=17, 15, 17, 7, 10	0.1 (3.89)	-0.5 (2.00)	1.1 (2.75)	-0.6 (1.51)	1.0 (4.08)
ALP, n=17, 15, 17, 7, 10	0.4 (10.05)	1.6 (4.90)	0.6 (5.93)	-0.4 (2.37)	1.2 (6.91)
AST, n=17, 13, 17, 6, 9	-0.1 (5.46)	-0.6 (2.87)	-1.6 (2.69)	-1.7 (1.03)	2.1 (5.84)
GGT, n=17, 15, 17, 7, 10	-2.0 (2.37)	-0.9 (3.99)	-0.5 (5.06)	-1.6 (2.88)	0.5 (5.21)
CK n=17, 15, 17, 7, 10	-18.1 (29.90)	-20.5 (36.07)	-38.1 (69.67)	-3.1 (15.99)	-19.9 (20.89)

9. Primary Outcome Measure:

Measure Title	Change From Baseline in Albumin and Total Protein at 24 Hours Post-dose on Day 1 of Each Treatment Period
Measure Description	Blood samples were collected for the measurement of albumin and total protein at Baseline and 24 hours post-dose on Day 1of each treatment period. Baseline is defined as the measurement at Screening (Day -28 to Day -1). Change from Baseline was calculated as the value at the post-Baseline time point minus the value at Baseline.
Time Frame	Baseline and Day 1 of each treatment period (up to Study Day 54)
Safety Issue?	No

Analysis Population Description

All Subjects Population. Only those participants available at the specified time points were analyzed (represented by n=X, X in the category titles). Different participants may have been analyzed for different parameters, so the overall number of participants analyzed reflects everyone in the All Subjects Population.

Reporting Groups

	Description
Placebo	Participants received placebo single dose in the morning from the dry powder inhaler (DPI) from the DISKUS/ ACCUHALER (one inhalation in the morning).

	Description
GW642444M 25 µg	Participants received GW642444M 25 µg single dose in the morning from the dry powder inhaler (DPI) from the DISKUS/ACCUHALER (one inhalation in the morning).
GW642444M 50 µg	Participants received GW642444M 50 µg single dose in the morning from the dry powder inhaler (DPI) from the DISKUS/ACCUHALER (one inhalation in the morning).
GW642444M 100 µg	Participants received GW642444M 100 µg single dose in the morning from the dry powder inhaler (DPI) from the DISKUS/ACCUHALER (one inhalation in the morning).
GW642444H 100 µg	Participants received GW642444H 100 µg single dose in the morning from the dry powder inhaler (DPI) from the DISKUS/ACCUHALER (one inhalation in the morning).

Measured Values

	Placebo	GW642444M 25 µg	GW642444M 50 µg	GW642444M 100 µg	GW642444H 100 µg
Number of Participants Analyzed	17	15	17	7	10
Change From Baseline in Albumin and Total Protein at 24 Hours Post-dose on Day 1 of Each Treatment Period [units: Grams per liter] Mean (Standard Deviation)					
Albumin, n=17, 15, 17, 7, 10	-0.9 (2.30)	-0.1 (1.85)	-0.2 (1.51)	-0.9 (1.95)	0.1 (0.88)
Total protein, n=17, 15, 17, 7, 10	-1.7 (4.22)	-0.5 (2.59)	0.1 (2.34)	-0.7 (3.40)	0.8 (1.55)

10. Primary Outcome Measure:

Measure Title	Change From Baseline in Cholesterol, Chloride, Potassium, Sodium, Triglycerides, and Urea at 24 Hours Post-dose on Day 1 of Each Treatment Period
Measure Description	Blood samples were collected for the measurement of cholesterol, chloride, potassium, sodium, triglycerides, and urea at Baseline and 24 hours post-dose on Day 1of each treatment period. Baseline is defined as the measurement at Screening (Day -28 to Day -1). Change from Baseline was calculated as the value at the post-Baseline time point minus the value at Baseline.
Time Frame	Baseline and Day 1 of each treatment period (up to Study Day 54)
Safety Issue?	No

Analysis Population Description

All Subjects Population. Only those participants available at the specified time points were analyzed (represented by n=X, X in the category titles). Different participants may have been analyzed for different parameters, so the overall number of participants analyzed reflects everyone in the All Subjects Population.

Reporting Groups

	Description
Placebo	Participants received placebo single dose in the morning from the dry powder inhaler (DPI) from the DISKUS/ ACCUHALER (one inhalation in the morning).
GW642444M 25 µg	Participants received GW642444M 25 µg single dose in the morning from the dry powder inhaler (DPI) from the DISKUS/ACCUHALER (one inhalation in the morning).
GW642444M 50 µg	Participants received GW642444M 50 µg single dose in the morning from the dry powder inhaler (DPI) from the DISKUS/ACCUHALER (one inhalation in the morning).
GW642444M 100 µg	Participants received GW642444M 100 µg single dose in the morning from the dry powder inhaler (DPI) from the DISKUS/ACCUHALER (one inhalation in the morning).
GW642444H 100 µg	Participants received GW642444H 100 µg single dose in the morning from the dry powder inhaler (DPI) from the DISKUS/ACCUHALER (one inhalation in the morning).

Measured Values

	Placebo	GW642444M 25 µg	GW642444M 50 µg	GW642444M 100 µg	GW642444H 100 µg
Number of Participants Analyzed	17	15	17	7	10
Change From Baseline in Cholesterol, Chloride, Potassium, Sodium, Triglycerides, and Urea at 24 Hours Post-dose on Day 1 of Each Treatment Period [units: Millimoles per liter (mmol/L)] Mean (Standard Deviation)					
Cholesterol, n=17, 15, 17, 7, 10	-0.085 (0.3416)	0.121 (0.3764)	0.032 (1.2588)	-0.251 (0.5630)	0.082 (0.2447)
Chloride, n=17, 15, 17, 7, 10	0.6 (2.65)	0.0 (2.80)	-0.3 (2.31)	-0.3 (1.70)	0.6 (1.43)
Potassium, n=17, 13, 17, 6, 9	0.12 (0.263)	0.14 (0.384)	0.06 (0.374)	0.10 (0.358)	0.16 (0.305)
Sodium, n=17, 15, 17, 7, 10	0.9 (2.03)	-0.1 (1.83)	0.4 (1.41)	0.0 (1.15)	0.9 (1.79)
Triglyceride, n=17, 15, 17, 7, 10	-0.106 (0.4625)	0.024 (0.5789)	-0.015 (0.3800)	-0.300 (0.5812)	0.142 (0.2629)
Urea, n=17, 15, 17, 7, 10	0.29 (1.092)	-0.17 (0.964)	-0.38 (1.109)	-0.17 (0.427)	0.20 (0.918)

11. Primary Outcome Measure:

Measure Title	Change From Baseline in Total Bilirubin and Creatinine at 24 Hours Post-dose on Day 1 of Each Treatment Period
Measure Description	Blood samples were collected for the measurement of total bilirubin and creatinine at Baseline and 24 hours post-dose on Day 1of each treatment period. Baseline is defined as the measurement at Screening (Day -28 to Day -1). Change from Baseline was calculated as the value at the post-Baseline time point minus the value at Baseline.
Time Frame	Baseline and Day 1 of each treatment period (up to Study Day 54)
Safety Issue?	No

Analysis Population Description

All Subjects Population. Only those participants available at the specified time points were analyzed (represented by n=X, X in the category titles). Different participants may have been analyzed for different parameters, so the overall number of participants analyzed reflects everyone in the All Subjects Population.

Reporting Groups

	Description
Placebo	Participants received placebo single dose in the morning from the dry powder inhaler (DPI) from the DISKUS/ ACCUHALER (one inhalation in the morning).
GW642444M 25 µg	Participants received GW642444M 25 µg single dose in the morning from the dry powder inhaler (DPI) from the DISKUS/ACCUHALER (one inhalation in the morning).
GW642444M 50 µg	Participants received GW642444M 50 µg single dose in the morning from the dry powder inhaler (DPI) from the DISKUS/ACCUHALER (one inhalation in the morning).
GW642444M 100 µg	Participants received GW642444M 100 µg single dose in the morning from the dry powder inhaler (DPI) from the DISKUS/ACCUHALER (one inhalation in the morning).
GW642444H 100 µg	Participants received GW642444H 100 µg single dose in the morning from the dry powder inhaler (DPI) from the DISKUS/ACCUHALER (one inhalation in the morning).

Measured Values

	Placebo	GW642444M 25 µg	GW642444M 50 µg	GW642444M 100 µg	GW642444H 100 µg
Number of Participants Analyzed	17	15	17	7	10
Change From Baseline in Total Bilirubin and Creatinine at 24 Hours Post-dose on Day 1 of Each Treatment Period [units: Micromoles per liter (µmol/L)] Mean (Standard Deviation)					
Creatinine, n=17, 15, 17, 7, 10	3.5 (5.96)	4.9 (5.62)	4.9 (6.62)	1.0 (5.07)	1.5 (5.28)
Total Bilirubin, n=17, 15, 17, 7, 10	-1.1 (2.33)	-0.1 (4.04)	-0.8 (3.60)	0.3 (1.38)	1.0 (3.92)

12. Primary Outcome Measure:

Measure Title	Change From Baseline in C-reactive Protein at 24 Hours Post-dose on Day 1 of Each Treatment Period
Measure Description	Blood samples were collected for the measurement of c-reactive protein at Baseline and 24 hours post-dose on Day 1of each treatment period. Baseline is defined as the measurement at Screening (Day -28 to Day -1). Change from Baseline was calculated as the value at the post-Baseline time point minus the value at Baseline.
Time Frame	Baseline and Day 1 of each treatment period (up to Study Day 54)
Safety Issue?	No

Analysis Population Description

All Subjects Population. Only those participants available at the specified time points were analyzed (represented by n=X, X in the category titles). Different participants may have been analyzed for different parameters, so the overall number of participants analyzed reflects everyone in the All Subjects Population.

Reporting Groups

	Description
Placebo	Participants received placebo single dose in the morning from the dry powder inhaler (DPI) from the DISKUS/ ACCUHALER (one inhalation in the morning).
GW642444M 25 µg	Participants received GW642444M 25 µg single dose in the morning from the dry powder inhaler (DPI) from the DISKUS/ACCUHALER (one inhalation in the morning).
GW642444M 50 µg	Participants received GW642444M 50 µg single dose in the morning from the dry powder inhaler (DPI) from the DISKUS/ACCUHALER (one inhalation in the morning).
GW642444M 100 µg	Participants received GW642444M 100 µg single dose in the morning from the dry powder inhaler (DPI) from the DISKUS/ACCUHALER (one inhalation in the morning).
GW642444H 100 µg	Participants received GW642444H 100 µg single dose in the morning from the dry powder inhaler (DPI) from the DISKUS/ACCUHALER (one inhalation in the morning).

Measured Values

	Placebo	GW642444M 25 µg	GW642444M 50 µg	GW642444M 100 µg	GW642444H 100 µg
Number of Participants Analyzed	18	18	19	8	10
Change From Baseline in C-reactive Protein at 24 Hours Post-dose on Day 1 of Each Treatment Period [units: Milligrams per liter (Mg/L)] Mean (Standard Deviation)	-1.36 (3.837)	0.20 (1.015)	-0.47 (3.500)	-0.76 (2.123)	-0.93 (2.965)

13. Primary Outcome Measure:

Measure Title	Change From Baseline in Systolic Blood Pressure (SBP) and Diastolic Blood Pressure (DBP) Over the Post-dose 24 Hour (h) Period
Measure Description	SBP and DBP were measured at Baseline and over the post-dose 24 h period at the following scheduled time points: 20 minutes (M), 45 M, 1h, 2h, 3h, 4h, 6h, and 24 h. Baseline is defined as the measurement at Screening (Day -28 to Day -1). Change from Baseline was calculated as the value at the post-Baseline time point minus the value at Baseline.
Time Frame	Baseline and Day 1 of each treatment period (up to Study Day 54)
Safety Issue?	No

Analysis Population Description

All Subjects Population. Only those participants available at the specified time points were analyzed (represented by n=X, X in the category titles). Different participants may have been analyzed for different parameters, so the overall number of participants analyzed reflects everyone in the All Subjects Population.

Reporting Groups

	Description
Placebo	Participants received placebo single dose in the morning from the dry powder inhaler (DPI) from the DISKUS/ ACCUHALER (one inhalation in the morning).
GW642444M 25 µg	Participants received GW642444M 25 µg single dose in the morning from the dry powder inhaler (DPI) from the DISKUS/ACCUHALER (one inhalation in the morning).
GW642444M 50 µg	Participants received GW642444M 50 µg single dose in the morning from the dry powder inhaler (DPI) from the DISKUS/ACCUHALER (one inhalation in the morning).
GW642444M 100 µg	Participants received GW642444M 100 µg single dose in the morning from the dry powder inhaler (DPI) from the DISKUS/ACCUHALER (one inhalation in the morning).
GW642444H 100 µg	Participants received GW642444H 100 µg single dose in the morning from the dry powder inhaler (DPI) from the DISKUS/ACCUHALER (one inhalation in the morning).

Measured Values

	Placebo	GW642444M 25 µg	GW642444M 50 µg	GW642444M 100 µg	GW642444H 100 µg
Number of Participants Analyzed	19	19	19	8	11
Change From Baseline in Systolic Blood Pressure (SBP) and Diastolic Blood Pressure (DBP) Over the Post-dose 24 Hour (h) Period					

	Placebo	GW642444M 25 µg	GW642444M 50 µg	GW642444M 100 µg	GW642444H 100 µg
[units: Millimeters of mercury (mmHg)] Mean (Standard Deviation)					
SBP, 20 M, n=19, 19, 19, 8, 11	-1.1 (7.20)	-0.6 (6.01)	1.5 (4.59)	0.2 (5.38)	-5.2 (8.63)
SBP, 45 M, n=19, 19, 19, 8, 11	-1.1 (6.13)	-0.5 (9.16)	-2.6 (8.34)	1.0 (7.12)	-3.5 (8.23)
SBP, 1 h, n=19, 19, 19, 8, 11	-1.0 (8.11)	-0.6 (5.83)	-1.7 (8.46)	-3.1 (10.20)	-4.8 (5.29)
SBP, 2 h, n=19, 19, 19, 8, 11	2.5 (7.77)	-1.2 (9.23)	0.6 (11.16)	2.2 (7.73)	-2.7 (6.43)
SBP, 3 h, n=19, 19, 19, 8, 11	-0.6 (7.58)	0.9 (9.75)	2.6 (7.92)	4.7 (8.68)	-0.1 (5.60)
SBP, 4 h, n=19, 19, 19, 8, 11	1.1 (6.10)	0.3 (9.99)	0.7 (8.18)	2.2 (7.59)	-0.1 (8.66)
SBP, 6 h, n=19, 19, 19, 8, 11	0.1 (9.41)	-1.4 (10.21)	-0.7 (9.35)	3.9 (9.82)	-3.2 (9.75)
SBP, 24 h, n=19, 19, 19, 8, 11	0.4 (7.53)	0.0 (9.01)	-1.8 (8.70)	3.5 (9.10)	-5.3 (8.21)
DBP, 20 M, n=19, 19, 19, 8, 11	-1.9 (4.17)	-0.9 (4.59)	-0.6 (3.95)	1.3 (1.93)	-4.5 (7.31)
DBP, 45 M, n=19, 19, 19, 8, 11	-1.9 (4.65)	-0.1 (6.53)	-3.2 (5.91)	0.9 (6.63)	-3.8 (5.27)
DBP, 1 h, n=19, 19, 19, 8, 11	-2.2 (7.12)	-1.0 (4.46)	-2.3 (4.81)	-0.1 (9.03)	-6.5 (5.99)
DBP, 2 h, n=19, 19, 19, 8, 11	0.2 (6.65)	0.2 (7.21)	-1.7 (5.73)	1.3 (6.35)	-3.4 (8.15)
DBP, 3 h, n=19, 19, 19, 8, 11	-2.0 (7.32)	-0.0 (5.94)	-1.7 (5.62)	2.5 (5.10)	-4.0 (7.35)
DBP, 4 h, n=19, 19, 19, 8, 11	-2.3 (5.05)	-0.6 (5.15)	-1.7 (5.33)	1.7 (5.08)	-4.7 (7.76)
DBP, 6 h, n=19, 19, 19, 8, 11	-3.2 (7.03)	-0.9 (6.05)	-2.9 (5.05)	-1.1 (5.61)	-7.6 (7.13)
DBP, 24 h, n=19, 19, 19, 8, 11	0.6 (4.49)	-0.5 (5.62)	-1.4 (6.88)	-0.1 (5.38)	-4.1 (6.32)

14. Primary Outcome Measure:

Measure Title	Change From Baseline in Heart Rate Over the Post-dose 24 Hour (h) Period
Measure Description	Heart rate (HR) was measured at Baseline and over the post-dose 24 h period at the following scheduled time points: 20 minutes (M), 45 M, 1 h, 2 h, 3 h, 4 h, 6 h, and 24 h. Baseline is defined as the measurement at Screening (Day -28 to Day -1). Change from Baseline was calculated as the value at the post-Baseline time point minus the value at Baseline.
Time Frame	Baseline and Day 1 of each treatment period (up to Study Day 54)
Safety Issue?	No

Analysis Population Description

Per Protocol (PP) Population: all participants included in the All Subjects population excluding a participant deemed not to have heart rate or other ECG parameters deemed suitable for evaluation. Only those participants available at the specified time points were analyzed (represented by n=X, X in the category titles).

Reporting Groups

	Description
Placebo	Participants received placebo single dose in the morning from the dry powder inhaler (DPI) from the DISKUS/ ACCUHALER (one inhalation in the morning).
GW642444M 25 µg	Participants received GW642444M 25 µg single dose in the morning from the dry powder inhaler (DPI) from the DISKUS/ACCUHALER (one inhalation in the morning).
GW642444M 50 µg	Participants received GW642444M 50 µg single dose in the morning from the dry powder inhaler (DPI) from the DISKUS/ACCUHALER (one inhalation in the morning).
GW642444M 100 µg	Participants received GW642444M 100 µg single dose in the morning from the dry powder inhaler (DPI) from the DISKUS/ACCUHALER (one inhalation in the morning).
GW642444H 100 µg	Participants received GW642444H 100 µg single dose in the morning from the dry powder inhaler (DPI) from the DISKUS/ACCUHALER (one inhalation in the morning).

Measured Values

	Placebo	GW642444M 25 µg	GW642444M 50 µg	GW642444M 100 µg	GW642444H 100 µg
Number of Participants Analyzed	19	19	19	8	11
Change From Baseline in Heart Rate Over the Post-dose 24 Hour (h) Period [units: Beats per minute(bpm)] Mean (Standard Deviation)					
20 M, n=19, 19, 19, 8, 11	-2.9 (4.49)	0.7 (6.60)	0.1 (5.58)	2.2 (6.67)	-2.4 (3.62)
45 M, n=19, 19, 19, 8, 11	0.3 (6.70)	-0.2 (5.51)	0.3 (5.49)	4.0 (7.49)	-1.9 (6.70)
1 h, n=19, 19, 19, 8, 11	-0.9 (5.33)	-2.1 (5.92)	0.7 (6.74)	1.7 (5.36)	-2.2 (5.59)
2 h, n=19, 19, 19, 8, 11	1.6 (7.41)	3.0 (11.76)	3.3 (8.34)	3.0 (7.00)	-0.1 (7.46)
3 h, n=19, 19, 19, 8, 11	1.7 (7.06)	6.2 (13.76)	0.7 (8.09)	2.2 (6.84)	0.4 (5.43)
4 h, n=19, 19, 19, 8, 11	0.1 (6.57)	4.8 (13.87)	2.0 (6.40)	0.7 (7.72)	0.1 (6.10)
6 h, n=19, 19, 19, 8, 11	5.7 (10.31)	2.1 (14.37)	6.0 (9.32)	7.4 (11.35)	3.6 (8.40)
24 h, n=19, 19, 19, 8, 11	1.9 (9.39)	0.4 (9.05)	0.2 (6.19)	0.3 (11.35)	-0.2 (7.91)

15. Primary Outcome Measure:

Measure Title	Change From Baseline in Electrocardiographic (ECG) Parameters Over the Post-dose 24 Hour (h) Period
Measure Description	ECG parameters [PR, QRS, RR, QT (uncorrected), QTcB (QT corrected by Bazett's formula) and QTcF (QT corrected by Fridericia's formula) intervals] were measured at Baseline and over the post-dose 24h period at the following scheduled time points: 20 minutes (min), 45 min, 1 h, 2 h, 3 h, 4 h, 6 h, and 24 h. Baseline was defined as the measurement at Screening (Day -28 to Day -1). Change from Baseline was calculated as the value at the post-Baseline time point minus the value at Baseline.
Time Frame	Baseline and Day 1 of each treatment period (up to Study Day 54)
Safety Issue?	No

Analysis Population Description

PP Population. Only those participants available at the specified time points were analyzed (represented by n=X, X in the category titles). Different participants may have been analyzed for different parameters, so the overall number of participants analyzed reflects everyone in the PP Population.

Reporting Groups

	Description
Placebo	Participants received placebo single dose in the morning from the dry powder inhaler (DPI) from the DISKUS/ ACCUHALER (one inhalation in the morning).
GW642444M 25 µg	Participants received GW642444M 25 µg single dose in the morning from the dry powder inhaler (DPI) from the DISKUS/ACCUHALER (one inhalation in the morning).
GW642444M 50 µg	Participants received GW642444M 50 µg single dose in the morning from the dry powder inhaler (DPI) from the DISKUS/ACCUHALER (one inhalation in the morning).
GW642444M 100 µg	Participants received GW642444M 100 µg single dose in the morning from the dry powder inhaler (DPI) from the DISKUS/ACCUHALER (one inhalation in the morning).
GW642444H 100 µg	Participants received GW642444H 100 µg single dose in the morning from the dry powder inhaler (DPI) from the DISKUS/ACCUHALER (one inhalation in the morning).

Measured Values

	Placebo	GW642444M 25 µg	GW642444M 50 µg	GW642444M 100 µg	GW642444H 100 µg
Number of Participants Analyzed	19	19	19	8	11
Change From Baseline in Electrocardiographic (ECG) Parameters Over the Post-dose 24 Hour (h) Period [units: milliseconds (msec)] Mean (Standard Deviation)					

	Placebo	GW642444M 25 µg	GW642444M 50 µg	GW642444M 100 µg	GW642444H 100 µg
PR, 20 min, n=19, 19, 19, 8, 11	-7.3 (17.172)	-1.4 (15.486)	1.0 (8.650)	0.5 (11.295)	-8.9 (15.095)
PR, 45 min, n=19, 19, 19, 8, 10	-2.7 (7.846)	-3.7 (15.106)	1.3 (13.588)	-4.5 (12.912)	-4.7 (11.038)
PR, 1 h, n=19, 19, 19, 8, 11	-2.8 (17.926)	-2.7 (14.946)	-1.7 (9.511)	4.3 (19.070)	-3.3 (12.014)
PR, 2 h, n=19, 19, 19, 8, 11	-3.3 (12.978)	-1.1 (11.047)	-0.1 (13.800)	-10.1 (44.279)	2.8 (15.513)
PR, 3 h, n=19, 19, 19, 8, 11	0.1 (12.837)	-3.1 (15.130)	1.5 (10.602)	2.8 (20.863)	-3.3 (12.741)
PR, 4 h, n=19, 19, 19, 8, 11	-3.0 (13.613)	-1.7 (14.909)	1.5 (11.102)	16.98 (25.887)	-2.5 (14.057)
PR, 6 h, n=18, 19, 19, 8, 11	-4.0 (10.157)	0.5 (15.174)	-2.1 (9.437)	23.59 (21.544)	3.5 (11.536)
PR, 24 h, n=19, 19, 18, 8, 11	-1.4 (18.636)	-1.6 (17.618)	0.4 (9.101)	27.07 (20.769)	2.1 (19.400)
QRS, 20 min, n=19, 19, 19, 8, 11	-1.9 (5.031)	-1.0 (3.886)	0.6 (2.150)	1.0 (4.719)	1.4 (4.222)
QRS, 45 min, n=19, 19, 19, 8, 10	-1.6 (4.789)	0.2 (3.928)	0.2 (3.534)	0.0 (2.156)	0.1 (4.601)
QRS, 1 h, n=19, 19, 19, 8, 11	-2.0 (5.562)	-0.9 (4.449)	-0.2 (2.155)	2.7 (4.714)	1.0 (4.958)
QRS, 2 h, n=19, 19, 19, 8, 11	0.9 (5.393)	-0.3 (3.888)	0.7 (4.579)	1.2 (1.265)	-1.0 (6.513)
QRS, 3 h, n=19, 19, 19, 8, 11	0.3 (6.324)	1.2 (5.194)	0.3 (3.045)	0.9 (1.389)	0.6 (4.670)
QRS, 4 h, n=19, 19, 19, 8, 11	-1.0 (4.812)	-0.9 (3.961)	1.0 (4.937)	1.0 (4.759)	1.7 (3.666)
QRS, 6 h, n=19, 19, 19, 8, 11	-1.0 (5.156)	-0.1 (4.485)	-0.0 (5.145)	0.1 (4.254)	2.0 (4.177)
QRS, 24 h, n=19, 19, 18, 8, 11	-1.4 (6.090)	-1.5 (3.736)	0.7 (2.923)	-0.0 (4.783)	-0.5 (5.546)
RR, 20 min, n=19, 19, 19, 8, 11	48.9 (57.110)	-9.0 (75.077)	3.9 (73.786)	-29.2 (123.015)	4.7 (31.266)
RR, 45 min, n=19, 19, 19, 8, 10	5.6 (96.803)	9.1 (65.366)	-5.7 (81.079)	-73.0 (130.999)	4.0 (69.539)
RR, 1 h, n=19, 19, 19, 8, 11	29.8 (91.489)	39.9 (65.636)	-3.7 (84.143)	-29.1 (101.900)	11.3 (66.621)
RR, 2 h, n=19, 19, 19, 8, 11	-0.3 (108.528)	-25.1 (153.206)	-24.2 (127.159)	-29.3 (105.815)	-15.3 (90.415)
RR, 3 h, n=19, 19, 19, 8, 11	-12.7 (95.030)	-55.0 (175.742)	5.6 (129.790)	-35.7 (112.038)	13.1 (78.368)
RR, 4 h, n=19, 19, 19, 8, 11	-21.9 (86.948)	-54.7 (173.646)	-24.6 (85.316)	-17.9 (97.684)	7.3 (94.243)
RR, 6 h, n=19, 19, 19, 8, 11	-61.0 (125.922)	-23.2 (183.705)	-64.1 (127.976)	-106.1 (160.044)	-45.5 (71.133)
RR, 24 h, n=19, 19, 18, 8, 11	-4.7 (108.355)	10.5 (95.865)	6.0 (103.940)	-1.6 (76.068)	-18.8 (81.880)
QT, 20 min, n=19, 19, 19, 8, 11	4.8 (15.094)	-7.8 (13.891)	-1.7 (9.306)	2.2 (18.150)	-2.7 (24.051)
QT, 45 min, n=19, 19, 19, 8, 10	5.6 (15.245)	-0.8 (12.037)	-0.1 (11.856)	2.1 (8.750)	0.3 (17.997)

	Placebo	GW642444M 25 µg	GW642444M 50 µg	GW642444M 100 µg	GW642444H 100 µg
QT, 1 h, n=19, 19, 19, 8, 11	5.1 (14.820)	1.3 (13.453)	0.5 (13.096)	2.6 (14.876)	-0.1 (23.941)
QT, 2 h, n=19, 19, 19, 8, 11	-4.4 (19.879)	-9.2 (19.465)	-5.6 (18.786)	-10.5 (15.296)	-0.7 (15.403)
QT, 3 h, n=19, 19, 19, 8, 11	-5.2 (21.154)	-12.4 (28.408)	0.8 (18.469)	-10.8 (15.253)	-1.6 (15.403)
QT, 4 h, n=19, 19, 19, 8, 11	-7.1 (27.773)	-16.6 (29.661)	-6.3 (14.699)	-5.0 (16.399)	-0.9 (16.693)
QT, 6 h, n=19, 19, 19, 8, 11	-17.4 (22.329)	-14.1 (26.540)	-16.9 (20.348)	-20.0 (22.842)	-8.6 (11.990)
QT, 24 h, n=19, 19, 18, 8, 11	-9.3 (39.366)	-4.8 (19.461)	1.1 (30.186)	-0.3 (14.331)	-1.1 (17.099)
QTc(B), 20 min, n=19, 19, 19, 8, 11	-5.6 (10.206)	-5.7 (18.465)	-2.5 (13.058)	7.6 (24.453)	-4.8 (27.410)
QTc(B), 45 min, n=19, 19, 19, 8, 10	4.5 (21.312)	-2.8 (13.737)	0.9 (13.972)	18.5 (20.184)	-1.8 (24.471)
QTc(B), 1 h, n=19, 19, 19, 8, 11	-0.9 (19.298)	-7.5 (15.779)	1.2 (12.743)	7.9 (11.202)	-3.8 (30.201)
QTc(B), 2 h, n=19, 19, 19, 8, 11	-4.3 (16.691)	-3.9 (18.963)	0.0 (16.015)	-4.4 (22.214)	2.1 (17.456)
QTc(B), 3 h, n=19, 19, 19, 8, 11	-1.8 (20.177)	0.0 (19.550)	0.4 (20.161)	-3.8 (17.665)	-3.9 (13.908)
QTc(B), 4 h, n=19, 19, 19, 8, 11	-0.6 (30.768)	-4.4 (13.490)	-1.3 (11.909)	-1.5 (14.136)	-1.6 (11.578)
QTc(B), 6 h, n=19, 19, 19, 8, 11	-3.9 (16.976)	-9.3 (18.612)	-2.9 (15.326)	3.4 (12.821)	2.0 (10.667)
QTc(B), 24 h, n=19, 19, 18, 8, 11	-9.0 (32.387)	-7.1 (15.386)	-0.2 (14.676)	0.3 (9.022)	3.8 (18.294)
QTc(F), 20 min, n=19, 19, 18, 8, 11	-2.0 (10.761)	-6.5 (14.867)	-2.2 (9.227)	5.9 (19.428)	-4.0 (26.022)
QTc(F), 45 min, n=19, 19, 19, 8, 10	4.9 (16.508)	-2.1 (11.430)	0.6 (9.920)	13.0 (12.102)	-0.9 (20.795)
QTc(F), 1 h, n=19, 19, 19, 8, 11	1.1 (15.088)	-4.4 (13.387)	1.0 (9.193)	6.2 (8.626)	-2.4 (26.900)
QTc(F), 2 h, n=19, 19, 19, 8, 11	-4.4 (14.122)	-5.8 (10.606)	-2.0 (11.272)	-6.5 (16.576)	1.2 (13.750)
QTc(F), 3 h, n=19, 19, 19, 8, 11	-3.1 (17.341)	-4.4 (13.383)	0.5 (14.498)	-6.2 (11.842)	-3.2 (10.836)
QTc(F), 4 h, n=19, 19, 19, 8, 11	-3.1 (28.679)	-8.8 (10.344)	-3.0 (9.373)	-2.7 (11.136)	10.836 (8.648)
QTc(F), 6 h, n=19, 19, 19, 8, 11	-8.7 (13.113)	-11.1 (10.871)	-7.8 (10.278)	-4.7 (5.959)	-1.7 (6.561)
QTc(F), 24 h, n=19, 19, 18, 8, 11	-9.2 (33.102)	-6.4 (13.364)	0.0 (17.882)	0.0 (0.0)	2.0 (15.496)

16. Secondary Outcome Measure:

Measure Title	Mean FEV1 Over 23 and 24 Hours After Dosing

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. FEV1 was measured electronically by spirometry. The data is presented as adjusted mean of the FEV1 values over 23 and 24 hours after dosing. Changed in trough FEV1 will be analysed using a model with baseline, treatment, period, as fixed effects .
Time Frame	Baseline and Day 1 of each treatment period (up to Study Day 54)
Safety Issue?	No

Analysis Population Description

PP Population. Only those participants available at the indicated time points were assessed.

Reporting Groups

	Description
Placebo	Participants received placebo single dose in the morning from the dry powder inhaler (DPI) from the DISKUS/ ACCUHALER (one inhalation in the morning).
GW642444M 25 µg	Participants received GW642444M 25 µg single dose in the morning from the dry powder inhaler (DPI) from the DISKUS/ACCUHALER (one inhalation in the morning).
GW642444M 50 µg	Participants received GW642444M 50 µg single dose in the morning from the dry powder inhaler (DPI) from the DISKUS/ACCUHALER (one inhalation in the morning).
GW642444M 100 µg	Participants received GW642444M 100 µg single dose in the morning from the dry powder inhaler (DPI) from the DISKUS/ACCUHALER (one inhalation in the morning).
GW642444H 100 µg	Participants received GW642444H 100 µg single dose in the morning from the dry powder inhaler (DPI) from the DISKUS/ACCUHALER (one inhalation in the morning).

Measured Values

	Placebo	GW642444M 25 µg	GW642444M 50 µg	GW642444M 100 µg	GW642444H 100 µg
Number of Participants Analyzed	17	20	19	6	12
Mean FEV1 Over 23 and 24 Hours After Dosing [units: Liters] Mean (Standard Error)	1.432 (0.0402)	1.622 (0.0431)	1.638 (0.0415)	1.642 (0.0650)	1.569 (0.0501)

17. Secondary Outcome Measure:

Measure Title	Weighted Mean and Maximum Value (0 - 4 Hours) QTc(B) and QTc(F)

Measure Description	QT interval is a measure of the time between the start of the Q wave and the end of the T wave in the 12-lead ECG. QTcB is the QT interval corrected for heart rate using Bazett's formula; QTcF is the QT interval corrected for heart rate using Fridericia's formula. Weighted mean (WM) is derived by calculating the area under curve (AUC), and then dividing by the relevant time interval. QTcB and QTcF recorded at 20 minutes, 45 minutes, 1, 2, 3, and 4 hours post-dose on Day 1 of each treatment period were used for analysis. The data is presented as the adjusted means of WM and maximum QTc(B) and QTc(F).
Time Frame	Baseline and Day 1 of each treatment period (up to Study Day 54)
Safety Issue?	No

Analysis Population Description

PP Population. Only those participants available at the indicated time points were assessed.

Reporting Groups

	Description
Placebo	Participants received placebo single dose in the morning from the dry powder inhaler (DPI) from the DISKUS/ ACCUHALER (one inhalation in the morning).
GW642444M 25 µg	Participants received GW642444M 25 µg single dose in the morning from the dry powder inhaler (DPI) from the DISKUS/ACCUHALER (one inhalation in the morning).
GW642444M 50 µg	Participants received GW642444M 50 µg single dose in the morning from the dry powder inhaler (DPI) from the DISKUS/ACCUHALER (one inhalation in the morning).
GW642444M 100 µg	Participants received GW642444M 100 µg single dose in the morning from the dry powder inhaler (DPI) from the DISKUS/ACCUHALER (one inhalation in the morning).
GW642444H 100 µg	Participants received GW642444H 100 µg single dose in the morning from the dry powder inhaler (DPI) from the DISKUS/ACCUHALER (one inhalation in the morning).

Measured Values

	Placebo	GW642444M 25 µg	GW642444M 50 µg	GW642444M 100 µg	GW642444H 100 µg
Number of Participants Analyzed	19	19	19	8	11
Weighted Mean and Maximum Value (0 - 4 Hours) QTc(B) and QTc(F) [units: Milliseconds (msec)] Mean (Standard Error)					
WM QTcB	419.68 (2.150)	419.56 (2.378)	424.18 (2.230)	422.36 (3.517)	419.70 (2.714)
Max QTcB	439.37 (3.714)	437.06 (4.104)	434.62 (3.850)	438.14 (6.059)	436.75 (4.681)
WM QTcF,	409.13 (1.696)	408.31 (1.898)	412.99 (1.760)	409.50 (2.842)	409.82 (2.163)

	Placebo	GW642444M 25 µg	GW642444M 50 µg	GW642444M 100 µg	GW642444H 100 µg
Max QTcB	425.34 (2.900)	421.73 (3.286)	422.55 (3.025)	422.41 (5.000)	422.99 (3.766)

18. Secondary Outcome Measure:

Measure Title	Weighted Mean and Maximum Value (0 - 4 Hours) Supine Heart Rate
Measure Description	Weighted mean (WM) is derived by calculating the area under curve (AUC), and then dividing by the relevant time interval. Heart rate was recorded at Screening, prior to dosing, and at 20 minutes, 45 minutes, 1, 2, 3, 4 and 6 hours post-dose on Day 1of each treatment period. Heart rate recorded at 20 minutes, 45 minutes and 1, 2, 3 and 4 hours post-dose on Day 1of the each treatment period were used for analysis. Heart rate measurement was taken in a supine position having rested in this position for at least 10 minutes before each reading. The data is presented as adjusted mean of WM and maximum heart rate.
Time Frame	Baseline and Day 1 of each treatment period (up to Study Day 54)
Safety Issue?	No

Analysis Population Description

PP Population. Only those participants available at the indicated time points were assessed.

Reporting Groups

	Description
Placebo	Participants received placebo single dose in the morning from the dry powder inhaler (DPI) from the DISKUS/ ACCUHALER (one inhalation in the morning).
GW642444M 25 µg	Participants received GW642444M 25 µg single dose in the morning from the dry powder inhaler (DPI) from the DISKUS/ACCUHALER (one inhalation in the morning).
GW642444M 50 µg	Participants received GW642444M 50 µg single dose in the morning from the dry powder inhaler (DPI) from the DISKUS/ACCUHALER (one inhalation in the morning).
GW642444M 100 µg	Participants received GW642444M 100 µg single dose in the morning from the dry powder inhaler (DPI) from the DISKUS/ACCUHALER (one inhalation in the morning).
GW642444H 100 µg	Participants received GW642444H 100 µg single dose in the morning from the dry powder inhaler (DPI) from the DISKUS/ACCUHALER (one inhalation in the morning).

Measured Values

	Placebo	GW642444M 25 µg	GW642444M 50 µg	GW642444M 100 µg	GW642444H 100 µg
Number of Participants Analyzed	19	19	19	8	11
Weighted Mean and Maximum Value (0 - 4 Hours) Supine Heart Rate [units: Beats per minute] Mean (Standard Error)					
WM Heart rate	71.12 (1.320)	71.76 (1.473)	71.57 (1.377)	73.50 (2.179)	71.22 (1.734)
Max Heart rate	77.88 (1.784)	79.95 (1.948)	76.13 (1.845)	77.77 (2.764)	77.16 (2.248)

19. Secondary Outcome Measure:

Measure Title	Weighted Mean and Maximum Value (0 - 4 Hours) of Supine Systolic and Diastolic Blood Pressure
Measure Description	Blood pressure (BP) measurement included systolic blood pressure (SBP) and diastolic BP (DBP). Weighted mean (WM) is derived by calculating the area under curve (AUC), and then dividing by the relevant time interval. SBP and DBP were recorded at Screening, prior to dosing, and at 20 minutes, 45 minutes, 1,2, 3, 4 and 6 hours post-dose on Day 1of the each treatment period. SBP and DBP recorded at 20 minutes, 45 minutes and 1, 2, 3 and 4 hours post-dose on Day 1of the each treatment period were used for analysis. Heart rate measurement was taken in a supine position having rested in this position for at least 10 minutes before each reading. The data is presented as adjusted mean of WM and maximum SBP and DBP.
Time Frame	Baseline and Day 1 of each treatment period (up to Study Day 54)
Safety Issue?	No

Analysis Population Description

PP Population. Only those participants available at the indicated time points were assessed.

Reporting Groups

	Description
Placebo	Participants received placebo single dose in the morning from the dry powder inhaler (DPI) from the DISKUS/ ACCUHALER (one inhalation in the morning).
GW642444M 25 µg	Participants received GW642444M 25 µg single dose in the morning from the dry powder inhaler (DPI) from the DISKUS/ACCUHALER (one inhalation in the morning).
GW642444M 50 µg	Participants received GW642444M 50 µg single dose in the morning from the dry powder inhaler (DPI) from the DISKUS/ACCUHALER (one inhalation in the morning).

	Description
GW642444M 100 µg	Participants received GW642444M 100 µg single dose in the morning from the dry powder inhaler (DPI) from the DISKUS/ACCUHALER (one inhalation in the morning).
GW642444H 100 µg	Participants received GW642444H 100 µg single dose in the morning from the dry powder inhaler (DPI) from the DISKUS/ACCUHALER (one inhalation in the morning).

Measured Values

	Placebo	GW642444M 25 µg	GW642444M 50 µg	GW642444M 100 µg	GW642444H 100 µg
Number of Participants Analyzed	19	19	19	8	11
Weighted Mean and Maximum Value (0 - 4 Hours) of Supine Systolic and Diastolic Blood Pressure [units: Millimeters of mercury] Mean (Standard Error)					
WM SBP	126.92 (1.223)	126.28 (1.388)	127.82 (1.284)	128.99 (2.146)	125.10 (1.621)
Max SBP	133.23 (1.521)	133.06 (1.714)	133.91 (1.591)	135.24 (2.625)	131.13 (1.994)
WM DBP	80.36 (1.017)	79.74 (1.133)	80.04 (1.056)	83.46 (1.721)	77.46 (1.321)
Max DBP	76.13 (1.147)	75.08 (1.272)	76.30 (1.189)	79.92 (1.917)	71.63 (1.478)

20. Secondary Outcome Measure:

Measure Title	Weighted Mean and Maximum/Minimum Value (0 - 4 Hours) for Glucose and Potassium
Measure Description	Blood samples were collected for the measurement of potassium and glucose at Screening, prior to dosing, and at 20 minutes, 45 minutes, 1,2, 3 and 4 hours post-dose on Day 1of the each treatment period. Whole blood samples (approximately 1.0 milliliter [mL]) was analysed for potassium and glucose using the i-STAT1 portable chemical analyser. The i-STAT1 system is an analyser designed for point of care testing and employs a hand-held chemistry analyzer and disposable cartridges, which in the configuration tested, are capable of measuring potassium, glucose, blood gases, electrolytes, metabolites and coagulation. Weighted mean (WM) is derived by calculating the area under curve (AUC), and then dividing by the relevant time interval. The data is presented as adjusted mean of WM and maximum (max) glucose /minimum (min) potassium.
Time Frame	Baseline and Day 1 of each treatment period (up to Study Day 54)
Safety Issue?	No

Analysis Population Description

PP Population. Only those participants available at the indicated time points were assessed.

Reporting Groups

	Description
Placebo	Participants received placebo single dose in the morning from the dry powder inhaler (DPI) from the DISKUS/ ACCUHALER (one inhalation in the morning).
GW642444M 25 µg	Participants received GW642444M 25 µg single dose in the morning from the dry powder inhaler (DPI) from the DISKUS/ACCUHALER (one inhalation in the morning).
GW642444M 50 µg	Participants received GW642444M 50 µg single dose in the morning from the dry powder inhaler (DPI) from the DISKUS/ACCUHALER (one inhalation in the morning).
GW642444M 100 µg	Participants received GW642444M 100 µg single dose in the morning from the dry powder inhaler (DPI) from the DISKUS/ACCUHALER (one inhalation in the morning).
GW642444H 100 µg	Participants received GW642444H 100 µg single dose in the morning from the dry powder inhaler (DPI) from the DISKUS/ACCUHALER (one inhalation in the morning).

Measured Values

	Placebo	GW642444M 25 µg	GW642444M 50 µg	GW642444M 100 µg	GW642444H 100 µg
Number of Participants Analyzed	17	20	19	6	12
Weighted Mean and Maximum/Minimum Value (0 - 4 Hours) for Glucose and Potassium [units: Millimoles per liter (mmol/L)] Mean (Standard Error)					
WM Glucose, n=16,18,19,6,10	5.94 (0.204)	5.86 (0.227)	5.95 (0.200)	6.25 (0.345)	5.71 (0.251)
Max Glucose, n=17, 20, 19, 6,10	6.73 (0.342)	6.61 (0.370)	6.65 (0.342)	6.99 (0.608)	6.09 (0.436)
WM Potassium, n=15, 16, 17, 5,12	4.29 (0.058)	4.29 (0.067)	4.14 (0.057)	4.22 (0.102)	4.27 (0.073)
Min Potassium, n=16, 20, 18, 6,12	4.02 (0.052)	4.03 (0.053)	3.97 (0.052)	4.08 (0.082)	4.08 (0.065)

21. Secondary Outcome Measure:

Measure Title	AUC(0- t) and up to 1 Hour Post-dose (AUC[0-1]) of GW642444 and Its Metabolites GI179710, GW630200, and GSK932009, After a Single Dose of GW642444

Measure Description	Blood samples were collected pre-dose and at 2, 5, 10, 20, and 30 minutes, 1, 2, 4, 6, 8, 10, and 24 hour post-dose. Blood samples were analyzed for GW642444 and its metabolites GI179710, GW630200 and GSK932009 using a high performance liquid chromatography/mass spectrometry/mass (HPLC/MS/MS) spectrometry. AUC defined as area under the plasma concentration curve from time zero to the last quantifiable concentration (AUC(0-t)), and up to 1 hour post-dose (AUC(0-1)) were determined by non-compartmental methods. Assay censoring refers to some of the values being below the limit of quantification such that this parameter could not be defined.
Time Frame	Baseline and Day 1 of each treatment period (up to Study Day 54)
Safety Issue?	No

Analysis Population Description

Pharmacokinetic (PK) Population: all participants who received at least one dose and for whom a PK sample was obtained and analyzed

Reporting Groups

	Description
Placebo	Participants received placebo single dose in the morning from the dry powder inhaler (DPI) from the DISKUS/ ACCUHALER (one inhalation in the morning).
GW642444M 25 µg	Participants received GW642444M 25 µg single dose in the morning from the dry powder inhaler (DPI) from the DISKUS/ACCUHALER (one inhalation in the morning).
GW642444M 50 µg	Participants received GW642444M 50 µg single dose in the morning from the dry powder inhaler (DPI) from the DISKUS/ACCUHALER (one inhalation in the morning).
GW642444M 100 µg	Participants received GW642444M 100 µg single dose in the morning from the dry powder inhaler (DPI) from the DISKUS/ACCUHALER (one inhalation in the morning).
GW642444H 100 µg	Participants received GW642444H 100 µg single dose in the morning from the dry powder inhaler (DPI) from the DISKUS/ACCUHALER (one inhalation in the morning).

Measured Values

	Placebo	GW642444M 25 µg	GW642444M 50 µg	GW642444M 100 µg	GW642444H 100 µg
Number of Participants Analyzed	0	17	19	8	10
AUC(0- t) and up to 1 Hour Post-dose (AUC[0-1]) of GW642444 and Its Metabolites GI179710, GW630200, and GSK932009, After a Single Dose of GW642444 [units: picograms.Hour/milliliter (pg.hr/mL)] Geometric Mean (Geometric Coefficient of Variation)					
GW642444, AUC(0-t), n=0, 17, 19, 8, 10		56.49 (86.2%)	222.36 (96.5%)	572.99 (45.3%)	98.13 (0.782%)
GW64244, AUC(0-1), n=0, 11, 18, 8, 10		58.01 (25.4%)	106.31 (44.5%)	196.24 (23.9%)	54.85 (28.3%)

	Placebo	GW642444M 25 µg	GW642444M 50 µg	GW642444M 100 µg	GW642444H 100 µg
GI179710, AUC (0-t), n=0, 0, 0, 1, 0		NA (NA%) [1]	NA (NA%) [1]	NA (NA%) [1]	NA (NA%) [1]
GW630200, AUC(0-t), n=0, 0, 0, 0, 0		NA (NA%) [1]	NA (NA%) [1]	NA (NA%) [1]	NA (NA%) [1]
GSK932009, AUC(0-t), n=0, 0, 0, 0, 0		NA (NA%) [1]	NA (NA%) [1]	NA (NA%) [1]	NA (NA%) [1]

[1] Insufficient data to define due to assay censoring.

22. Secondary Outcome Measure:

Measure Title	Cmax of GW642444 and Its Metabolites GI179710, GW630200, and GSK932009, After a Single Dose of GW642444
Measure Description	Blood samples were collected pre-dose and at 2, 5, 10, 20, and 30 minutes, 1, 2, 4, 6, 8, 10, and 24 hour post-dose. Blood samples were analyzed for GW642444 and its metabolites GI179710, GW630200 and GSK932009, using a high performance liquid chromatography/mass spectrometry/mass (HPLC/MS/MS) spectrometry. The maximum observed plasma concentration (Cmax) was determined from the concentration time data by non-compartmental methods. Assay censoring refers to some of the values being below the limit of quantification such that this parameter could not be defined.
Time Frame	Day 1 of each treatment period (up to Study Day 54)
Safety Issue?	No

Analysis Population Description

PK Population: all participants who received at least one dose and for whom a PK sample was obtained and analyzed

Reporting Groups

	Description
Placebo	Participants received placebo single dose in the morning from the dry powder inhaler (DPI) from the DISKUS/ ACCUHALER (one inhalation in the morning).
GW642444M 25 µg	Participants received GW642444M 25 µg single dose in the morning from the dry powder inhaler (DPI) from the DISKUS/ACCUHALER (one inhalation in the morning).
GW642444M 50 µg	Participants received GW642444M 50 µg single dose in the morning from the dry powder inhaler (DPI) from the DISKUS/ACCUHALER (one inhalation in the morning).
GW642444M 100 µg	Participants received GW642444M 100 µg single dose in the morning from the dry powder inhaler (DPI) from the DISKUS/ACCUHALER (one inhalation in the morning).
GW642444H 100 µg	Participants received GW642444H 100 µg single dose in the morning from the dry powder inhaler (DPI) from the DISKUS/ACCUHALER (one inhalation in the morning).

Measured Values

	Placebo	GW642444M 25 µg	GW642444M 50 µg	GW642444M 100 µg	GW642444H 100 µg
Number of Participants Analyzed	0	20	19	8	12
Cmax of GW642444 and Its Metabolites GI179710, GW630200, and GSK932009, After a Single Dose of GW642444 [units: picograms/milliliter (pg/mL)] Geometric Mean (Geometric Coefficient of Variation)					
GW642444,n=0, 20, 19, 8, 12		78.16 (43.9%)	150.60 (53.1%)	259.96 (22.2%)	73.70 (35.7%)
GI179710,n=0, 0, 4, 7, 0		NA (NA%) [1]	NA (NA%) [1]	NA (NA%) [1]	NA (NA%) [1]
GW630200, n=0, 0, 0, 0, 0		NA (NA%) [1]	NA (NA%) [1]	NA (NA%) [1]	NA (NA%) [1]
GSK932009, n=0, 0, 0, 0, 0		NA (NA%) [1]	NA (NA%) [1]	NA (NA%) [1]	NA (NA%) [1]

[1] Insufficient data to define due to assay censoring.

23. Secondary Outcome Measure:

Measure Title	Tmax of GW642444 and Its Metabolites GI179710, GW630200, and GSK932009, After a Single Dose of GW642444
Measure Description	Blood samples were collected pre-dose and at 2, 5, 10, 20, and 30 minutes, 1, 2, 4, 6, 8, 10, and 24 hour post-dose. Blood samples were analyzed for GW642444 and its metabolites GI179710, GW630200 and GSK932009, using a high performance liquid chromatography/mass spectrometry/mass (HPLC/MS/MS) spectrometry. The Time to maximum plasma concentration (Tmax) was determined from the concentration time data by non-compartmental methods. Assay censoring refers to some of the values being below the limit of quantification such that this parameter could not be defined.
Time Frame	Day 1 of each treatment period (up to Study Day 54)
Safety Issue?	No

Analysis Population Description

PK Population: all participants who received at least one dose and for whom a PK sample was obtained and analyzed

Reporting Groups

	Description
Placebo	Participants received placebo single dose in the morning from the dry powder inhaler (DPI) from the DISKUS/ ACCUHALER (one inhalation in the morning).

	Description
GW642444M 25 µg	Participants received GW642444M 25 µg single dose in the morning from the dry powder inhaler (DPI) from the DISKUS/ACCUHALER (one inhalation in the morning).
GW642444M 50 µg	Participants received GW642444M 50 µg single dose in the morning from the dry powder inhaler (DPI) from the DISKUS/ACCUHALER (one inhalation in the morning).
GW642444M 100 µg	Participants received GW642444M 100 µg single dose in the morning from the dry powder inhaler (DPI) from the DISKUS/ACCUHALER (one inhalation in the morning).
GW642444H 100 µg	Participants received GW642444H 100 µg single dose in the morning from the dry powder inhaler (DPI) from the DISKUS/ACCUHALER (one inhalation in the morning).

Measured Values

	Placebo	GW642444M 25 µg	GW642444M 50 µg	GW642444M 100 µg	GW642444H 100 µg
Number of Participants Analyzed	0	20	19	8	12
Tmax of GW642444 and Its Metabolites GI179710, GW630200, and GSK932009, After a Single Dose of GW642444 [units: Hours] Median (Full Range)					
GW642444,n=0, 20, 19, 8, 12		0.175 (0.03 to 2.00)	0.200 (0.08 to 1.00)	0.425 (0.15 to 1.03)	0.500 (0.20 to 2.07)
GI179710,n=0, 0, 4, 7, 0		NA (NA to NA) [1]	0.140 (0.0 to 0.18)	0.170 (0.07 to 0.33)	NA (NA to NA) [1]
GW630200, n=0, 0, 0, 0, 0		NA (NA to NA) [1]	NA (NA to NA) [1]	NA (NA to NA) [1]	NA (NA to NA) [1]
GSK932009, n=0, 0, 0, 0, 0		NA (NA to NA) [1]	NA (NA to NA) [1]	NA (NA to NA) [1]	NA (NA to NA) [1]

[1] Insufficient data to define due to assay censoring.

Reported Adverse Events

Time Frame	Serious adverse events (SAEs) and non-serious adverse events (AEs) were collected from the start of the study medication to the end of treatment (up to Study Day 60).
Additional Description	SAEs and non-serious AEs were reported for members of the Intent-to-Treat (ITT) Population, comprised of all participants randomized to treatment who received at least one dose of trial medication during the treatment period.

Reporting Groups

	Description
Placebo	Participants received placebo single dose in the morning from the dry powder inhaler (DPI) from the DISKUS/ ACCUHALER (one inhalation in the morning).
GW642444M 25 µg	Participants received GW642444M 25 µg single dose in the morning from the dry powder inhaler (DPI) from the DISKUS/ACCUHALER (one inhalation in the morning).
GW642444M 50 µg	Participants received GW642444M 50 µg single dose in the morning from the dry powder inhaler (DPI) from the DISKUS/ACCUHALER (one inhalation in the morning).
GW642444M 100 µg	Participants received GW642444M 100 µg single dose in the morning from the dry powder inhaler (DPI) from the DISKUS/ACCUHALER (one inhalation in the morning).
GW642444H 100 µg	Participants received GW642444H 100 µg single dose in the morning from the dry powder inhaler (DPI) from the DISKUS/ACCUHALER (one inhalation in the morning).

Serious Adverse Events

	Placebo	GW642444M 25 µg	GW642444M 50 µg	GW642444M 100 µg	GW642444H 100 µg
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Total	0/19 (0%)	0/20 (0%)	0/19 (0%)	0/8 (0%)	0/12 (0%)

Other Adverse Events

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

	Placebo	GW642444M 25 µg	GW642444M 50 µg	GW642444M 100 µg	GW642444H 100 µg
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Total	2/19 (10.53%)	1/20 (5%)	2/19 (10.53%)	0/8 (0%)	0/12 (0%)
Infections and infestations					

	Placebo	GW642444M 25 µg	GW642444M 50 µg	GW642444M 100 µg	GW642444H 100 µg
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Nasopharyngitis [A] †	1/19 (5.26%)	0/20 (0%)	1/19 (5.26%)	0/8 (0%)	0/12 (0%)
Nervous system disorders					
Dysgeusia [A] †	0/19 (0%)	0/20 (0%)	1/19 (5.26%)	0/8 (0%)	0/12 (0%)
Headache [A] †	1/19 (5.26%)	1/20 (5%)	1/19 (5.26%)	0/8 (0%)	0/12 (0%)

† 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:

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