Study to Evaluate the Safety and Dose-Range of Navarixin (SCH 527123, MK-7123) in Participants With Moderate to Severe Chronic Obstructive Pulmonary Disease (COPD) (MK-7123-012)

This study has been terminated.

Sponsor:
Merck Sharp & Dohme Corp.

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

ClinicalTrials.gov Identifier:
NCT00441701

First received: February 28, 2007
Last updated: July 29, 2015
Last verified: July 2015
History of Changes

Purpose

This is a two-part study conducted at multiple centers, of navarixin (SCH 527123, MK-7123) in participants with moderate to severe chronic obstructive pulmonary disease (COPD). Part 1 of the study is a double-blind, placebo-controlled, randomized, rising-dose study consisting of four treatment groups enrolled in three cohorts. The duration of treatment, for each cohort, will be a 2-week run-in period, followed by a 12-week double-blind treatment period. Treatment initiation for each cohort was staggered by 4 weeks to allow for safety assessment prior to use of higher doses of navarixin. Part 2 of the study will be a double-blind, placebo-controlled, randomized, parallel group study consisting of four treatment groups enrolled as one cohort. The duration of treatment will consist of a 2-week run-in period, followed by a 12-week double-blind treatment period.

Condition	Intervention	Phase
Chronic Obstructive Pulmonary Disease	Drug: Navarixin 1 mg Drug: Navarixin 10 mg Drug: Placebo to match navarixin Drug: Rescue medication	Phase 2

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

Official Title: Safety and Dose-Ranging Study of the Effects of SCH 527123 in Subjects With Moderate to Severe COPD

Resource links provided by NLM:

MedlinePlus related topics: COPD Lung Diseases

U.S. FDA Resources

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

Primary Outcome Measures:

- Part 1: Number of Participants Who Experience at Least One Adverse Event (AE) [Time Frame: Up to 12 weeks] [Designated as safety issue: Yes]

  An AE is any untoward medical occurrence in a participant administered a pharmaceutical product, biologic (at any dose), or medical device, which does not necessarily have a causal relationship with the treatment. AEs may include the onset of new illness and the exacerbation of pre-existing conditions. The number of participants who experienced an AE, regardless of causality or severity, was summarized.

- Part 1: Number of Participants Who Discontinue Study Drug Due to an AE [Time Frame: Up to 12 weeks] [Designated as safety issue: Yes]

  An AE is any untoward medical occurrence in a participant administered a pharmaceutical product, biologic (at any dose), or medical device, which does not necessarily have a causal relationship with the treatment. AEs may include the onset of new illness and the exacerbation of pre-existing conditions. The number of participants who discontinued study drug, whether permanently or temporarily, due to an AE was summarized.

- Part 1: Change From Baseline in Absolute Peripheral Blood Neutrophil (PBN) Count [Time Frame: Baseline and Week 12] [Designated as safety issue: Yes]

  Participants were assessed for absolute PBN counts at Baseline and Week 12. The reported standard deviations (SDs) are pooled across all treatment groups. The rationale for the use of an analysis of variance (ANOVA) method using pooled SD values is the assumption that the SDs are similar across treatment groups.

- Part 2: Change From Baseline in Pre-bronchodilator Forced Expiratory Volume in 1 Second (FEV1) [Time Frame: Baseline and the Average over 12 weeks] [Designated as safety issue: No]

  FEV1, as measured in liters via spirometry, is a measure of the amount of air expired in 1 second. Participants were to be assessed for pre-bronchodilator FEV1 immediately before dosing with bronchodilator (albuterol sulfate or equivalent) at Baseline and at Week 12. Pre-bronchodilator FEV1 data were to be averaged weekly over the 12-week treatment period for analysis.

- Part 2: Change From Baseline in Daily Morning/Nighttime Sputum Production, Cough, and Dyspnea (SCDS) Score [Time Frame: Baseline and the Average over 12 weeks] [Designated as safety issue: No]

  Participants were to assess their morning (AM) and nighttime (PM) COPD symptoms (sputum production, cough, and dyspnea) on a daily basis in their e-Diaries. Baseline SCDS was defined as the average of AM and PM values over the week prior to and including Day 1 (AM) prior to the first dose of study drug. SCDS data were to be averaged weekly over the 12-week treatment period for analysis.

Secondary Outcome Measures:

- Part 1: Change From Baseline in Percent PBN Count [Time Frame: Baseline and Week 12] [Designated as safety issue: No]

  Participants were to be assessed for percent PBN counts at Baseline and at Week 12.

- Part 1: Change From Baseline in Sputum Absolute Neutrophil Count (Induced Sputum) [Time Frame: Baseline and Week 12] [Designated as safety issue: No]

  Participants were assessed for induced sputum absolute neutrophil counts via the nebulized method at Baseline and at Week 12. The reported SDs are pooled across all treatment groups. The rationale for the use of an ANOVA method using pooled SD values is the assumption that the SDs are similar across treatment groups.

- Part 1: Change From Baseline in Sputum Percent Neutrophil Count (Induced Sputum) [Time Frame: Baseline and Week 12] [Designated as safety issue: No]

  Sputum neutrophils were to be measured as percent of total white blood cells. Participants were to be assessed for induced sputum percent neutrophil counts via the nebulized method at Baseline and at Week 12.

- Part 2: Change From Baseline in Post-Bronchodilator FEV1 [Time Frame: Baseline and the Average over 12 weeks] [Designated as safety issue: No]

  FEV1, as measured in liters via spirometry, is a measure of the amount of air expired in 1 second. Participants were to be assessed for post-bronchodilator FEV1 30 minutes after dosing with bronchodilator (albuterol sulfate or equivalent) (reversibility test) at Baseline and Week 12. Post-bronchodilator data were to be averaged weekly over the 12-week treatment period for analysis.

- Part 2: Change From Baseline in Forced Expiratory Flow During Middle Half of Forced Vital Capacity (FVC) (FEF25%-75%)

[Time Frame: Baseline and Week 12] [Designated as safety issue: No]

Mid-Breath Forced Expiratory Flow (FEF25%-75%), as measured in liters/minute via spirometry, is the rate at which participants breathe out air from 25 percent of their breath to 75 percent of their breath. Participants were to be assessed for FEF25%-75% at Baseline and Week 12.

- Part 2: Change From Baseline in FVC [Time Frame: Baseline and Week 12] [Designated as safety issue: No]

  FVC, as measured in liters via spirometry, is the amount of air forcibly exhaled from the lungs after taking the deepest breath possible. Post-bronchodilator FVC was to be assessed 30 minutes after bronchodilator administration at Baseline and Week 12.

- Part 2: Change From Baseline in Functional Residual Capacity (FRC) [Time Frame: Baseline and Week 12] [Designated as safety issue: No]

  FRC, as measured in liters via body plethysmography, is the volume of air present in the lungs, specifically the parenchyma tissues, at the end of passive expiration. Participants were to be assessed for FRC at Baseline and Week 12.

- Part 2: Number of Participants Who Experience a COPD Exacerbation [Time Frame: Up to Week 12] [Designated as safety issue: No]

  COPD exacerbation is defined as any change in symptoms or functional status that leads to administration of systemic corticosteroids, antibiotics, an emergency room visit or a hospitalization. The number of participants who experienced a COPD exacerbation was to be summarized.

- Part 2: Change From Baseline in Peak Expiratory Flow (PEF) [Time Frame: Baseline and Week 12] [Designated as safety issue: No]

  PEF, as measured in liters/minute via peak flow meter, is the maximum speed of expiration. Participants were to measure their PEF in triplicate every morning before taking study drug and again every evening.

- Part 2: Change From Baseline in Induced Sputum Absolute Neutrophil Count [Time Frame: Baseline and Week 12] [Designated as safety issue: No]

  Participants were to be assessed for induced sputum absolute neutrophil counts via the nebulized method at Baseline and at Week 12.

- Part 2: Change From Baseline in Induced Sputum Percent Neutrophil Count [Time Frame: Baseline and Week 12] [Designated as safety issue: No]

  Sputum neutrophils were to be measured as percent of total white blood cells. Participants were to be assessed for induced sputum percent neutrophil counts via the nebulized method at Baseline and at Week 12.

- Part 2: Change From Baseline in Individual Symptom Scores [Time Frame: Baseline and Week 12] [Designated as safety issue: No]

  Participants were to be assessed for individual symptom scores at Baseline and Week 12 using the following scales: Sputum Production (0=none, unaware of any sputum production to 4=severe, an almost constant problem), Cough (0=none, unaware of coughing to 4=severe, never free of cough or need to cough), and Dyspnea (0=none, unaware of any difficulty to 4=severe, almost constant: present even when resting).

- Part 2: Change From Baseline in St George's Respiratory Questionnaire (SGRQ) Individual/Total Domains [Time Frame: Baseline and Week 12] [Designated as safety issue: No]

  SGRQ consists of 76 items aggregated into 3 domain scores: Symptoms (frequency/severity), Activity (cause or limited by breathlessness), Impact (social functioning, psychological disturbances from airway disease), and total score. Participants were to assess their symptoms, activity and impact at Baseline and Week 12.

Enrollment:	99
Study Start Date:	December 2006
Study Completion Date:	October 2008
Primary Completion Date:	October 2008 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Experimental: Part 1: Navarixin 3 mg Cohort 1: Participants receive navarixin 3 mg (three 1 mg capsules) once daily (QD) for up to 12 weeks	Drug: Navarixin 1 mg Navarixin 1 mg capsules Drug: Rescue medication Salbutamol/albuterol - 2 puffs of salbutamol/albuterol approximately every 4 hours as needed for dyspnea relief
Placebo Comparator: Part 1: Placebo to navarixin 3 mg	Drug: Placebo to match navarixin

Cohort 1: Participants receive placebo to navarixin (three capsules) QD for up to 12 weeks	Placebo to navarixin capsules Drug: Rescue medication Salbutamol/albuterol - 2 puffs of salbutamol/albuterol approximately every 4 hours as needed for dyspnea relief
Experimental: Part 1: Navarixin 10 mg Cohort 2: Participants receive navarixin 10 mg (one 10 mg capsule and two placebo capsules) QD for up to 12 weeks	Drug: Navarixin 10 mg Navarixin 10 mg capsules Drug: Placebo to match navarixin Placebo to navarixin capsules Drug: Rescue medication Salbutamol/albuterol - 2 puffs of salbutamol/albuterol approximately every 4 hours as needed for dyspnea relief
Placebo Comparator: Part 1: Placebo to navarixin 10 mg Cohort 2: Participants receive placebo to navarixin (three capsules) QD for up to 12 weeks	Drug: Placebo to match navarixin Placebo to navarixin capsules Drug: Rescue medication Salbutamol/albuterol - 2 puffs of salbutamol/albuterol approximately every 4 hours as needed for dyspnea relief
Experimental: Part 1: Navarixin 30 mg Cohort 3: Participants receive navarixin 30 mg (three 10 mg capsules) QD for up to 12 weeks	Drug: Navarixin 10 mg Navarixin 10 mg capsules Drug: Rescue medication Salbutamol/albuterol - 2 puffs of salbutamol/albuterol approximately every 4 hours as needed for dyspnea relief
Placebo Comparator: Part 1: Placebo to navarixin 30 mg Cohort 3: Participants receive placebo to navarixin (three capsules) QD for up to 12 weeks	Drug: Placebo to match navarixin Placebo to navarixin capsules Drug: Rescue medication Salbutamol/albuterol - 2 puffs of salbutamol/albuterol approximately every 4 hours as needed for dyspnea relief
Experimental: Part 2: Navarixin 3 mg Cohort 4: Participants receive navarixin 3 mg (three 1 mg capsules) QD for up to 12 weeks	Drug: Navarixin 1 mg Navarixin 1 mg capsules Drug: Rescue medication Salbutamol/albuterol - 2 puffs of salbutamol/albuterol approximately every 4 hours as needed for dyspnea relief
Experimental: Part 2: Navarixin 10 mg Cohort 4: Participants receive navarixin 10 mg (one 10 mg capsule and two placebo capsules) QD for up to 12 weeks	Drug: Navarixin 10 mg Navarixin 10 mg capsules Drug: Placebo to match navarixin Placebo to navarixin capsules Drug: Rescue medication Salbutamol/albuterol - 2 puffs of salbutamol/albuterol approximately every 4 hours as needed for dyspnea relief
Experimental: Part 2: Navarixin 30 mg Cohort 4: Participants receive navarixin 30 mg (three 10 mg capsules) QD for up to 12 weeks	Drug: Navarixin 10 mg Navarixin 10 mg capsules Drug: Rescue medication Salbutamol/albuterol - 2 puffs of salbutamol/albuterol approximately every 4 hours as needed for dyspnea relief
Placebo Comparator: Part 2: Placebo to navarixin Cohort 4: Participants receive placebo to navarixin (three capsules) QD for up to 12 weeks	Drug: Placebo to match navarixin Placebo to navarixin capsules Drug: Rescue medication Salbutamol/albuterol - 2 puffs of salbutamol/albuterol approximately every 4 hours as needed for dyspnea relief

Eligibility

Ages Eligible for Study: 41 Years to 75 Years
Genders Eligible for Study: Both
Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:

- Diagnosis of COPD based on the American Thoracic Society (ATS)/European Respiratory Society (ERS) criteria.
- >40 to <=75 years of age, of either sex, and of any race.
- Current smoker with at least 10 pack-years of smoking history (eg, 10 pack-year history is equal to smoking 1 pack of cigarettes per day for 10 years or 2 packs per day for 5 years). Participant will be counseled on the risks of smoking and available smoking cessation programs prior to enrollment. Participant who elects to continue to smoke will be eligible for enrollment. Once enrolled, if a participant elects to discontinue smoking, or reduces cigarette consumption, he/she will be allowed to complete the study.
- History of daily sputum production for at least the past 3 months.
- Post-bronchodilator FEV1 must be >=800 mL, and >=40% to <=70% of predicted FEV1.
- Post-bronchodilator ratio of FEV1 to forced vital capacity (FVC) must be <=70%.
- Female participants of childbearing potential must be using a medically acceptable, highly effective, adequate form of birth control (ie, failure rate less than 1% per year when used consistently and correctly) prior to Screening and agree to continue using it while in the study (Screening and Treatment Periods). Medically acceptable, highly effective forms of birth control are hormonal implants, oral contraceptives, medically acceptable prescribed intrauterine devices (IUDs), and monogamous relationship with a male partner who has had a vasectomy.

Female participants should be encouraged to continue using a highly effective method of birth control 30 days following the end of treatment.

- Female participant of child-bearing potential who is not currently sexually active must agree to use a highly effective method of contraception should she become sexually active while participating in the study.
- Male participant must agree to use an adequate form of contraception for the duration of the study and agree to have sexual relations only with women using a highly effective birth control method according to the note for guidance on non-clinical safety studies for the conduct of human clinical trials for pharmaceuticals (CPMP/ICH/286/95 mod).

A highly effective method of birth control is defined as that which results in a low failure rate (ie, less that 1% per year) when used consistently and correctly, such as hormonal implants, injectables, combined oral contraceptives, hormonal IUDs.

- Female participant who is not of childbearing potential must have a medical record of being surgically sterile (eg, hysterectomy, tubal ligation), or be at least 1 year postmenopausal. Absence of menses for at least 1 year will indicate that a female is postmenopausal.
- Capable of complying with the dosing regimen and visit schedules.
- Willing to give written informed consent to participate in the study.

Exclusion Criteria:

- Diagnosed with asthma or other clinically relevant lung disease (other than COPD), eg, sarcoidosis, tuberculosis, pulmonary fibrosis, bronchiectasis, or lung cancer.
- History of previous lung surgery (eg, lobectomy, pneumonectomy, or lung volume reduction).
- Lower respiratory tract infection within 4 weeks prior to the Screening Visit.
- Receiving chronic antibiotic therapy.
- Exacerbation of COPD within the 4 weeks prior to the Screening Visit.
- >20% change at Screening in post-bronchodilator FEV1.
- Female participant who is breast-feeding, pregnant, or intends to become pregnant during the study.
- Clinically relevant medical conditions (eg, hematologic, cardiovascular, renal, hepatic, neurologic, or metabolic).
- Taken inhaled or systemic steroids within 4 weeks of Screening Visit (Visit 1).
- Received an investigational drug within the last 30 days.
- Produced an inadequate amount of sputum at the Screening Visit (Visit 1) or is known to have difficulty producing sputum.
- PBN count of <3000 cells/microliters at Screening Visit (Visit 1).
- Part of the staff personnel directly involved with this study.
- Family member of the investigational study staff.
- Received any study prohibited medication more recently than the indicated washout period, prior to (Screening), or who must continue to receive any prohibited treatment.

Contacts and Locations

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

information, see Learn About Clinical Studies.

Please refer to this study by its ClinicalTrials.gov identifier: NCT00441701

Sponsors and Collaborators

Merck Sharp & Dohme Corp.

Investigators

Study Director: Medical Director Merck Sharp & Dohme Corp.

More Information

Responsible Party:	Merck Sharp & Dohme Corp.
ClinicalTrials.gov Identifier:	NCT00441701 History of Changes
Other Study ID Numbers:	P04592 P04592 2005-004287-23
Study First Received:	February 28, 2007
Results First Received:	August 11, 2014
Last Updated:	July 29, 2015
Health Authority:	Germany: Bundesinstitut fuer Arzneimittel und Medizinprodukte

Additional relevant MeSH terms:
Lung Diseases
Lung Diseases, Obstructive
Pulmonary Disease, Chronic Obstructive
Respiratory Tract Diseases

ClinicalTrials.gov processed this record on May 08, 2016

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Study to Evaluate the Safety and Dose-Range of Navarixin (SCH 527123, MK-7123) in Participants With Moderate to Severe Chronic Obstructive Pulmonary Disease (COPD) (MK-7123-012)

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First received: February 28, 2007
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Results First Received: August 11, 2014

Study Type:	Interventional
Study Design:	Allocation: Randomized; Endpoint Classification: Safety/Efficacy Study; Intervention Model: Parallel Assignment; Masking: Double Blind (Subject, Investigator); Primary Purpose: Treatment
Condition:	Chronic Obstructive Pulmonary Disease
Interventions:	Drug: Navarixin 1 mg Drug: Navarixin 10 mg Drug: Placebo to match navarixin Drug: Rescue medication

Participant Flow

Hide Participant Flow

Recruitment Details

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

Pre-Assignment Details

Significant events and approaches for the overall study following participant enrollment, but prior to group assignment
No text entered.

Reporting Groups

	Description

Part 1: Navarixin 3 mg	Cohort 1: Participants receive navarixin 3 mg (three 1 mg capsules) once daily (QD) for up to 12 weeks
Part 1: Placebo to Navarixin 3 mg	Cohort 1: Participants receive placebo to navarixin (three capsules) QD for up to 12 weeks
Part 1: Navarixin 10 mg	Cohort 2: Participants receive navarixin 10 mg (one 10 mg capsule and two placebo capsules) QD for up to 12 weeks
Part 1: Placebo to Navarixin 10 mg	Cohort 2: Participants receive placebo to navarixin (three capsules) QD for up to 12 weeks
Part 1: Navarixin 30 mg	Cohort 3: Participants receive navarixin 30 mg (three 10 mg capsules) QD for up to 12 weeks
Part 1: Placebo to Navarixin 30 mg	Cohort 3: Participants receive placebo to navarixin (three capsules) QD for up to 12 weeks
Part 2: Navarixin 3 mg	Cohort 4: Participants receive navarixin 3 mg (three 1 mg capsules) QD for up to 12 weeks
Part 2: Navarixin 10 mg	Cohort 4: Participants receive navarixin 10 mg (one 10 mg capsule and two placebo capsules) QD for up to 12 weeks
Part 2: Navarixin 30 mg	Cohort 4: Participants receive navarixin 30 mg (three 10 mg capsules) QD for up to 12 weeks
Part 2: Placebo to Navarixin	Cohort 4: Participants receive placebo to navarixin (three capsules) QD for up to 12 weeks

Participant Flow: Overall Study

	Part 1: Navarixin 3 mg	Part 1: Placebo to Navarixin 3 mg	Part 1: Navarixin 10 mg	Part 1: Placebo to Navarixin 10 mg	Part 1: Navarixin 30 mg	Part 1: Placebo to Navarixin 30 mg	Part 2: Navarixin 3 mg	Part 2: Navarixin 10 mg	Part 2: Navarixin 30 mg	Part 2: Placebo to Navarixin
STARTED	22	11	22	11	22	11	0	0	0	0
COMPLETED	17	7	18	8	20	8	0	0	0	0
NOT COMPLETED	5	4	4	3	2	3	0	0	0	0
Adverse Event	3	2	1	0	2	2	0	0	0	0
Lack of Efficacy	2	0	2	2	0	1	0	0	0	0
Withdrawal by Subject	0	2	1	1	0	0	0	0	0	0

Baseline Characteristics

Hide Baseline Characteristics

Population Description

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

Reporting Groups

	Description
Part 1: Navarixin 3 mg	Cohort 1: Participants receive navarixin 3 mg (three 1 mg capsules) QD for up to 12 weeks
Part 1: Placebo to Navarixin 3 mg	Cohort 1: Participants receive placebo to navarixin (three capsules) QD for up to 12 weeks
Part 1: Navarixin 10 mg	Cohort 2: Participants receive navarixin 10 mg (one 10 mg capsule and two placebo capsules) QD for up to 12 weeks
Part 1: Placebo to Navarixin 10 mg	Cohort 2: Participants receive placebo to navarixin (three capsules) QD for up to 12 weeks

Part 1: Navarixin 30 mg	Cohort 3: Participants receive navarixin 30 mg (three 10 mg capsules) QD for up to 12 weeks
Part 1: Placebo to Navarixin 30 mg	Cohort 3: Participants receive placebo to navarixin (three capsules) QD for up to 12 weeks
Part 2: Navarixin 3 mg	Cohort 4: Participants receive navarixin 3 mg (three 1 mg capsules) QD for up to 12 weeks
Part 2: Navarixin 10 mg	Cohort 4: Participants receive navarixin 10 mg (one 10 mg capsule and two placebo capsules) QD for up to 12 weeks
Part 2: Navarixin 30 mg	Cohort 4: Participants receive navarixin 30 mg (three 10 mg capsules) QD for up to 12 weeks
Part 2: Placebo to Navarixin	Cohort 4: Participants receive placebo to navarixin (three capsules) QD for up to 12 weeks
Total	Total of all reporting groups

Baseline Measures

	Part 1: Navarixin 3 mg	Part 1: Placebo to Navarixin 3 mg	Part 1: Navarixin 10 mg	Part 1: Placebo to Navarixin 10 mg	Part 1: Navarixin 30 mg	Part 1: Placebo to Navarixin 30 mg	Part 2: Navarixin 3 mg	Part 2: Navarixin 10 mg	Part 2: Navarixin 30 mg	Part 2: Placebo to Navarixin	Total
Number of Participants [units: participants]	**22**	**11**	**22**	**11**	**22**	**11**	**0**	**0**	**0**	**0**	**99**
Age [units: Years] Mean (Standard Deviation)	**54.7 (5.5)**	**57.2 (8.6)**	**61.8 (7.3)**	**60.2 (7.8)**	**56.1 (7.8)**	**58.3 (9.4)**					**57.9 (7.8)**
Gender [units: Participants]											
Female	**8**	**6**	**8**	**4**	**8**	**3**					**37**
Male	**14**	**5**	**14**	**7**	**14**	**8**					**62**

Outcome Measures

Hide All Outcome Measures

1. Primary: Part 1: Number of Participants Who Experience at Least One Adverse Event (AE) [Time Frame: Up to 12 weeks]

Measure Type	Primary
Measure Title	Part 1: Number of Participants Who Experience at Least One Adverse Event (AE)
Measure Description	An AE is any untoward medical occurrence in a participant administered a pharmaceutical product, biologic (at any dose), or medical device, which does not necessarily have a causal relationship with the treatment. AEs may include the onset of new illness and the exacerbation of pre-existing conditions. The number of participants who experienced an AE, regardless of causality or severity, was summarized.
Time Frame	Up to 12 weeks
Safety Issue	Yes

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The population consisted of all Part 1 participants who were randomized and received at least one dose of study drug.

Reporting Groups

	Description
Part 1: Navarixin 3 mg	Cohort 1: Participants receive navarixin 3 mg (three 1 mg capsules) QD for up to 12 weeks
Part 1: Navarixin 10 mg	Cohort 2: Participants receive navarixin 10 mg (one 10 mg capsule and two placebo capsules) QD for up to 12 weeks
Part 1: Navarixin 30 mg	Cohort 3: Participants receive navarixin 30 mg (three 10 mg capsules) QD for up to 12 weeks
Part 1: Placebo to Navarixin (Pooled)	Pooled Placebo Cohorts: Participants receive placebo to navarixin (three capsules) QD for up to 12 weeks

Measured Values

	Part 1: Navarixin 3 mg	Part 1: Navarixin 10 mg	Part 1: Navarixin 30 mg	Part 1: Placebo to Navarixin (Pooled)
Number of Participants Analyzed [units: participants]	**22**	**22**	**22**	**33**
Part 1: Number of Participants Who Experience at Least One Adverse Event (AE) [units: Participants]	**10**	**12**	**12**	**20**

No statistical analysis provided for Part 1: Number of Participants Who Experience at Least One Adverse Event (AE)

2. Primary: Part 1: Number of Participants Who Discontinue Study Drug Due to an AE [Time Frame: Up to 12 weeks]

Measure Type	Primary
Measure Title	Part 1: Number of Participants Who Discontinue Study Drug Due to an AE
Measure Description	An AE is any untoward medical occurrence in a participant administered a pharmaceutical product, biologic (at any dose), or medical device, which does not necessarily have a causal relationship with the treatment. AEs may include the onset of new illness and the exacerbation of pre-existing conditions. The number of participants who discontinued study drug, whether permanently or temporarily, due to an AE was summarized.
Time Frame	Up to 12 weeks
Safety Issue	Yes

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The population consisted of all Part 1 participants who were randomized and received at least one dose of study drug.

Reporting Groups

	Description
Part 1: Navarixin 3 mg	Cohort 1: Participants receive navarixin 3 mg (three 1 mg capsules) QD for up to 12 weeks
Part 1: Navarixin 10 mg	Cohort 2: Participants receive navarixin 10 mg (one 10 mg capsule and two placebo capsules) QD for up to 12 weeks
Part 1: Navarixin 30 mg	Cohort 3: Participants receive navarixin 30 mg (three 10 mg capsules) QD for up to 12 weeks
Part 1: Placebo to Navarixin (Pooled)	Pooled Placebo Cohorts: Participants receive placebo to navarixin (three capsules) QD for up to 12 weeks

Measured Values

	Part 1: Navarixin 3 mg	Part 1: Navarixin 10 mg	Part 1: Navarixin 30 mg	Part 1: Placebo to Navarixin (Pooled)

Number of Participants Analyzed [units: participants]	**22**	**22**	**22**	**33**
Part 1: Number of Participants Who Discontinue Study Drug Due to an AE [units: Participants]	**3**	**1**	**2**	**4**

No statistical analysis provided for Part 1: Number of Participants Who Discontinue Study Drug Due to an AE

3. Primary: Part 1: Change From Baseline in Absolute Peripheral Blood Neutrophil (PBN) Count [Time Frame: Baseline and Week 12]

Measure Type	Primary
Measure Title	Part 1: Change From Baseline in Absolute Peripheral Blood Neutrophil (PBN) Count
Measure Description	Participants were assessed for absolute PBN counts at Baseline and Week 12. The reported standard deviations (SDs) are pooled across all treatment groups. The rationale for the use of an analysis of variance (ANOVA) method using pooled SD values is the assumption that the SDs are similar across treatment groups.
Time Frame	Baseline and Week 12
Safety Issue	Yes

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The population consisted of all Part 1 participants who were randomized and received at least one dose of study drug and had a Baseline and a Week 12 assessment for absolute PBN count.

Reporting Groups

	Description
Part 1: Navarixin 3 mg	Cohort 1: Participants receive navarixin 3 mg (three 1 mg capsules) QD for up to 12 weeks
Part 1: Navarixin 10 mg	Cohort 2: Participants receive navarixin 10 mg (one 10 mg capsule and two placebo capsules) QD for up to 12 weeks
Part 1: Navarixin 30 mg	Cohort 3: Participants receive navarixin 30 mg (three 10 mg capsules) QD for up to 12 weeks
Part 1: Placebo to Navarixin (Pooled)	Pooled Placebo Cohorts: Participants receive placebo to navarixin (three capsules) QD for up to 12 weeks

Measured Values

	Part 1: Navarixin 3 mg	**Part 1: Navarixin 10 mg**	**Part 1: Navarixin 30 mg**	**Part 1: Placebo to Navarixin (Pooled)**
Number of Participants Analyzed [units: participants]	**17**	**19**	**20**	**24**
Part 1: Change From Baseline in Absolute Peripheral Blood Neutrophil (PBN) Count [units: 10^9 cells/L] Mean (Standard Deviation)	**-0.33 (1.67)**	**-1.06 (1.67)**	**-0.56 (1.67)**	**0.06 (1.67)**

No statistical analysis provided for Part 1: Change From Baseline in Absolute Peripheral Blood Neutrophil (PBN) Count

4. Primary: Part 2: Change From Baseline in Pre-bronchodilator Forced Expiratory Volume in 1 Second (FEV1) [Time Frame: Baseline and the

Average over 12 weeks]

Measure Type	Primary
Measure Title	Part 2: Change From Baseline in Pre-bronchodilator Forced Expiratory Volume in 1 Second (FEV1)
Measure Description	FEV1, as measured in liters via spirometry, is a measure of the amount of air expired in 1 second. Participants were to be assessed for pre-bronchodilator FEV1 immediately before dosing with bronchodilator (albuterol sulfate or equivalent) at Baseline and at Week 12. Pre-bronchodilator FEV1 data were to be averaged weekly over the 12-week treatment period for analysis.
Time Frame	Baseline and the Average over 12 weeks
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The population was to consist of all Part 2 participants who were randomized, received at least one dose of study drug, and had a Baseline and at least one post-Baseline assessment for FEV1. Part 2 of this study was not conducted under this protocol.

Reporting Groups

	Description
Part 2: Navarixin 3 mg	Cohort 4: Participants receive navarixin 3 mg (three 1 mg capsules) QD for up to 12 weeks
Part 2: Navarixin 10 mg	Cohort 4: Participants receive navarixin 10 mg (one 10 mg capsule and two placebo capsules) QD for up to 12 weeks
Part 2: Navarixin 30 mg	Cohort 4: Participants receive navarixin 30 mg (three 10 mg capsules) QD for up to 12 weeks
Part 2: Placebo to Navarixin	Cohort 4: Participants receive placebo to navarixin (three capsules) QD for up to 12 weeks

Measured Values

	Part 2: Navarixin 3 mg	**Part 2: Navarixin 10 mg**	**Part 2: Navarixin 30 mg**	**Part 2: Placebo to Navarixin**
Number of Participants Analyzed [units: participants]	**0**	**0**	**0**	**0**
Part 2: Change From Baseline in Pre-bronchodilator Forced Expiratory Volume in 1 Second (FEV1)				

No statistical analysis provided for Part 2: Change From Baseline in Pre-bronchodilator Forced Expiratory Volume in 1 Second (FEV1)

5. Primary: Part 2: Change From Baseline in Daily Morning/Nighttime Sputum Production, Cough, and Dyspnea (SCDS) Score [Time Frame: Baseline and the Average over 12 weeks]

Measure Type	Primary
Measure Title	Part 2: Change From Baseline in Daily Morning/Nighttime Sputum Production, Cough, and Dyspnea (SCDS) Score
Measure Description	Participants were to assess their morning (AM) and nighttime (PM) COPD symptoms (sputum production, cough, and dyspnea) on a daily basis in their e-Diaries. Baseline SCDS was defined as the average of AM and PM values over the week prior to and including Day 1 (AM) prior to the first dose of study drug. SCDS data were to be averaged weekly over the 12-week treatment period for analysis.
Time Frame	Baseline and the Average over 12 weeks
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The population was to consist of all Part 2 participants who were randomized, received at least one dose of study drug, and had a Baseline and at least one post-Baseline assessment for AM/PM SCDS scores. Part 2 of this study was not conducted under this protocol.

Reporting Groups

	Description
Part 2: Navarixin 3 mg	Cohort 4: Participants receive navarixin 3 mg (three 1 mg capsules) QD for up to 12 weeks
Part 2: Navarixin 10 mg	Cohort 4: Participants receive navarixin 10 mg (one 10 mg capsule and two placebo capsules) QD for up to 12 weeks
Part 2: Navarixin 30 mg	Cohort 4: Participants receive navarixin 30 mg (three 10 mg capsules) QD for up to 12 weeks
Part 2: Placebo to Navarixin	Cohort 4: Participants receive placebo to navarixin (three capsules) QD for up to 12 weeks

Measured Values

	Part 2: Navarixin 3 mg	Part 2: Navarixin 10 mg	Part 2: Navarixin 30 mg	Part 2: Placebo to Navarixin
Number of Participants Analyzed [units: participants]	**0**	**0**	**0**	**0**
Part 2: Change From Baseline in Daily Morning/Nighttime Sputum Production, Cough, and Dyspnea (SCDS) Score				

No statistical analysis provided for Part 2: Change From Baseline in Daily Morning/Nighttime Sputum Production, Cough, and Dyspnea (SCDS) Score

6. Secondary: Part 1: Change From Baseline in Percent PBN Count [Time Frame: Baseline and Week 12]

Measure Type	Secondary
Measure Title	Part 1: Change From Baseline in Percent PBN Count
Measure Description	Participants were to be assessed for percent PBN counts at Baseline and at Week 12.
Time Frame	Baseline and Week 12
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The population was to consist of all Part 1 participants who were randomized, received at least one dose of study drug, and had a Baseline and a Week 12 assessment for percent PBN count. Since sufficient data for analysis were collected for absolute PBN count, percent PBN count was not assessed.

Reporting Groups

	Description
Part 1: Navarixin 3 mg	Cohort 1: Participants receive navarixin 3 mg (three 1 mg capsules) QD for up to 12 weeks
Part 1: Navarixin 10 mg	Cohort 2: Participants receive navarixin 10 mg (one 10 mg capsule and two placebo capsules) QD for up to 12 weeks
Part 1: Navarixin 30 mg	Cohort 3: Participants receive navarixin 30 mg (three 10 mg capsules) QD for up to 12 weeks

Part 1: Placebo to Navarixin (Pooled)	Pooled Placebo Cohorts: Participants receive placebo to navarixin (three capsules) QD for up to 12 weeks

Measured Values

	Part 1: Navarixin 3 mg	Part 1: Navarixin 10 mg	Part 1: Navarixin 30 mg	Part 1: Placebo to Navarixin (Pooled)
Number of Participants Analyzed [units: participants]	**0**	**0**	**0**	**0**
Part 1: Change From Baseline in Percent PBN Count				

No statistical analysis provided for Part 1: Change From Baseline in Percent PBN Count

7. Secondary: Part 1: Change From Baseline in Sputum Absolute Neutrophil Count (Induced Sputum) [Time Frame: Baseline and Week 12]

Measure Type	Secondary
Measure Title	Part 1: Change From Baseline in Sputum Absolute Neutrophil Count (Induced Sputum)
Measure Description	Participants were assessed for induced sputum absolute neutrophil counts via the nebulized method at Baseline and at Week 12. The reported SDs are pooled across all treatment groups. The rationale for the use of an ANOVA method using pooled SD values is the assumption that the SDs are similar across treatment groups.
Time Frame	Baseline and Week 12
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The population consisted of all Part 1 participants who were randomized, received at least one dose of study drug, and had a Baseline and Week 12 assessment for induced sputum absolute neutrophil count.

Reporting Groups

	Description
Part 1: Navarixin 3 mg	Cohort 1: Participants receive navarixin 3 mg (three 1 mg capsules) QD for up to 12 weeks
Part 1: Navarixin 10 mg	Cohort 2: Participants receive navarixin 10 mg (one 10 mg capsule and two placebo capsules) QD for up to 12 weeks
Part 1: Navarixin 30 mg	Cohort 3: Participants receive navarixin 30 mg (three 10 mg capsules) QD for up to 12 weeks
Part 1: Placebo to Navarixin (Pooled)	Pooled Placebo Cohorts: Participants receive placebo to navarixin (three capsules) QD for up to 12 weeks

Measured Values

	Part 1: Navarixin 3 mg	Part 1: Navarixin 10 mg	Part 1: Navarixin 30 mg	Part 1: Placebo to Navarixin (Pooled)
Number of Participants Analyzed [units: participants]	**12**	**18**	**18**	**20**
Part 1: Change From Baseline in Sputum Absolute Neutrophil Count (Induced Sputum) [units: 10^9 cells/L] Mean (Standard Deviation)	**-1.30 (7.83)**	**-0.84 (7.83)**	**-4.04 (7.83)**	**-0.22 (7.83)**

No statistical analysis provided for Part 1: Change From Baseline in Sputum Absolute Neutrophil Count (Induced Sputum)

8. Secondary: Part 1: Change From Baseline in Sputum Percent Neutrophil Count (Induced Sputum) [Time Frame: Baseline and Week 12]

Measure Type	Secondary
Measure Title	Part 1: Change From Baseline in Sputum Percent Neutrophil Count (Induced Sputum)
Measure Description	Sputum neutrophils were to be measured as percent of total white blood cells. Participants were to be assessed for induced sputum percent neutrophil counts via the nebulized method at Baseline and at Week 12.
Time Frame	Baseline and Week 12
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The population was to consist of all Part 1 participants who were randomized, received at least 1 dose of study drug, and had a Baseline and Week 12 assessment for sputum percent neutrophil count. Since sufficient data for analysis were collected for absolute sputum neutrophil count, percent sputum neutrophil count was not assessed.

Reporting Groups

	Description
Part 1: Navarixin 3 mg	Cohort 1: Participants receive navarixin 3 mg (three 1 mg capsules) QD for up to 12 weeks
Part 1: Navarixin 10 mg	Cohort 2: Participants receive navarixin 10 mg (one 10 mg capsule and two placebo capsules) QD for up to 12 weeks
Part 1: Navarixin 30 mg	Cohort 3: Participants receive navarixin 30 mg (three 10 mg capsules) QD for up to 12 weeks
Part 1: Placebo to Navarixin (Pooled)	Pooled Placebo Cohorts: Participants receive placebo to navarixin (three capsules) QD for up to 12 weeks

Measured Values

	Part 1: Navarixin 3 mg	**Part 1: Navarixin 10 mg**	**Part 1: Navarixin 30 mg**	**Part 1: Placebo to Navarixin (Pooled)**
Number of Participants Analyzed [units: participants]	**0**	**0**	**0**	**0**
Part 1: Change From Baseline in Sputum Percent Neutrophil Count (Induced Sputum)				

No statistical analysis provided for Part 1: Change From Baseline in Sputum Percent Neutrophil Count (Induced Sputum)

9. Secondary: Part 2: Change From Baseline in Post-Bronchodilator FEV1 [Time Frame: Baseline and the Average over 12 weeks]

Measure Type	Secondary
Measure Title	Part 2: Change From Baseline in Post-Bronchodilator FEV1
Measure Description	FEV1, as measured in liters via spirometry, is a measure of the amount of air expired in 1 second. Participants were to be assessed for post-bronchodilator FEV1 30 minutes after dosing with bronchodilator (albuterol sulfate or equivalent) (reversibility test) at Baseline and Week 12. Post-bronchodilator data were to be averaged weekly over the 12-week treatment period for analysis.
Time Frame	Baseline and the Average over 12 weeks
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The population was to consist of all Part 2 participants who were randomized, received at least one dose of study drug, and had a Baseline and Week 12 efficacy assessment for post-bronchodilator FEV1. Part 2 of this study was not conducted under this protocol.

Reporting Groups

	Description
Part 2: Navarixin 3 mg	Cohort 4: Participants receive navarixin 3 mg (three 1 mg capsules) QD for up to 12 weeks
Part 2: Navarixin 10 mg	Cohort 4: Participants receive navarixin 10 mg (one 10 mg capsule and two placebo capsules) QD for up to 12 weeks
Part 2: Navarixin 30 mg	Cohort 4: Participants receive navarixin 30 mg (three 10 mg capsules) QD for up to 12 weeks
Part 2: Placebo to Navarixin	Cohort 4: Participants receive placebo to navarixin (three capsules) QD for up to 12 weeks

Measured Values

	Part 2: Navarixin 3 mg	**Part 2: Navarixin 10 mg**	**Part 2: Navarixin 30 mg**	**Part 2: Placebo to Navarixin**
Number of Participants Analyzed [units: participants]	**0**	**0**	**0**	**0**
Part 2: Change From Baseline in Post-Bronchodilator FEV1				

No statistical analysis provided for Part 2: Change From Baseline in Post-Bronchodilator FEV1

10. Secondary: Part 2: Change From Baseline in Forced Expiratory Flow During Middle Half of Forced Vital Capacity (FVC) (FEF25%-75%) [Time Frame: Baseline and Week 12]

Measure Type	Secondary
Measure Title	Part 2: Change From Baseline in Forced Expiratory Flow During Middle Half of Forced Vital Capacity (FVC) (FEF25%-75%)
Measure Description	Mid-Breath Forced Expiratory Flow (FEF25%-75%), as measured in liters/minute via spirometry, is the rate at which participants breathe out air from 25 percent of their breath to 75 percent of their breath. Participants were to be assessed for FEF25%-75% at Baseline and Week 12.
Time Frame	Baseline and Week 12
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The population was to consist of all Part 2 participants who were randomized, received at least one dose of study drug, and had a Baseline and Week 12 assessment for FEF25%-75%. Part 2 of this study was not conducted under this protocol.

Reporting Groups

	Description
Part 2: Navarixin 3 mg	Cohort 4: Participants receive navarixin 3 mg (three 1 mg capsules) QD for up to 12 weeks
Part 2: Navarixin 10 mg	Cohort 4: Participants receive navarixin 10 mg (one 10 mg capsule and two placebo capsules) QD for up to 12 weeks

Part 2: Navarixin 30 mg	Cohort 4: Participants receive navarixin 30 mg (three 10 mg capsules) QD for up to 12 weeks
Part 2: Placebo to Navarixin	Cohort 4: Participants receive placebo to navarixin (three capsules) QD for up to 12 weeks

Measured Values

	Part 2: Navarixin 3 mg	Part 2: Navarixin 10 mg	Part 2: Navarixin 30 mg	Part 2: Placebo to Navarixin
Number of Participants Analyzed [units: participants]	**0**	**0**	**0**	**0**
Part 2: Change From Baseline in Forced Expiratory Flow During Middle Half of Forced Vital Capacity (FVC) (FEF25%-75%)				

No statistical analysis provided for Part 2: Change From Baseline in Forced Expiratory Flow During Middle Half of Forced Vital Capacity (FVC) (FEF25%-75%)

11. Secondary: Part 2: Change From Baseline in FVC [Time Frame: Baseline and Week 12]

Measure Type	Secondary
Measure Title	Part 2: Change From Baseline in FVC
Measure Description	FVC, as measured in liters via spirometry, is the amount of air forcibly exhaled from the lungs after taking the deepest breath possible. Post-bronchodilator FVC was to be assessed 30 minutes after bronchodilator administration at Baseline and Week 12.
Time Frame	Baseline and Week 12
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The population was to consist of all Part 2 participants who were randomized, received at least one dose of study drug, and had a Baseline and Week 12 efficacy assessment for FVC. Part 2 of this study was not conducted under this protocol.

Reporting Groups

	Description
Part 2: Navarixin 3 mg	Cohort 4: Participants receive navarixin 3 mg (three 1 mg capsules) QD for up to 12 weeks
Part 2: Navarixin 10 mg	Cohort 4: Participants receive navarixin 10 mg (one 10 mg capsule and two placebo capsules) QD for up to 12 weeks
Part 2: Navarixin 30 mg	Cohort 4: Participants receive navarixin 30 mg (three 10 mg capsules) QD for up to 12 weeks
Part 2: Placebo to Navarixin	Cohort 4: Participants receive placebo to navarixin (three capsules) QD for up to 12 weeks

Measured Values

	Part 2: Navarixin 3 mg	Part 2: Navarixin 10 mg	Part 2: Navarixin 30 mg	Part 2: Placebo to Navarixin
Number of Participants Analyzed [units: participants]	**0**	**0**	**0**	**0**
Part 2: Change From Baseline in FVC				

No statistical analysis provided for Part 2: Change From Baseline in FVC

12. Secondary: Part 2: Change From Baseline in Functional Residual Capacity (FRC) [Time Frame: Baseline and Week 12]

Measure Type	Secondary
Measure Title	Part 2: Change From Baseline in Functional Residual Capacity (FRC)
Measure Description	FRC, as measured in liters via body plethysmography, is the volume of air present in the lungs, specifically the parenchyma tissues, at the end of passive expiration. Participants were to be assessed for FRC at Baseline and Week 12.
Time Frame	Baseline and Week 12
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The population was to consist of all Part 2 participants who were randomized, received at least one dose of study drug, and had a Baseline and Week 12 efficacy assessment for FRC. Part 2 of this study was not conducted under this protocol.

Reporting Groups

	Description
Part 2: Navarixin 3 mg	Cohort 4: Participants receive navarixin 3 mg (three 1 mg capsules) QD for up to 12 weeks
Part 2: Navarixin 10 mg	Cohort 4: Participants receive navarixin 10 mg (one 10 mg capsule and two placebo capsules) QD for up to 12 weeks
Part 2: Navarixin 30 mg	Cohort 4: Participants receive navarixin 30 mg (three 10 mg capsules) QD for up to 12 weeks
Part 2: Placebo to Navarixin	Cohort 4: Participants receive placebo to navarixin (three capsules) QD for up to 12 weeks

Measured Values

	Part 2: Navarixin 3 mg	**Part 2: Navarixin 10 mg**	**Part 2: Navarixin 30 mg**	**Part 2: Placebo to Navarixin**
Number of Participants Analyzed [units: participants]	**0**	**0**	**0**	**0**
Part 2: Change From Baseline in Functional Residual Capacity (FRC)				

No statistical analysis provided for Part 2: Change From Baseline in Functional Residual Capacity (FRC)

13. Secondary: Part 2: Number of Participants Who Experience a COPD Exacerbation [Time Frame: Up to Week 12]

Measure Type	Secondary
Measure Title	Part 2: Number of Participants Who Experience a COPD Exacerbation
Measure Description	COPD exacerbation is defined as any change in symptoms or functional status that leads to administration of systemic corticosteroids, antibiotics, an emergency room visit or a hospitalization. The number of participants who experienced a COPD exacerbation was to be summarized.
Time Frame	Up to Week 12
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The population was to consist of all Part 2 participants who were randomized, received at least one dose of study drug, and had a at least one post-Baseline assessment for presence of COPD exacerbation. Part 2 of this study was not conducted under this protocol.

Reporting Groups

	Description
Part 2: Navarixin 3 mg	Cohort 4: Participants receive navarixin 3 mg (three 1 mg capsules) QD for up to 12 weeks
Part 2: Navarixin 10 mg	Cohort 4: Participants receive navarixin 10 mg (one 10 mg capsule and two placebo capsules) QD for up to 12 weeks
Part 2: Navarixin 30 mg	Cohort 4: Participants receive navarixin 30 mg (three 10 mg capsules) QD for up to 12 weeks
Part 2: Placebo to Navarixin	Cohort 4: Participants receive placebo to navarixin (three capsules) QD for up to 12 weeks

Measured Values

	Part 2: Navarixin 3 mg	Part 2: Navarixin 10 mg	Part 2: Navarixin 30 mg	Part 2: Placebo to Navarixin
Number of Participants Analyzed [units: participants]	**0**	**0**	**0**	**0**
Part 2: Number of Participants Who Experience a COPD Exacerbation				

No statistical analysis provided for Part 2: Number of Participants Who Experience a COPD Exacerbation

14. Secondary: Part 2: Change From Baseline in Peak Expiratory Flow (PEF) [Time Frame: Baseline and Week 12]

Measure Type	Secondary
Measure Title	Part 2: Change From Baseline in Peak Expiratory Flow (PEF)
Measure Description	PEF, as measured in liters/minute via peak flow meter, is the maximum speed of expiration. Participants were to measure their PEF in triplicate every morning before taking study drug and again every evening.
Time Frame	Baseline and Week 12
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The population was to consist of all Part 2 participants who were randomized, received at least one dose of study drug, and had a Baseline and Week 12 efficacy assessment for PEF. Part 2 of this study was not conducted under this protocol.

Reporting Groups

	Description
Part 2: Navarixin 3 mg	Cohort 4: Participants receive navarixin 3 mg (three 1 mg capsules) QD for up to 12 weeks
Part 2: Navarixin 10 mg	Cohort 4: Participants receive navarixin 10 mg (one 10 mg capsule and two placebo capsules) QD for up to 12 weeks
Part 2: Navarixin 30 mg	Cohort 4: Participants receive navarixin 30 mg (three 10 mg capsules) QD for up to 12 weeks
Part 2: Placebo to Navarixin	Cohort 4: Participants receive placebo to navarixin (three capsules) QD for up to 12 weeks

Measured Values

	Part 2: Navarixin 3 mg	Part 2: Navarixin 10 mg	Part 2: Navarixin 30 mg	Part 2: Placebo to Navarixin
Number of Participants Analyzed [units: participants]	0	0	0	0
Part 2: Change From Baseline in Peak Expiratory Flow (PEF)				

No statistical analysis provided for Part 2: Change From Baseline in Peak Expiratory Flow (PEF)

15. Secondary: Part 2: Change From Baseline in Induced Sputum Absolute Neutrophil Count [Time Frame: Baseline and Week 12]

Measure Type	Secondary
Measure Title	Part 2: Change From Baseline in Induced Sputum Absolute Neutrophil Count
Measure Description	Participants were to be assessed for induced sputum absolute neutrophil counts via the nebulized method at Baseline and at Week 12.
Time Frame	Baseline and Week 12
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The population was to consist of all Part 2 participants who were randomized, received at least one dose of study drug and had a Baseline and Week 12 assessment for induced sputum absolute neutrophil count. Part 2 of this study was not conducted under this protocol.

Reporting Groups

	Description
Part 2: Navarixin 3 mg	Cohort 4: Participants receive navarixin 3 mg (three 1 mg capsules) QD for up to 12 weeks
Part 2: Navarixin 10 mg	Cohort 4: Participants receive navarixin 10 mg (one 10 mg capsule and two placebo capsules) QD for up to 12 weeks
Part 2: Navarixin 30 mg	Cohort 4: Participants receive navarixin 30 mg (three 10 mg capsules) QD for up to 12 weeks
Part 2: Placebo to Navarixin	Cohort 4: Participants receive placebo to navarixin (three capsules) QD for up to 12 weeks

Measured Values

	Part 2: Navarixin 3 mg	Part 2: Navarixin 10 mg	Part 2: Navarixin 30 mg	Part 2: Placebo to Navarixin
Number of Participants Analyzed [units: participants]	0	0	0	0
Part 2: Change From Baseline in Induced Sputum Absolute Neutrophil Count				

No statistical analysis provided for Part 2: Change From Baseline in Induced Sputum Absolute Neutrophil Count

16. Secondary: Part 2: Change From Baseline in Induced Sputum Percent Neutrophil Count [Time Frame: Baseline and Week 12]

Measure Type	Secondary
Measure Title	Part 2: Change From Baseline in Induced Sputum Percent Neutrophil Count

Measure Description	Sputum neutrophils were to be measured as percent of total white blood cells. Participants were to be assessed for induced sputum percent neutrophil counts via the nebulized method at Baseline and at Week 12.
Time Frame	Baseline and Week 12
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The population was to consist of all Part 2 participants who were randomized, received at least one dose of study drug and had a Baseline and Week 12 assessment for sputum percent neutrophil count. Part 2 of this study was not conducted under this protocol.

Reporting Groups

	Description
Part 2: Navarixin 3 mg	Cohort 4: Participants receive navarixin 3 mg (three 1 mg capsules) QD for up to 12 weeks
Part 2: Navarixin 10 mg	Cohort 4: Participants receive navarixin 10 mg (one 10 mg capsule and two placebo capsules) QD for up to 12 weeks
Part 2: Navarixin 30 mg	Cohort 4: Participants receive navarixin 30 mg (three 10 mg capsules) QD for up to 12 weeks
Part 2: Placebo to Navarixin	Cohort 4: Participants receive placebo to navarixin (three capsules) QD for up to 12 weeks

Measured Values

	Part 2: Navarixin 3 mg	**Part 2: Navarixin 10 mg**	**Part 2: Navarixin 30 mg**	**Part 2: Placebo to Navarixin**
Number of Participants Analyzed [units: participants]	**0**	**0**	**0**	**0**
Part 2: Change From Baseline in Induced Sputum Percent Neutrophil Count				

No statistical analysis provided for Part 2: Change From Baseline in Induced Sputum Percent Neutrophil Count

17. Secondary: Part 2: Change From Baseline in Individual Symptom Scores [Time Frame: Baseline and Week 12]

Measure Type	Secondary
Measure Title	Part 2: Change From Baseline in Individual Symptom Scores
Measure Description	Participants were to be assessed for individual symptom scores at Baseline and Week 12 using the following scales: Sputum Production (0=none, unaware of any sputum production to 4=severe, an almost constant problem), Cough (0=none, unaware of coughing to 4=severe, never free of cough or need to cough), and Dyspnea (0=none, unaware of any difficulty to 4=severe, almost constant: present even when resting).
Time Frame	Baseline and Week 12
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The population was to consist of all Part 2 participants who were randomized, received at least one dose of study drug and had a Baseline and Week 12 efficacy assessment for individual symptom scores. Part 2 of this study was not conducted under this protocol.

Reporting Groups

	Description

Part 2: Navarixin 3 mg	Cohort 4: Participants receive navarixin 3 mg (three 1 mg capsules) QD for up to 12 weeks
Part 2: Navarixin 10 mg	Cohort 4: Participants receive navarixin 10 mg (one 10 mg capsule and two placebo capsules) QD for up to 12 weeks
Part 2: Navarixin 30 mg	Cohort 4: Participants receive navarixin 30 mg (three 10 mg capsules) QD for up to 12 weeks
Part 2: Placebo to Navarixin	Cohort 4: Participants receive placebo to navarixin (three capsules) QD for up to 12 weeks

Measured Values

	Part 2: Navarixin 3 mg	Part 2: Navarixin 10 mg	Part 2: Navarixin 30 mg	Part 2: Placebo to Navarixin
Number of Participants Analyzed [units: participants]	**0**	**0**	**0**	**0**
Part 2: Change From Baseline in Individual Symptom Scores				

No statistical analysis provided for Part 2: Change From Baseline in Individual Symptom Scores

18. Secondary: Part 2: Change From Baseline in St George's Respiratory Questionnaire (SGRQ) Individual/Total Domains [Time Frame: Baseline and Week 12]

Measure Type	Secondary
Measure Title	Part 2: Change From Baseline in St George's Respiratory Questionnaire (SGRQ) Individual/Total Domains
Measure Description	SGRQ consists of 76 items aggregated into 3 domain scores: Symptoms (frequency/severity), Activity (cause or limited by breathlessness), Impact (social functioning, psychological disturbances from airway disease), and total score. Participants were to assess their symptoms, activity and impact at Baseline and Week 12.
Time Frame	Baseline and Week 12
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The population was to consist of all Part 2 participants who were randomized, received at least one dose of study drug and had a Baseline and Week 12 efficacy assessment for SGRQ. Part 2 of this study was not conducted under this protocol.

Reporting Groups

	Description
Part 2: Navarixin 3 mg	Cohort 4: Participants receive navarixin 3 mg (three 1 mg capsules) QD for up to 12 weeks
Part 2: Navarixin 10 mg	Cohort 4: Participants receive navarixin 10 mg (one 10 mg capsule and two placebo capsules) QD for up to 12 weeks
Part 2: Navarixin 30 mg	Cohort 4: Participants receive navarixin 30 mg (three 10 mg capsules) QD for up to 12 weeks
Part 2: Placebo to Navarixin	Cohort 4: Participants receive placebo to navarixin (three capsules) QD for up to 12 weeks

Measured Values

	Part 2: Navarixin 3 mg	Part 2: Navarixin 10 mg	Part 2: Navarixin 30 mg	Part 2: Placebo to Navarixin
Number of Participants Analyzed [units: participants]	**0**	**0**	**0**	**0**
Part 2: Change From Baseline in St George's Respiratory				

Questionnaire (SGRQ) Individual/Total Domains				

No statistical analysis provided for Part 2: Change From Baseline in St George's Respiratory Questionnaire (SGRQ) Individual/Total Domains

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	Up to 30 days after last dose of study drug (Up to 16 weeks)
Additional Description	Part 2 was not conducted under this protocol.

Reporting Groups

	Description
Part 1: Navarixin 3 mg	Cohort 1: Participants receive navarixin 3 mg (three 1 mg capsules) QD for up to 12 weeks
Part 1: Navarixin 10 mg	Cohort 2: Participants receive navarixin 10 mg (one 10 mg capsule and two placebo capsules) QD for up to 12 weeks
Part 1: Navarixin 30 mg	Cohort 3: Participants receive navarixin 30 mg (three 10 mg capsules) QD for up to 12 weeks
Part 1: Placebo to Navarixin (Pooled)	Pooled Placebo Cohorts: Participants receive placebo to navarixin (three capsules) QD for up to 12 weeks
Part 2: Navarixin 3 mg	Cohort 4: Participants receive navarixin 3 mg (three 1 mg capsules) QD for up to 12 weeks
Part 2: Navarixin 10 mg	Cohort 4: Participants receive navarixin 10 mg (one 10 mg capsule and two placebo capsules) QD for up to 12 weeks
Part 2: Navarixin 30 mg	Cohort 4: Participants receive navarixin 30 mg (three 10 mg capsules) QD for up to 12 weeks
Part 2: Placebo to Navarixin	Cohort 4: Participants receive placebo to navarixin (three capsules) QD for up to 12 weeks

Serious Adverse Events

	Part 1: Navarixin 3 mg	Part 1: Navarixin 10 mg	Part 1: Navarixin 30 mg	Part 1: Placebo to Navarixin (Pooled)	Part 2: Navarixin 3 mg	Part 2: Navarixin 10 mg	Part 2: Navarixin 30 mg	Part 2: Placebo to Navarixin
Total, serious adverse events								
# participants affected / at risk	**1/22 (4.55%)**	**1/22 (4.55%)**	**1/22 (4.55%)**	**4/33 (12.12%)**	**0/0**	**0/0**	**0/0**	**0/0**
Cardiac disorders								
Congestive cardiomyopathy † 1								
# participants affected / at risk	**0/22 (0.00%)**	**0/22 (0.00%)**	**0/22 (0.00%)**	**1/33 (3.03%)**	**0/0**	**0/0**	**0/0**	**0/0**
# events	**0**	**0**	**0**	**1**	**0**	**0**	**0**	**0**
Left ventricular failure † 1								
# participants affected / at risk	**0/22 (0.00%)**	**0/22 (0.00%)**	**0/22 (0.00%)**	**1/33 (3.03%)**	**0/0**	**0/0**	**0/0**	**0/0**
# events	**0**	**0**	**0**	**1**	**0**	**0**	**0**	**0**

Myocardial infarction † 1								
# participants affected / at risk	**0/22 (0.00%)**	**1/22 (4.55%)**	**1/22 (4.55%)**	**0/33 (0.00%)**	**0/0**	**0/0**	**0/0**	**0/0**
# events	**0**	**1**	**1**	**0**	**0**	**0**	**0**	**0**
Injury, poisoning and procedural complications								
Fall † 1								
# participants affected / at risk	**1/22 (4.55%)**	**0/22 (0.00%)**	**0/22 (0.00%)**	**0/33 (0.00%)**	**0/0**	**0/0**	**0/0**	**0/0**
# events	**1**	**0**	**0**	**0**	**0**	**0**	**0**	**0**
Neoplasms benign, malignant and unspecified (incl cysts and polyps)								
Rectal adenoma † 1								
# participants affected / at risk	**0/22 (0.00%)**	**0/22 (0.00%)**	**0/22 (0.00%)**	**1/33 (3.03%)**	**0/0**	**0/0**	**0/0**	**0/0**
# events	**0**	**0**	**0**	**1**	**0**	**0**	**0**	**0**
Nervous system disorders								
Cerebrovascular accident † 1								
# participants affected / at risk	**0/22 (0.00%)**	**0/22 (0.00%)**	**0/22 (0.00%)**	**1/33 (3.03%)**	**0/0**	**0/0**	**0/0**	**0/0**
# events	**0**	**0**	**0**	**1**	**0**	**0**	**0**	**0**
Psychiatric disorders								
Alcohol abuse † 1								
# participants affected / at risk	**0/22 (0.00%)**	**0/22 (0.00%)**	**0/22 (0.00%)**	**1/33 (3.03%)**	**0/0**	**0/0**	**0/0**	**0/0**
# events	**0**	**0**	**0**	**1**	**0**	**0**	**0**	**0**
Respiratory, thoracic and mediastinal disorders								
Dyspnoea † 1								
# participants affected / at risk	**0/22 (0.00%)**	**0/22 (0.00%)**	**0/22 (0.00%)**	**1/33 (3.03%)**	**0/0**	**0/0**	**0/0**	**0/0**
# events	**0**	**0**	**0**	**1**	**0**	**0**	**0**	**0**

† Events were collected by systematic assessment
1 Term from vocabulary, MedDRA 11.1

Other Adverse Events

Hide Other Adverse Events

Time Frame	Up to 30 days after last dose of study drug (Up to 16 weeks)
Additional Description	Part 2 was not conducted under this protocol.

Frequency Threshold

Threshold above which other adverse events are reported	5%

Reporting Groups

	Description
Part 1: Navarixin 3 mg	Cohort 1: Participants receive navarixin 3 mg (three 1 mg capsules) QD for up to 12 weeks
Part 1: Navarixin 10 mg	Cohort 2: Participants receive navarixin 10 mg (one 10 mg capsule and two placebo capsules) QD for up to 12 weeks
Part 1: Navarixin 30 mg	Cohort 3: Participants receive navarixin 30 mg (three 10 mg capsules) QD for up to 12 weeks
Part 1: Placebo to Navarixin (Pooled)	Pooled Placebo Cohorts: Participants receive placebo to navarixin (three capsules) QD for up to 12 weeks
Part 2: Navarixin 3 mg	Cohort 4: Participants receive navarixin 3 mg (three 1 mg capsules) QD for up to 12 weeks
Part 2: Navarixin 10 mg	Cohort 4: Participants receive navarixin 10 mg (one 10 mg capsule and two placebo capsules) QD for up to 12 weeks
Part 2: Navarixin 30 mg	Cohort 4: Participants receive navarixin 30 mg (three 10 mg capsules) QD for up to 12 weeks
Part 2: Placebo to Navarixin	Cohort 4: Participants receive placebo to navarixin (three capsules) QD for up to 12 weeks

Other Adverse Events

	Part 1: Navarixin 3 mg	Part 1: Navarixin 10 mg	Part 1: Navarixin 30 mg	Part 1: Placebo to Navarixin (Pooled)	Part 2: Navarixin 3 mg	Part 2: Navarixin 10 mg	Part 2: Navarixin 30 mg	Part 2: Placebo to Navarixin
Total, other (not including serious) adverse events								
# participants affected / at risk	**8/22 (36.36%)**	**8/22 (36.36%)**	**7/22 (31.82%)**	**10/33 (30.30%)**	**0/0**	**0/0**	**0/0**	**0/0**
Gastrointestinal disorders								
Toothache † 1								
# participants affected / at risk	**1/22 (4.55%)**	**0/22 (0.00%)**	**2/22 (9.09%)**	**0/33 (0.00%)**	**0/0**	**0/0**	**0/0**	**0/0**
# events	**1**	**0**	**2**	**0**	**0**	**0**	**0**	**0**
Infections and infestations								
Nasopharyngitis † 1								
# participants affected / at risk	**5/22 (22.73%)**	**7/22 (31.82%)**	**6/22 (27.27%)**	**5/33 (15.15%)**	**0/0**	**0/0**	**0/0**	**0/0**
# events	**5**	**8**	**7**	**5**	**0**	**0**	**0**	**0**
Rhinitis † 1								
# participants affected / at risk	**0/22 (0.00%)**	**1/22 (4.55%)**	**1/22 (4.55%)**	**2/33 (6.06%)**	**0/0**	**0/0**	**0/0**	**0/0**
# events	**0**	**1**	**1**	**2**	**0**	**0**	**0**	**0**
Nervous system disorders								
Headache † 1								
# participants	**1/22 (4.55%)**	**1/22 (4.55%)**	**1/22 (4.55%)**					

affected / at risk				2/33 (6.06%)	0/0	0/0	0/0	0/0
# events	1	3	1	2	0	0	0	0
Respiratory, thoracic and mediastinal disorders								
Dysphonia † 1								
# participants affected / at risk	2/22 (9.09%)	0/22 (0.00%)	0/22 (0.00%)	1/33 (3.03%)	0/0	0/0	0/0	0/0
# events	2	0	0	1	0	0	0	0
Oropharyngeal pain † 1								
# participants affected / at risk	0/22 (0.00%)	2/22 (9.09%)	0/22 (0.00%)	0/33 (0.00%)	0/0	0/0	0/0	0/0
# events	0	2	0	0	0	0	0	0
Vascular disorders								
Hypertension † 1								
# participants affected / at risk	1/22 (4.55%)	0/22 (0.00%)	0/22 (0.00%)	2/33 (6.06%)	0/0	0/0	0/0	0/0
# events	1	0	0	2	0	0	0	0

† Events were collected by systematic assessment
1 Term from vocabulary, MedDRA 11.1

Limitations and Caveats

Hide Limitations and Caveats

Limitations of the study, such as early termination leading to small numbers of participants analyzed and technical problems with measurement leading to unreliable or uninterpretable data

No text entered.

More Information

Hide More Information

Certain Agreements:

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

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

The agreement is:

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

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

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

☑ **Restriction Description:** The investigator agrees to provide the sponsor 45 days prior to submission for publication or presentation, review copies of abstracts or manuscripts for publication (including, without limitation, slides and texts of oral or other public presentations and texts of any transmission through any electronic media, eg, any computer access system such as the Internet, World Wide Web, etc.) that report any results of the study.

Results Point of Contact:

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Responsible Party:	Merck Sharp & Dohme Corp.
ClinicalTrials.gov Identifier:	NCT00441701 History of Changes
Other Study ID Numbers:	P04592 P04592 (Other Identifier: Merck Protocol Number) 2005-004287-23 (EudraCT Number)
Study First Received:	February 28, 2007
Results First Received:	August 11, 2014
Last Updated:	July 29, 2015
Health Authority:	Germany: Bundesinstitut fuer Arzneimittel und Medizinprodukte

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For Patients and Families | For Researchers | For Study Record Managers

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