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Trial record **1 of 1** for: CTBM100C2302

Previous Study | Return to List | Next Study

Safety of Tobramycin Inhalation Powder (TIP) vs Tobramycin Solution for Inhalation in Patients With Cystic Fibrosis (EAGER)

This study has been completed.

Sponsor:
Novartis Pharmaceuticals

Information provided by (Responsible Party):
Novartis (Novartis Pharmaceuticals)

ClinicalTrials.gov Identifier:
NCT00388505

First received: October 16, 2006
Last updated: June 19, 2012
Last verified: June 2012
History of Changes

Full Text View | Tabular View | Study Results | Disclaimer | How to Read a Study Record

Results First Received: June 19, 2012

Study Type:	Interventional
Study Design:	Allocation: Randomized; Endpoint Classification: Safety Study; Intervention Model: Parallel Assignment; Masking: Open Label; Primary Purpose: Treatment
Condition:	Cystic Fibrosis
Interventions:	Drug: Tobramycin Inhalation Powder Drug: Tobramycin Solution for Inhalation

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
Tobramycin Inhalation Powder (TIP)	Participants received four 28 mg capsules of tobramycin inhalation powder (TIP) delivered with the T-326 inhaler twice daily for 28 days followed by 28 days off therapy (one cycle) for a total of three cycles.
Tobramycin Solution for Inhalation (TOBI)	Participants received one 300 mg (in 5 mL) ampoule of tobramycin solution for inhalation (TOBI) delivered with a nebulizer twice daily for 28 days followed by 28 days off therapy (one cycle) for a total of three cycles.

Participant Flow: Overall Study

	Tobramycin Inhalation Powder (TIP)	Tobramycin Solution for Inhalation (TOBI)
STARTED	**308** [1]	**209** [1]
COMPLETED	**225**	**171**
NOT COMPLETED	**83**	**38**
Adverse Event or Death	**43**	**17**
Withdrawal by Subject	**24**	**9**

Lost to Follow-up	**5**	**3**
Inappropriate Enrollment	**0**	**1**
Administrative Reason	**1**	**0**
Protocol Violation	**6**	**5**
Unable to classify	**4**	**3**

[1] Randomized patients who received any amount of study medication

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
Tobramycin Inhalation Powder (TIP)	Participants received four 28 mg capsules of tobramycin inhalation powder (TIP) delivered with the T-326 inhaler twice daily for 28 days followed by 28 days off therapy (one cycle) for a total of three cycles.
Tobramycin Solution for Inhalation (TOBI)	Participants received one 300 mg (in 5 mL) ampoule of tobramycin solution for inhalation (TOBI) delivered with a nebulizer twice daily for 28 days followed by 28 days off therapy (one cycle) for a total of three cycles.
Total	Total of all reporting groups

Baseline Measures

	Tobramycin Inhalation Powder (TIP)	**Tobramycin Solution for Inhalation (TOBI)**	**Total**

Number of Participants [units: participants]	**308**	**209**	**517**
Age [units: years] Mean (Standard Deviation)	**25.9 (11.36)**	**25.2 (10.20)**	**25.6 (10.90)**
Age, Customized [units: participants]			
≥6 to <13 years	**28**	**18**	**46**
≥13 to <20 years	**66**	**48**	**114**
≥20 years	**214**	**143**	**357**
Gender [units: participants]			
Female	**137**	**94**	**231**
Male	**171**	**115**	**286**

Outcome Measures

Hide All Outcome Measures

1. Primary: Number of Participants With Treatment-emergent Adverse Events [Time Frame: 25 weeks]

Measure Type	Primary
Measure Title	Number of Participants With Treatment-emergent Adverse Events
Measure Description	An adverse event (AE) is any untoward medical occurrence, including any unfavorable and unintended sign, symptom or disease temporally associated with the use of the study medication that does not necessarily have a causal relationship with study medication. A serious AE (SAE) is an event that results in death, is life-threatening, requires or prolongs inpatient hospitalization, results in persistent or significant disability, is a congenital anomaly or defect, or is a significant medical event that may jeopardize the patient or require intervention to prevent one of the outcomes listed

	above.
Time Frame	25 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.
All Randomized Safety population.

Reporting Groups

	Description
Tobramycin Inhalation Powder (TIP)	Participants received four 28 mg capsules of tobramycin inhalation powder (TIP) delivered with the T-326 inhaler twice daily for 28 days followed by 28 days off therapy (one cycle) for a total of three cycles.
Tobramycin Solution for Inhalation (TOBI)	Participants received one 300 mg (in 5 mL) ampoule of tobramycin solution for inhalation (TOBI) delivered with a nebulizer twice daily for 28 days followed by 28 days off therapy (one cycle) for a total of three cycles.

Measured Values

	Tobramycin Inhalation Powder (TIP)	**Tobramycin Solution for Inhalation (TOBI)**
Number of Participants Analyzed [units: participants]	**308**	**209**
Number of Participants With Treatment-emergent Adverse Events [units: participants]		
Any adverse event	**278**	**176**
Serious adverse event	**85**	**61**

Death	**3**	**0**
Discontinued due to AE(s)	**46**	**17**
Discontinued due to SAE(s)	**14**	**6**

No statistical analysis provided for Number of Participants With Treatment-emergent Adverse Events

2. Secondary: Serum Tobramycin Concentrations [Time Frame: Weeks 1, 5, 17 and 21]

Measure Type	Secondary
Measure Title	Serum Tobramycin Concentrations
Measure Description	Serum tobramycin concentrations were measured in a subset of participants at Week 1 (start of cycle 1), Week 5 (End of Cycle 1), Week 17 (start of cycle 3) and Week 21 (end of cycle 3). Serum samples were collected at pre-dose and post-dose at specified intervals; one specimen between 0 to 2 hours; two additional specimens between 2 and 5 hours (sample times must have been a minimum of 2 hours apart).
Time Frame	Weeks 1, 5, 17 and 21
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.
Pharmacokinetic subpopulation

Reporting Groups

	Description
Tobramycin Inhalation Powder (TIP)	Participants received four 28 mg capsules of tobramycin inhalation powder (TIP) delivered with the T-326 inhaler twice daily for 28 days followed by 28 days off therapy (one cycle) for a total of three cycles.

Tobramycin Solution for Inhalation (TOBI)	Participants received one 300 mg (in 5 mL) ampoule of tobramycin solution for inhalation (TOBI) delivered with a nebulizer twice daily for 28 days followed by 28 days off therapy (one cycle) for a total of three cycles.

Measured Values

	Tobramycin Inhalation Powder (TIP)	Tobramycin Solution for Inhalation (TOBI)
Number of Participants Analyzed [units: participants]	**28**	**14**
Serum Tobramycin Concentrations [units: µg/mL] Mean (Standard Deviation)		
Week 1: Predose [N=28, 14]	**0.00 (0.02)**	**0.02 (0.05)**
Week 1: 0 to 2 hours [N=28, 14]	**0.82 (0.39)**	**0.61 (0.35)**
Week 1: 2 to 5 hours (1st sample) [N=26, 14]	**0.74 (0.34)**	**0.69 (0.39)**
Week 1: 2 to 5 hours (2nd sample) [N=25, 12]	**0.68 (0.24)**	**0.54 (0.25)**
Week 5: Predose [N=23, 13]	**0.47 (0.73)**	**0.21 (0.15)**
Week 5: 0 to 2 hours [N=23, 12]	**1.39 (0.80)**	**1.18 (0.72)**
Week 5: 2 to 5 hours (1st sample) [N=23, 11]	**1.41 (0.60)**	**1.08 (0.55)**
Week 5: 2 to 5 hours (2nd sample) [N=23, 8]	**1.09 (0.50)**	**0.83 (0.34)**
Week 17: Predose [N=24, 13]	**0.07 (0.22)**	**0.08 (0.25)**
Week 17: 0 to 2 hours [N=24, 13]	**0.75 (0.54)**	**0.87 (0.54)**
Week 17: 2 to 5 hours (1st sample) [N=24, 12]	**0.80 (0.34)**	**0.91 (0.64)**
Week 17: 2 to 5 hours (2nd sample) [N=23, 12]	**0.74 (0.30)**	**0.67 (0.40)**
Week 21: Predose [N=24, 13]	**0.36 (0.29)**	**0.24 (0.26)**
Week 21: 0 to 2 hours [N=24, 12]	**1.22 (0.57)**	**1.10 (0.64)**
Week 21: 2 to 5 hours (1st sample) [N=22, 12]	**1.19 (0.50)**	**1.02 (0.52)**

Week 21: 2 to 5 hours (2nd sample) [N=24, 11]	**1.03 (0.36)**	**0.84 (0.40)**

No statistical analysis provided for Serum Tobramycin Concentrations

3. Secondary: Percentage of Participants With a Decrease From Baseline in Auditory Acuity [Time Frame: Baseline and Day 28 of Cycles 1, 2 and 3 (Weeks 5, 13 and 21)]

Measure Type	Secondary
Measure Title	Percentage of Participants With a Decrease From Baseline in Auditory Acuity
Measure Description	Audiology testing was performed only at selected centers. Auditory acuity was measured from 250 to 8000 Hertz using a standard dual-channel audiometer.
Time Frame	Baseline and Day 28 of Cycles 1, 2 and 3 (Weeks 5, 13 and 21)
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.
Audiology subpopulation

Reporting Groups

	Description
Tobramycin Inhalation Powder (TIP)	Participants received four 28 mg capsules of tobramycin inhalation powder (TIP) delivered with the T-326 inhaler twice daily for 28 days followed by 28 days off therapy (one cycle) for a total of three cycles.
Tobramycin Solution for Inhalation (TOBI)	Participants received one 300 mg (in 5 mL) ampoule of tobramycin solution for inhalation (TOBI) delivered with a nebulizer twice daily for 28 days followed by 28 days off therapy (one cycle) for a total of three cycles.

Measured Values

	Tobramycin Inhalation Powder (TIP)	Tobramycin Solution for Inhalation (TOBI)
Number of Participants Analyzed [units: participants]	**73**	**42**
Percentage of Participants With a Decrease From Baseline in Auditory Acuity [units: percentage of participants]		
Cycle 1, Day 28 [N=60, 39]	**13.3**	**10.3**
Cycle 2, Day 28 [N=55, 34]	**12.7**	**0.0**
Cycle 3, Day 28 [N=54, 34]	**18.5**	**11.8**

No statistical analysis provided for Percentage of Participants With a Decrease From Baseline in Auditory Acuity

4. Secondary: Relative Change From Baseline in Percent Predicted Forced Expiratory Volume in One Second (%FEV1) [Time Frame: Baseline and Day 28 of Cycles 1, 2 and 3 (Weeks 5, 13 and 21) and Final Visit (Week 25)]

Measure Type	Secondary
Measure Title	Relative Change From Baseline in Percent Predicted Forced Expiratory Volume in One Second (%FEV1)
Measure Description	Forced expiratory volume in one second (FEV1) is the amount of air which can be forcibly exhaled from the lungs in the first second of a forced exhalation. FEV1 is then converted to a percentage of normal (percent predicted) based on height, weight, and race. FEV1 was measured at Baseline (prior to beginning study treatment) and predose on Day 28 of Cycles 1, 2 and 3 and at the follow-up visit. Relative change = 100 * ((Day 28 of Cycle 3 value – Baseline value)/ Baseline value).
Time Frame	Baseline and Day 28 of Cycles 1, 2 and 3 (Weeks 5, 13 and 21) and Final Visit (Week 25)
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Intent to treat population for patients with available data. For Final Visit, the last available post-baseline measurement is reported.

Reporting Groups

	Description
Tobramycin Inhalation Powder (TIP)	Participants received four 28 mg capsules of tobramycin inhalation powder (TIP) delivered with the T-326 inhaler twice daily for 28 days followed by 28 days off therapy (one cycle) for a total of three cycles.
Tobramycin Solution for Inhalation (TOBI)	Participants received one 300 mg (in 5 mL) ampoule of tobramycin solution for inhalation (TOBI) delivered with a nebulizer twice daily for 28 days followed by 28 days off therapy (one cycle) for a total of three cycles.

Measured Values

	Tobramycin Inhalation Powder (TIP)	**Tobramycin Solution for Inhalation (TOBI)**
Number of Participants Analyzed [units: participants]	**308**	**209**
Relative Change From Baseline in Percent Predicted Forced Expiratory Volume in One Second (%FEV1) [units: percent of predicted] Mean (Standard Deviation)		
Baseline [N=308, 209]	**52.9 (14.20)**	**52.8 (15.95)**
Change from Baseline at Week 5 [N=268, 194]	**2.8 (19.64)**	**3.6 (14.33)**
Change from Baseline at Week 13 [N=252, 178]	**2.3 (18.76)**	**4.3 (16.63)**
Change from Baseline at Week 21 [N=227, 171]	**3.1 (19.92)**	**2.3 (17.57)**
Change from Baseline: Final Visit [N=307, 209]	**-0.4 (17.15)**	**-1.6 (17.38)**

No statistical analysis provided for Relative Change From Baseline in Percent Predicted Forced Expiratory Volume in One Second (%FEV1)

5. Secondary: Patient Satisfaction Assessed Using the Treatment Satisfaction Questionnaire for Medication [Time Frame: Day 28 of Cycles 1, 2 and 3 (Weeks 5, 13 and 21).]

Measure Type	Secondary
Measure Title	Patient Satisfaction Assessed Using the Treatment Satisfaction Questionnaire for Medication
Measure Description	Patient's self-reported treatment satisfaction was measured using the Treatment Satisfaction Questionnaire for Medication (TSQM, a validated instrument) which was modified by adding four study-specific questions; the standard fourteen questions of the TSQM were not altered. Responses to nearly all items are rated on a five-point or seven-point rating scale and the items are factored into 4 domains. The TSQM domain scores range from 0 to 100 with higher scores representing higher satisfaction for that domain.
Time Frame	Day 28 of Cycles 1, 2 and 3 (Weeks 5, 13 and 21).
Safety Issue	No

Population Description

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

Reporting Groups

	Description
Tobramycin Inhalation Powder (TIP)	Participants received four 28 mg capsules of tobramycin inhalation powder (TIP) delivered with the T-326 inhaler twice daily for 28 days followed by 28 days off therapy (one cycle) for a total of three cycles.
Tobramycin Solution for Inhalation (TOBI)	Participants received one 300 mg (in 5 mL) ampoule of tobramycin solution for inhalation (TOBI) delivered with a nebulizer twice daily for 28 days followed by 28 days off therapy (one cycle) for a

	total of three cycles.

Measured Values

	Tobramycin Inhalation Powder (TIP)	Tobramycin Solution for Inhalation (TOBI)
Number of Participants Analyzed [units: participants]	**308**	**209**
Patient Satisfaction Assessed Using the Treatment Satisfaction Questionnaire for Medication [units: Scores on a scale] Mean (Standard Deviation)		
Cycle 1: Effectiveness [N=264, 189]	**74.1 (17.29)**	**64.6 (18.63)**
Cycle 1: Side Effects [N=263, 190]	**92.1 (15.58)**	**92.4 (15.99)**
Cycle 1: Convenience [N=264, 190]	**82.3 (14.95)**	**58.1 (20.64)**
Cycle 1: Global Satisfaction [N=264, 190]	**75.4 (20.19)**	**20.19 (18.67)**
Cycle 2: Effectiveness [N=241, 170]	**74.5 (17.62)**	**64.6 (17.42)**
Cycle 2: Side Effects [N=239, 170]	**93.6 (14.06)**	**93.8 (13.41)**
Cycle 2:Convenience [N=241, 170]	**81.1 (16.61)**	**57.0 (20.40)**
Cycle 2: Global Satisfaction [N=241, 170]	**76.6 (19.16)**	**70.2 (19.40)**
Cycle 3: Effectiveness [N=221, 162]	**74.9 (20.25)**	**65.5 (17.42)**
Cycle 3: Side Effects [N=215, 158]	**91.5 (17.78)**	**94.1 (14.48)**
Cycle 3: Convenience [N=221, 162]	**81.6 (16.89)**	**56.6 (20.90)**
Cycle 3: Global Satisfaction [N=221, 162]	**75.2 (24.00)**	**72.2 (17.90)**

No statistical analysis provided for Patient Satisfaction Assessed Using the Treatment Satisfaction Questionnaire for Medication

6. Secondary: Change From Baseline in Pseudomonas Aeruginosa Sputum Density [Time Frame: Baseline and Day 28 of Cycles 1, 2 and 3 (Weeks 5, 13 and 21) and Final Visit (Week 25).]

Measure Type	Secondary
Measure Title	Change From Baseline in Pseudomonas Aeruginosa Sputum Density
Measure Description	Three Pseudomonas aeruginosa biotypes were assessed in patient's sputum; mucoid, dry and small colony variant. Overall density is defined as the sum of all bio-types in Pseudomonas aeruginosa density.
Time Frame	Baseline and Day 28 of Cycles 1, 2 and 3 (Weeks 5, 13 and 21) and Final Visit (Week 25).
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Intent to treat population for patients with available data. For Final Visit, the last available post-baseline measurement is reported.

Reporting Groups

	Description
Tobramycin Inhalation Powder (TIP)	Participants received four 28 mg capsules of tobramycin inhalation powder (TIP) delivered with the T-326 inhaler twice daily for 28 days followed by 28 days off therapy (one cycle) for a total of three cycles.
Tobramycin Solution for Inhalation (TOBI)	Participants received one 300 mg (in 5 mL) ampoule of tobramycin solution for inhalation (TOBI) delivered with a nebulizer twice daily for 28 days followed by 28 days off therapy (one cycle) for a total of three cycles.

Measured Values

	Tobramycin Inhalation Powder (TIP)	**Tobramycin Solution for Inhalation (TOBI)**
Number of Participants Analyzed		

[units: participants]	**308**	**209**
Change From Baseline in Pseudomonas Aeruginosa Sputum Density [units: log10 Colony forming units/g] Mean (Standard Deviation)		
Baseline [N=279, 192]	**7.23 (1.49)**	**7.35 (1.54)**
Change from Baseline at Week 5 [N=202, 145]	**-1.76 (1.96)**	**-1.32 (2.03)**
Change from Baseline at Week 13 [N=170, 125]	**-1.54 (1.99)**	**-1.11 (1.91)**
Change from Baseline at Week 21 [N= 157, 126]	**-1.61 (2.03)**	**-0.77 (1.78)**
Change from Baseline: Final Visit [N=263, 179]	**-0.53 (1.92)**	**-0.33 (1.71)**

No statistical analysis provided for Change From Baseline in Pseudomonas Aeruginosa Sputum Density

7. Secondary: Change From Baseline in Tobramycin Minimum Inhibitory Concentration [Time Frame: Baseline and Day 28 of Cycles 1, 2 and 3 (Weeks 5, 13 and 21) and Final Visit (Week 25)]

Measure Type	Secondary
Measure Title	Change From Baseline in Tobramycin Minimum Inhibitory Concentration
Measure Description	The minimum inhibitory concentration (MIC) is the lowest concentration of an antimicrobial that will inhibit the visible growth of a microorganism after overnight incubation. The MIC of tobramycin against total Pseudomonas aeruginosa colonization was assessed over the course of the study.
Time Frame	Baseline and Day 28 of Cycles 1, 2 and 3 (Weeks 5, 13 and 21) and Final Visit (Week 25)
Safety Issue	No

Population Description

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

Intent to treat population for patients with available data. For Final Visit, the last available post-baseline measurement is reported.

Reporting Groups

	Description
Tobramycin Inhalation Powder (TIP)	Participants received four 28 mg capsules of tobramycin inhalation powder (TIP) delivered with the T-326 inhaler twice daily for 28 days followed by 28 days off therapy (one cycle) for a total of three cycles.
Tobramycin Solution for Inhalation (TOBI)	Participants received one 300 mg (in 5 mL) ampoule of tobramycin solution for inhalation (TOBI) delivered with a nebulizer twice daily for 28 days followed by 28 days off therapy (one cycle) for a total of three cycles.

Measured Values

	Tobramycin Inhalation Powder (TIP)	Tobramycin Solution for Inhalation (TOBI)
Number of Participants Analyzed [units: participants]	**308**	**209**
Change From Baseline in Tobramycin Minimum Inhibitory Concentration [units: µg/mL] Mean (Standard Deviation)		
Baseline [N=308, 208]	**35.39 (107.58)**	**42.45 (116.40)**
Change from Baseline at Week 5 [N=239, 173]	**38.47 (148.34)**	**5.80 (112.96)**
Change from Baseline at Week 8 [N=215, 157]	**35.59 (148.03)**	**20.68 (130.57)**
Change from Baseline at Week 21 [N=199, 154]	**29.83 (139.85)**	**14.13 (117.54)**
Change from Baseline: Final Visit [N=298, 202]	**30.89 (139.63)**	**3.27 (107.80)**

No statistical analysis provided for Change From Baseline in Tobramycin Minimum Inhibitory Concentration

8. Secondary: Antipseudomonal Antibiotic Usage During the Study [Time Frame: 25 Weeks]

Measure Type	Secondary
Measure Title	Antipseudomonal Antibiotic Usage During the Study
Measure Description	The average number of days patients required antipseudomonal antibiotics during the course of the study.
Time Frame	25 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.
Patients in the intent-to-treat population who required antipseudomonal antibiotics.

Reporting Groups

	Description
Tobramycin Inhalation Powder (TIP)	Participants received four 28 mg capsules of tobramycin inhalation powder (TIP) delivered with the T-326 inhaler twice daily for 28 days followed by 28 days off therapy (one cycle) for a total of three cycles.
Tobramycin Solution for Inhalation (TOBI)	Participants received one 300 mg (in 5 mL) ampoule of tobramycin solution for inhalation (TOBI) delivered with a nebulizer twice daily for 28 days followed by 28 days off therapy (one cycle) for a total of three cycles.

Measured Values

	Tobramycin Inhalation Powder (TIP)	**Tobramycin Solution for Inhalation (TOBI)**
Number of Participants Analyzed [units: participants]	**202**	**115**
Antipseudomonal Antibiotic Usage During the Study		

[units: days] Mean (Standard Deviation)	**34.5 (31.24)**	**40.1 (37.27)**

No statistical analysis provided for Antipseudomonal Antibiotic Usage During the Study

9. Secondary: Hospitalization Due to Respiratory Events During the Study [Time Frame: 25 Weeks]

Measure Type	Secondary
Measure Title	Hospitalization Due to Respiratory Events During the Study
Measure Description	The average number of days patients were hospitalized due to respiratory events during the course of the study.
Time Frame	25 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.
Patients in the intent-to-treat population who were hospitalized due to respiratory events.

Reporting Groups

	Description
Tobramycin Inhalation Powder (TIP)	Participants received four 28 mg capsules of tobramycin inhalation powder (TIP) delivered with the T-326 inhaler twice daily for 28 days followed by 28 days off therapy (one cycle) for a total of three cycles.
Tobramycin Solution for Inhalation (TOBI)	Participants received one 300 mg (in 5 mL) ampoule of tobramycin solution for inhalation (TOBI) delivered with a nebulizer twice daily for 28 days followed by 28 days off therapy (one cycle) for a total of three cycles.

Measured Values

	Tobramycin Inhalation Powder (TIP)	Tobramycin Solution for Inhalation (TOBI)
Number of Participants Analyzed [units: participants]	**75**	**46**
Hospitalization Due to Respiratory Events During the Study [units: days] Mean (Standard Deviation)	**15.6 (13.31)**	**15.3 (10.23)**

No statistical analysis provided for Hospitalization Due to Respiratory Events During the Study

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	No text entered.
Additional Description	No text entered.

Reporting Groups

	Description
Tobramycin Inhalation Powder (TIP)	Participants received four 28 mg capsules of tobramycin inhalation powder (TIP) delivered with the T-326 inhaler twice daily for 28 days followed by 28 days off therapy (one cycle) for a total of three cycles.
Tobramycin Solution for Inhalation (TOBI)	Participants received one 300 mg (in 5 mL) ampoule of tobramycin solution for inhalation (TOBI) delivered with a nebulizer twice daily for 28 days followed by 28 days off therapy (one cycle) for a total of three cycles.

Serious Adverse Events

	Tobramycin Inhalation Powder	Tobramycin Solution for Inhalation

	(TIP)	(TOBI)
Total, serious adverse events		
# participants affected / at risk	**85/308 (27.60%)**	**61/209 (29.19%)**
Congenital, familial and genetic disorders		
Cystic fibrosis lung † [1]		
# participants affected / at risk	**2/308 (0.65%)**	**2/209 (0.96%)**
Gastrointestinal disorders		
Abdominal pain † [1]		
# participants affected / at risk	**1/308 (0.32%)**	**1/209 (0.48%)**
Crohn's disease † [1]		
# participants affected / at risk	**0/308 (0.00%)**	**1/209 (0.48%)**
Diarrhoea † [1]		
# participants affected / at risk	**1/308 (0.32%)**	**0/209 (0.00%)**
Distal ileal obstruction syndrome † [1]		
# participants affected / at risk	**1/308 (0.32%)**	**0/209 (0.00%)**
Distal intestinal obstruction syndrome † [1]		
# participants affected / at risk	**1/308 (0.32%)**	**1/209 (0.48%)**
Frequent bowel movements † [1]		
# participants affected / at risk	**1/308 (0.32%)**	**0/209 (0.00%)**
Nausea † [1]		
# participants affected / at risk	**0/308 (0.00%)**	**1/209 (0.48%)**
Pancreatic insufficiency † [1]		
# participants affected / at risk	**0/308 (0.00%)**	**1/209 (0.48%)**
Pancreatitis † [1]		
# participants affected / at risk	**0/308 (0.00%)**	**1/209 (0.48%)**

Vomiting † [1]		
# participants affected / at risk	**0/308 (0.00%)**	**1/209 (0.48%)**
General disorders		
Chest pain † [1]		
# participants affected / at risk	**1/308 (0.32%)**	**0/209 (0.00%)**
Fatigue † [1]		
# participants affected / at risk	**3/308 (0.97%)**	**0/209 (0.00%)**
Pyrexia † [1]		
# participants affected / at risk	**1/308 (0.32%)**	**2/209 (0.96%)**
Hepatobiliary disorders		
Cholelithiasis † [1]		
# participants affected / at risk	**0/308 (0.00%)**	**1/209 (0.48%)**
Hepatosplenomegaly † [1]		
# participants affected / at risk	**1/308 (0.32%)**	**0/209 (0.00%)**
Infections and infestations		
Appendicitis † [1]		
# participants affected / at risk	**1/308 (0.32%)**	**0/209 (0.00%)**
Bronchitis † [1]		
# participants affected / at risk	**6/308 (1.95%)**	**1/209 (0.48%)**
Bronchopneumonia † [1]		
# participants affected / at risk	**1/308 (0.32%)**	**2/209 (0.96%)**
Bronchopulmonary aspergillosis allergic † [1]		
# participants affected / at risk	**0/308 (0.00%)**	**1/209 (0.48%)**
Influenza † [1]		
# participants affected / at risk	**1/308 (0.32%)**	**0/209 (0.00%)**

Lower respiratory tract infection † 1		
# participants affected / at risk	**2/308 (0.65%)**	**2/209 (0.96%)**
Lung abscess † 1		
# participants affected / at risk	**1/308 (0.32%)**	**1/209 (0.48%)**
Lung infection pseudomonal † 1		
# participants affected / at risk	**2/308 (0.65%)**	**1/209 (0.48%)**
Pneumonia † 1		
# participants affected / at risk	**2/308 (0.65%)**	**2/209 (0.96%)**
Pneumonia bacterial † 1		
# participants affected / at risk	**2/308 (0.65%)**	**2/209 (0.96%)**
Pseudomonas bronchitis † 1		
# participants affected / at risk	**1/308 (0.32%)**	**0/209 (0.00%)**
Pseudomonas infection † 1		
# participants affected / at risk	**1/308 (0.32%)**	**2/209 (0.96%)**
Respiratory tract infection † 1		
# participants affected / at risk	**1/308 (0.32%)**	**1/209 (0.48%)**
Sinusitis † 1		
# participants affected / at risk	**2/308 (0.65%)**	**1/209 (0.48%)**
Upper respiratory tract infection † 1		
# participants affected / at risk	**1/308 (0.32%)**	**0/209 (0.00%)**
Urinary tract infection † 1		
# participants affected / at risk	**1/308 (0.32%)**	**0/209 (0.00%)**
Injury, poisoning and procedural complications		
Accidental overdose † 1		
# participants affected / at risk	**1/308 (0.32%)**	**0/209 (0.00%)**

Ulna fracture † 1		
# participants affected / at risk	**0/308 (0.00%)**	**1/209 (0.48%)**
Investigations		
Blood glucose increased † 1		
# participants affected / at risk	**1/308 (0.32%)**	**0/209 (0.00%)**
Chest X-ray abnormal † 1		
# participants affected / at risk	**0/308 (0.00%)**	**1/209 (0.48%)**
Forced expiratory volume decreased † 1		
# participants affected / at risk	**1/308 (0.32%)**	**1/209 (0.48%)**
Oxygen saturation † 1		
# participants affected / at risk	**1/308 (0.32%)**	**0/209 (0.00%)**
Pulmonary function test decreased † 1		
# participants affected / at risk	**4/308 (1.30%)**	**3/209 (1.44%)**
Weight decreased † 1		
# participants affected / at risk	**0/308 (0.00%)**	**3/209 (1.44%)**
Metabolism and nutrition disorders		
Decreased appetite † 1		
# participants affected / at risk	**1/308 (0.32%)**	**0/209 (0.00%)**
Dehydration † 1		
# participants affected / at risk	**0/308 (0.00%)**	**1/209 (0.48%)**
Hypoglycaemia † 1		
# participants affected / at risk	**0/308 (0.00%)**	**1/209 (0.48%)**
Malnutrition † 1		
# participants affected / at risk	**0/308 (0.00%)**	**1/209 (0.48%)**
Musculoskeletal and connective tissue disorders		

Musculoskeletal chest pain † 1		
# participants affected / at risk	**1/308 (0.32%)**	**0/209 (0.00%)**
Myalgia † 1		
# participants affected / at risk	**1/308 (0.32%)**	**0/209 (0.00%)**
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		
Benign lung neoplasm † 1		
# participants affected / at risk	**0/308 (0.00%)**	**1/209 (0.48%)**
Nervous system disorders		
Cervicobrachial syndrome † 1		
# participants affected / at risk	**1/308 (0.32%)**	**0/209 (0.00%)**
Headache † 1		
# participants affected / at risk	**1/308 (0.32%)**	**0/209 (0.00%)**
Sinus headache † 1		
# participants affected / at risk	**1/308 (0.32%)**	**0/209 (0.00%)**
Psychiatric disorders		
Depression † 1		
# participants affected / at risk	**0/308 (0.00%)**	**1/209 (0.48%)**
Panic attack † 1		
# participants affected / at risk	**1/308 (0.32%)**	**0/209 (0.00%)**
Respiratory, thoracic and mediastinal disorders		
Asthma † 1		
# participants affected / at risk	**1/308 (0.32%)**	**0/209 (0.00%)**
Bronchiectasis † 1		
# participants affected / at risk	**0/308 (0.00%)**	**2/209 (0.96%)**

Cough † [1]		
# participants affected / at risk	**7/308 (2.27%)**	**5/209 (2.39%)**
Dyspnoea † [1]		
# participants affected / at risk	**5/308 (1.62%)**	**4/209 (1.91%)**
Dyspnoea exertional † [1]		
# participants affected / at risk	**2/308 (0.65%)**	**0/209 (0.00%)**
Epistaxis † [1]		
# participants affected / at risk	**2/308 (0.65%)**	**1/209 (0.48%)**
Haemoptysis † [1]		
# participants affected / at risk	**8/308 (2.60%)**	**4/209 (1.91%)**
Hypoxia † [1]		
# participants affected / at risk	**0/308 (0.00%)**	**2/209 (0.96%)**
Increased bronchial secretion † [1]		
# participants affected / at risk	**1/308 (0.32%)**	**0/209 (0.00%)**
Lung consolidation † [1]		
# participants affected / at risk	**1/308 (0.32%)**	**0/209 (0.00%)**
Lung disorder † [1]		
# participants affected / at risk	**60/308 (19.48%)**	**39/209 (18.66%)**
Nasal congestion † [1]		
# participants affected / at risk	**1/308 (0.32%)**	**0/209 (0.00%)**
Pleuritic pain † [1]		
# participants affected / at risk	**0/308 (0.00%)**	**1/209 (0.48%)**
Pneumonitis † [1]		
# participants affected / at risk	**1/308 (0.32%)**	**0/209 (0.00%)**
Pneumothorax † [1]		
# participants affected / at risk	**1/308 (0.32%)**	**0/209 (0.00%)**

Productive cough † 1		
# participants affected / at risk	**0/308 (0.00%)**	**1/209 (0.48%)**
Pulmonary congestion † 1		
# participants affected / at risk	**1/308 (0.32%)**	**1/209 (0.48%)**
Rales † 1		
# participants affected / at risk	**1/308 (0.32%)**	**0/209 (0.00%)**
Sputum discoloured † 1		
# participants affected / at risk	**1/308 (0.32%)**	**0/209 (0.00%)**
Sputum increased † 1		
# participants affected / at risk	**5/308 (1.62%)**	**1/209 (0.48%)**
Skin and subcutaneous tissue disorders		
Rash † 1		
# participants affected / at risk	**0/308 (0.00%)**	**1/209 (0.48%)**

† Events were collected by systematic assessment
1 Term from vocabulary, MedDRA 14.0

Other Adverse Events

Hide Other Adverse Events

Time Frame	No text entered.
Additional Description	No text entered.

Frequency Threshold

Threshold above which other adverse events are reported	5%

Reporting Groups

	Description
Tobramycin Inhalation Powder (TIP)	Participants received four 28 mg capsules of tobramycin inhalation powder (TIP) delivered with the T-326 inhaler twice daily for 28 days followed by 28 days off therapy (one cycle) for a total of three cycles.
Tobramycin Solution for Inhalation (TOBI)	Participants received one 300 mg (in 5 mL) ampoule of tobramycin solution for inhalation (TOBI) delivered with a nebulizer twice daily for 28 days followed by 28 days off therapy (one cycle) for a total of three cycles.

Other Adverse Events

	Tobramycin Inhalation Powder (TIP)	Tobramycin Solution for Inhalation (TOBI)
Total, other (not including serious) adverse events		
# participants affected / at risk	**241/308 (78.25%)**	**148/209 (70.81%)**
Gastrointestinal disorders		
Abdominal pain † [1]		
# participants affected / at risk	**12/308 (3.90%)**	**17/209 (8.13%)**
Nausea † [1]		
# participants affected / at risk	**23/308 (7.47%)**	**19/209 (9.09%)**
Vomiting † [1]		
# participants affected / at risk	**19/308 (6.17%)**	**11/209 (5.26%)**
General disorders		
Chest discomfort † [1]		
# participants affected / at risk	**20/308 (6.49%)**	**6/209 (2.87%)**
Fatigue † [1]		
# participants affected / at risk	**18/308 (5.84%)**	**10/209 (4.78%)**
Pyrexia † [1]		

# participants affected / at risk	47/308 (15.26%)	25/209 (11.96%)
Infections and infestations		
Sinusitis † [1]		
# participants affected / at risk	17/308 (5.52%)	15/209 (7.18%)
Upper respiratory tract infection † [1]		
# participants affected / at risk	21/308 (6.82%)	18/209 (8.61%)
Investigations		
Pulmonary function test decreased † [1]		
# participants affected / at risk	18/308 (5.84%)	14/209 (6.70%)
Nervous system disorders		
Headache † [1]		
# participants affected / at risk	34/308 (11.04%)	25/209 (11.96%)
Respiratory, thoracic and mediastinal disorders		
Cough † [1]		
# participants affected / at risk	145/308 (47.08%)	63/209 (30.14%)
Dysphonia † [1]		
# participants affected / at risk	42/308 (13.64%)	8/209 (3.83%)
Dyspnoea † [1]		
# participants affected / at risk	44/308 (14.29%)	22/209 (10.53%)
Haemoptysis † [1]		
# participants affected / at risk	35/308 (11.36%)	23/209 (11.00%)
Lung disorder † [1]		
# participants affected / at risk	57/308 (18.51%)	33/209 (15.79%)
Nasal congestion † [1]		
# participants affected / at risk	25/308 (8.12%)	15/209 (7.18%)

Oropharyngeal pain † 1		
# participants affected / at risk	**43/308 (13.96%)**	**22/209 (10.53%)**
Pulmonary congestion † 1		
# participants affected / at risk	**17/308 (5.52%)**	**8/209 (3.83%)**
Rales † 1		
# participants affected / at risk	**21/308 (6.82%)**	**13/209 (6.22%)**
Rhinorrhoea † 1		
# participants affected / at risk	**22/308 (7.14%)**	**15/209 (7.18%)**
Sputum increased † 1		
# participants affected / at risk	**49/308 (15.91%)**	**35/209 (16.75%)**
Wheezing † 1		
# participants affected / at risk	**21/308 (6.82%)**	**13/209 (6.22%)**

† Events were collected by systematic assessment
1 Term from vocabulary, MedDRA 14.0

Limitations and Caveats

Hide Limitations and Caveats

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

More Information

Hide More Information

Certain Agreements:

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

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

The agreement is:

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

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

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

☑ **Restriction Description:** The terms and conditions of Novartis' agreements with its investigators may vary. However, Novartis does not prohibit any investigator from publishing. Any publications from a single-site are postponed until the publication of the pooled data (i.e., data from all sites) in the clinical trial.

Results Point of Contact:

Name/Title: Study Director
Organization: Novartis Pharmaceuticals
phone: 862-778-8300

No publications provided

Responsible Party:	Novartis (Novartis Pharmaceuticals)
ClinicalTrials.gov Identifier:	NCT00388505 History of Changes
Other Study ID Numbers:	**CTBM100C2302**
Study First Received:	October 16, 2006
Results First Received:	June 19, 2012
Last Updated:	June 19, 2012
Health Authority:	United States: Food and Drug Administration France: Agence Française de Sécurité Sanitaire des produits de Santé

Germany: Federal Institute for Drugs and Medical Devices
Italy: Agenzia Italiana del Farmaco
Netherlands: College ter beoordeling van geneesmiddelen Medicines Evaluation Board
Spain: Ministerio de Sanidad y Consumo, Agencia Española del Medicamento y Productos Sanitarios
United Kingdom: Medicines and Healthcare Products Regulatory Agency