Trial record **1 of 1** for: tr02-107

Previous Study | Return to List | Next Study

Safety and Tolerability Study of 2 Dose Level of Arikayce™ in Patients With Bronchiectasis and Chronic Infection Due to Pseudomonas Aeruginosa.

ClinicalTrials.gov Identifier: NCT00775138

Recruitment Status : Completed
First Posted : October 17, 2008
Results First Posted : July 10, 2019
Last Update Posted : July 10, 2019

Sponsor:
Insmed Incorporated

Information provided by (Responsible Party):
Insmed Incorporated

Study Type	Interventional
Study Design	Allocation: Randomized; Intervention Model: Parallel Assignment; Masking: Triple (Participant, Care Provider, Investigator); Primary Purpose: Treatment
Condition	Bronchiectasis
Interventions	Drug: 280 mg Arikayce™ Drug: Matching Placebo for Cohort 1 Drug: 560 mg Arikayce™ Drug: Matching Placebo for Cohort 2
Enrollment	64

Participant Flow

Go to

Recruitment Details	
Pre-assignment Details	

Arm/Group Title	Arikayce™ at 280 mg	Matching Placebo (280 mg)	Arikayce™ at 560 mg	Matching Placebo (560 mg)
Arm/Group Description	Study subjects will receive Arikayce™ 280 mg on Days 1-28.	Study subjects will receive matching placebo on Days 1-28.	Study subjects will receive Arikayce™ 560 mg on Days 1-28.	Study subjects will receive matching placebo on Days 1-28.
Period Title: **Overall Study**				
Started	24	10	20	10
Completed	24	10	17	8
Not Completed	0	0	3	2

Not Completed	0	0	3	2
Reason Not Completed				
Withdrawal by Subject	0	0	2	2
Adverse Event	0	0	1	0

Baseline Characteristics

Go to

Arm/Group Title		Arikayce™ at 280 mg	Matching Placebo (280 mg)	Arikayce™ at 560 mg	Matching Placebo (560 mg)	Total
▼ Arm/Group Description		Study subjects will receive Arikayce™ 280 mg on Days 1-28.	Study subjects will receive matching placebo on Days 1-28.	Study subjects will receive Arikayce™ 560 mg on Days 1-28.	Study subjects will receive matching placebo on Days 1-28.	Total of all reporting groups
Overall Number of Baseline Participants		24	10	19	9	62
▼ Baseline Analysis Population Description		Modified intent-to-treat (mITT) population, defined as all randomized patients who received at least 1 dose of study drug.				
Age, Continuous Mean (Standard Deviation) Unit of measure: Years						
	Number Analyzed	24 participants	10 participants	19 participants	9 participants	62 participants
		49.9 (21.1)	46.8 (15.0)	58.5 (16.0)	52.3 (11.1)	52.4 (17.7)
Sex: Female,						

Male Measure Type: Count of Participants Unit of measure: Participants						
	Number Analyzed	24 participants	10 participants	19 participants	9 participants	62 participants
	Female	10 41.7%	4 40.0%	11 57.9%	5 55.6%	30 48.4%
	Male	14 58.3%	6 60.0%	8 42.1%	4 44.4%	32 51.6%

Outcome Measures

Go to

1. Primary Outcome

Title	Number of Participants Reporting Treatment-emergent AEs (TEAEs) up to End of Treatment
▼ Description	Number of Subjects reporting TEAE in the Arikayce™ groups and the placebo groups during the study. The table shows the events incidents, not the number of participants.
Time Frame	Day 1 through 56.

▼ Outcome Measure Data

▼ Analysis Population Description
Safety population, the same as the mITT population, defined as all randomized patients who received at least 1 dose of study drug.

Arm/Group Title	Arikace™ 280 mg	Matching Placebo (280 mg)	Arikace™ 560 mg	Matching Placebo (560 mg)

▼ Arm/Group Description:	Study subjects will receive Arikace™ 280 mg on Days 1-28.		Study subjects will receive matching placebo on Days 1-28.		Study subjects will receive Arikace™ 560 mg on Days 1-28.		Study subjects will receive matching placebo on Days 1-28.	
Overall Number of Participants Analyzed	24		10		19		9	
Measure Type: Count of Participants Unit of Measure: Participants								
Productive Cough	2	8.3%	3	30.0%	2	10.5%	3	33.3%
Bronchial disorder	3	12.5%	0	0.0%	1	5.3%	0	0.0%
Cough	1	4.2%	2	20.0%	5	26.3%	0	0.0%
Haemoptysis	2	8.3%	1	10.0%	1	5.3%	0	0.0%
Pyrexia	2	8.3%	1	10.0%	1	5.3%	2	22.2%
Wheezing	1	4.2%	2	20.0%	1	5.3%	0	0.0%
Dyspnoea	0	0.0%	2	20.0%	3	15.8%	1	11.1%
Headache	1	4.2%	1	10.0%	4	21.1%	1	11.1%
Nasopharyngitis	1	4.2%	1	10.0%	1	5.3%	0	0.0%
Sneezing	0	0.0%	2	20.0%	0	0.0%	0	0.0%
Agitation	1	4.2%	0	0.0%	0	0.0%	0	0.0%
Aphthous stomatitis	0	0.0%	1	10.0%	0	0.0%	0	0.0%
Arthralgia	1	4.2%	0	0.0%	0	0.0%	0	0.0%
Cervicobrachial syndrome	0	0.0%	1	10.0%	0	0.0%	0	0.0%

Chronic obstructive pulmonary disease	1	4.2%	0	0.0%	0	0.0%	0	0.0%
Dizziness	0	0.0%	1	10.0%	1	5.3%	0	0.0%
Dysgeusia	1	4.2%	0	0.0%	0	0.0%	0	0.0%
Dysphonia	1	4.2%	0	0.0%	2	10.5%	0	0.0%
Forced expiratory volume decreased	1	4.2%	0	0.0%	0	0.0%	0	0.0%
Pharyngolaryngeal pain	1	4.2%	0	0.0%	0	0.0%	0	0.0%
Pruritus	0	0.0%	1	10.0%	0	0.0%	0	0.0%
Rash	0	0.0%	1	10.0%	0	0.0%	0	0.0%
Rhinorrhoea	0	0.0%	1	10.0%	0	0.0%	1	11.1%
Sinus bradycardia	0	0.0%	1	10.0%	0	0.0%	0	0.0%
Tinnitus	1	4.2%	0	0.0%	0	0.0%	0	0.0%
Toothache	1	4.2%	0	0.0%	0	0.0%	0	0.0%
Upper respiratory tract infection	1	4.2%	0	0.0%	1	5.3%	0	0.0%
Anorexia	0	0.0%	0	0.0%	1	5.3%	1	11.1%
Bronchiectasis	0	0.0%	0	0.0%	1	5.3%	1	11.1%
Fatigue	0	0.0%	0	0.0%	1	5.3%	1	11.1%
Insomnia	0	0.0%	0	0.0%	1	5.3%	1	11.1%
Abortion incomplete	0	0.0%	0	0.0%	1	5.3%	0	0.0%
Blood creatinine increased	0	0.0%	0	0.0%	1	5.3%	0	0.0%
Constipation	0	0.0%	0	0.0%	0	0.0%	1	11.1%
Laryngitis	0	0.0%	0	0.0%	1	5.3%	0	0.0%
Lung abscess	0	0.0%	0	0.0%	0	0.0%	1	11.1%

Nausea	0	0.0%	0	0.0%	1	5.3%	0	0.0%
Palpitations	0	0.0%	0	0.0%	1	5.3%	0	0.0%

2. Primary Outcome

Title	Treatment-emergent Marked Laboratory Abnormalities up to 28 Days After Study Medication Discontinuation
▼ Description	Number of subjects reporting Incidence of clinically significant abnormalities in clinical values (Common Terminology Criteria for Adverse Events [CTCAE] grade >= 3) in Arikayce™ and placebo groups.
Time Frame	Day 1 through 56.

▼ Outcome Measure Data

▼ Analysis Population Description
The safety population is the mITT population.

Arm/Group Title	Arikace™ 280 mg	Matching Placebo (280 mg)	Arikace™ 560 mg	Matching Placebo (560 mg)
▼ Arm/Group Description:	Study subjects will receive Arikace™ 280 mg on Days 1-28.	Study subjects will receive matching placebo on Days 1-28.	Study subjects will receive Arikace™ 560 mg on Days 1-28.	Study subjects will receive matching placebo on Days 1-28.
Overall Number of Participants Analyzed	24	10	19	9
Measure Type: Count of Participants Unit of Measure: Participants				
Leukocytes	1 4.2%	0 0.0%	0 0.0%	0 0.0%
Neutrophils Abs	4 16.7%	0 0.0%	1 5.3%	0 0.0%

Sodium	1	4.2%	0	0.0%	0	0.0%	0	0.0%
Uric acid	0	0.0%	1	10.0%	1	5.3%	1	11.1%

3. Primary Outcome

Title	Treatment-emergent Pulmonary Function Test (PFT) for Acute Tolerability Assessment
▼ Description	Changes in PFT from pre-dose during the study were measured on Days 1, 14, and 28. Acute tolerability of the study treatment was assessed by examining the relative (rel.) changes in FEV1 from pre-dose assessments to 0-1 hour post-dose and 2-4 hours post-dose for each time point at which post-dose spirometry was conducted.
Time Frame	Pre-dose, 0-1 hour post-dose and 2-4 hours post-dose on day 1, 0-1 hour post-dose and 2-4 hours post-dose on day 14, and 0-1 hour post-dose and 2-4 hours post-dose on day 28

▼ Outcome Measure Data

▼ Analysis Population Description

The analysis population is the safety population, the same as the mITT population, defined as all randomized patients who received at least 1 dose of study drug.

Arm/Group Title	Arikace™ 280 mg	Matching Placebo (280 mg)	Arikace™ 560 mg	Matching Placebo (560 mg)
▼ Arm/Group Description:	Study subjects will receive Arikace™ 280 mg on Days 1-28.	Study subjects will receive matching placebo on Days 1-28.	Study subjects will receive Arikace™ 560 mg on Days 1-28.	Study subjects will receive matching placebo on Days 1-28.
Overall Number of Participants Analyzed	24	10	19	9
Mean (Standard Deviation) Unit of Measure: L				
Day 1: Pre-Dose	1.917 (0.703)	1.841 (0.536)	1.939 (0.515)	1.758 (0.654)

Day 1: Pre-Dose	1.917 (0.793)	1.841 (0.536)	1.939 (0.515)	1.758 (0.654)
Day 1: 0 - 1 Hr Post-Dose	1.922 (0.780)	1.820 (0.546)	1.907 (0.475)	1.807 (0.666)
Day 1: 2 - 4 Hrs Post-Dose	1.955 (0.766)	1.864 (0.520)	1.912 (0.477)	1.812 (0.675)
Day1:0-1 Hr Post-Dose Rel. Change from Pre-dose	0.816 (9.317)	-1.186 (3.028)	-0.873 (9.640)	3.128 (12.088)
Day1:2-4 Hrs Post-Dose Rel. Change from Pre-dose	3.323 (11.181)	1.484 (3.507)	-0.661 (8.374)	3.082 (11.671)
Day 14: Pre-Dose	1.892 (0.759)	1.761 (0.550)	1.864 (0.607)	1.895 (0.592)
Day 14: 0 - 1 Hr Post-Dose	1.907 (0.776)	1.794 (0.556)	1.856 (0.555)	1.908 (0.611)
Day 14: 2 - 4 Hr Post-Dose	1.931 (0.771)	1.797 (0.520)	1.843 (0.567)	1.901 (0.542)
Day14:0-1 Hr Post-Dose Rel. Change from Pre-dose	0.800 (8.818)	2.061 (4.509)	-1.629 (9.961)	0.589 (4.558)
Day14:2-4 Hr Post-Dose Rel. Change from Pre-dose	2.388 (9.020)	2.711 (6.620)	-3.114 (8.506)	1.228 (9.617)
Day 28: Pre-Dose	1.919 (0.761)	1.794 (0.507)	1.846 (0.532)	1.934 (0.560)
Day 28: 0 - 1 Hr Post-Dose	1.928 (0.751)	1.803 (0.502)	1.797 (0.541)	1.901 (0.550)
Day 28: 2 - 4 Hrs Post-Dose	1.908 (0.754)	1.809 (0.527)	1.799 (0.578)	1.940 (0.641)
Day 28:0-1 Hr Post-Dose Rel. Change	0.635 (7.647)	0.654 (3.675)	0.607 (4.185)	-1.437 (6.454)

from Pre-dose				
Day 28:2-4 Hrs Post-Dose Rel. Change from Pre-dose	-0.356 (8.858)	0.601 (3.184)	-0.006 (6.156)	-0.542 (7.690)

4. Primary Outcome

Title	Treatment-emergent PFT Abnormalities up to the End of Study
▼ Description	Number of Subjects with Decrease of >= 15% in FEV1 (L) from Pre- to Post-dose by Study Day
Time Frame	Day 1, Day 14 and Day 28

▼ Outcome Measure Data

▼ Analysis Population Description

The analysis population is the safety population, the same as the mITT population, defined as all randomized patients who received at least 1 dose of study drug.

Arm/Group Title	Arikace™ 280 mg	Matching Placebo (280 mg)	Arikace™ 560 mg	Matching Placebo (560 mg)
▼ Arm/Group Description:	Study subjects will receive Arikace™ 280 mg on Days 1-28.	Study subjects will receive matching placebo on Days 1-28.	Study subjects will receive Arikace™ 560 mg on Days 1-28.	Study subjects will receive matching placebo on Days 1-28.
Overall Number of Participants Analyzed	24	10	19	9
Measure Type: Count of Participants Unit of Measure: Participants				
Day 1 No	22 91.7%	10 100.0%	17 89.5%	9 100.0%

	Yes	2	8.3%	0	0.0%	2	10.5%	0	0.0%
Day 14	No	23	95.8%	10	100.0%	18	94.7%	9	100.0%
	Yes	1	4.2%	0	0.0%	1	5.3%	0	0.0%
Day 28	No	23	95.8%	10	100.0%	19	100.0%	9	100.0%
	Yes	1	4.2%	0	0.0%	0	0.0%	0	0.0%

5. Primary Outcome

Title	Number of Subjects With an Adverse Event Leading to Permanent Discontinuation of Study Medication
▼ Description	[Not Specified]
Time Frame	Screening to Day 56

▼ Outcome Measure Data

▼ Analysis Population Description

The analysis population is the safety population, the same as the mITT population, defined as all randomized patients who received at least 1 dose of study drug.

Arm/Group Title	Arikace™ 280 mg	Matching Placebo (280 mg)	Arikace™ 560 mg	Matching Placebo (560 mg)
▼ Arm/Group Description:	Study subjects will receive Arikace™ 280 mg on Days 1-28.	Study subjects will receive matching placebo on Days 1-28.	Study subjects will receive Arikace™ 560 mg on Days 1-28.	Study subjects will receive matching placebo on Days 1-28.
Overall Number of Participants Analyzed	24	10	19	9
Measure Type: Count of Participants				

Unit of Measure: Participants				
	0 0.0%	0 0.0%	1 5.3%	0 0.0%

6. Primary Outcome

Title	Serious Adverse Events up to 28 Days After Study Medication Discontinuation
▼ Description	Number of subjects with a SAE in the Arikace™ groups and the placebo group up to 28 days after study medication discontinuation. See SAE table in the safety section for details.
Time Frame	Screening to Day 56

▼ Outcome Measure Data

▼ Analysis Population Description

The safety population is the modified intent-to-treat (mITT) population, defined as all randomized patients who received at least 1 dose of study drug.

Arm/Group Title	Arikace™ 280 mg	Matching Placebo (280 mg)	Arikace™ 560 mg	Matching Placebo (560 mg)
▼ Arm/Group Description:	Study subjects will receive Arikace™ 280 mg on Days 1-28.	Study subjects will receive matching placebo on Days 1-28.	Study subjects will receive Arikace™ 280 mg on Days 1-28.	Study subjects will receive matching placebo on Days 1-28.
Overall Number of Participants Analyzed	24	10	19	9
Measure Type: Count of Participants Unit of Measure:				

Participants				
	1 4.2%	0 0.0%	1 5.3%	1 11.1%

7. Secondary Outcome

Title	Change From Baseline in Log10CFU Per Gram (Density) of Pseudomonas Aeruginosa in Sputum.
▼ Description	The change in Pseudomonas aeruginosa density from from baseline to Day 14, 28, and 42 were evaluated.Treatment differences with respect to the changes from baseline to each measured study day, defined as the log10 of the sum of all morphotypes (colony-forming units [CFU]) per gram of sputum in (log10CFU/gram [g]), was estimated for each treatment group; standard deviations accompanied the treatment differences.
Time Frame	Baseline to Day 14, Day 28 and Day 42.

▼ Outcome Measure Data

▼ Analysis Population Description
Per source, this is the Pa population, which includes patients who grew Pa on day 1, analyzed as treated.

Arm/Group Title	Arikace™ 280 mg	Matching Placebo (280 mg)	Arikace™ 560 mg	Matching Placebo (560 mg)
▼ Arm/Group Description:	Study subjects will receive Arikace™ 280 mg on Days 1-28.	Study subjects will receive matching placebo on Days 1-28.	Study subjects will receive Arikace™ 560 mg on Days 1-28.	Study subjects will receive matching placebo on Days 1-28.
Overall Number of Participants Analyzed	17	9	15	8
Mean (Standard Deviation) Unit of Measure: log10CFU per gram				
Day 14 Change	-0.227 (0.805)	-0.333 (0.515)	-2.016 (1.942)	-0.474 (1.942)

from Baseline				
Day 28 Change from Baseline	-0.094 (0.975)	0.315 (0.732)	-1.013 (1.099)	-0.302 (0.443)
Day 42 Change from Baseline	0.101 (0.788)	-0.057 (0.627)	0.046 (0.705)	-0.641 (1.095)

8. Secondary Outcome

Title	Total Pulmonary Symptom Severity Score (PSSS)
▼ Description	Changes in the severity and intensity (frequency x severity) of individual symptoms and change in composite PSSS from baseline to Days 14, 28, 42 and 56. The Pulmonary Symptom Severity Score (PSSS) was assessed on patient's responses to the Patients Symptoms Questionnaire, which employs symptom frequency and severity scales described for the validated Memorial Symptoms Assessment Scale. Symptom severity was scored on a scale of 0 (not applicable or symptom not present) to 4 (very severe) for each of the 5 symptoms (cough, shortness of breath, sputum production [frequency and severity], fatigue, and wheezing), and a composite score (range, 0 to 20 [low score represents better outcome]) was obtained as the sum of the severity scores for each symptom.
Time Frame	Baseline to Day 14, Day 28, Day 42 and Day 56.

▼ Outcome Measure Data

▼ Analysis Population Description
The safety population is used for this analysis. It is the same as the mITT population, defined as all randomized patients who received at least one dose of study medication.

Arm/Group Title	Arikace™ 280 mg	Matching Placebo (280 mg)	Arikace™ 560 mg	Matching Placebo (560 mg)
▼ Arm/Group	Study subjects will	Study subjects will	Study subjects will	Study subjects will

Description:	receive Arikace™ 280 mg on Days 1-28.	receive matching placebo on Days 1-28.	receive Arikace™ 560 mg on Days 1-28.	receive matching placebo on Days 1-28.

Overall Number of Participants Analyzed	24	10	19	9
Mean (Standard Deviation) Unit of Measure: score on a scale				
Day 14 change from Day 1	-1.125 (2.213)	-0.200 (0.789)	-0.471 (2.035)	-0.250 (2.053)
Day 28 change from Day 1	-2.167 (2.988)	0.000 (2.357)	-1.000 (4.087)	-0.125 (4.257)
Day 42 change from Day 1	-2.458 (3.476)	-1.000 (1.491)	-1.882 (4.285)	1.125 (3.137)
Day 56 change from Day 1	-2.458 (2.874)	-1.500 (2.121)	-2.167 (3.053)	-2.000 (1.690)

9. Secondary Outcome

Title	To Evaluate Change in St. George's Respiratory Questionnaire Measurements
▼ Description	A composite total score is derived as the sum of domain scores for symptoms, activity, and impact, with 0 as the best possible score and 100 as the worst possible score. A reduction in score of 4 points is generally recognized as a clinically meaningful improvement in quality of life. This analysis compared the changes from Day 1 (prior to first dosing) to Days 14, 28, 42, and 56.
Time Frame	Day 1 to Day 14, Day 28, Day 42 and Day 56.

▼ Outcome Measure Data

▼ Analysis Population Description

The analysis population is the mITT population, defined as all randomized patients who received at least one dose of study medication.

Arm/Group Title	Arikace™ 280 mg	Matching Placebo (280 mg)	Arikace™ 560 mg	Matching Placebo (560 mg)
▼ Arm/Group Description:	Study subjects will receive Arikace™ 280 mg on Days 1-28.	Study subjects will receive matching placebo on Days 1-28.	Study subjects will receive Arikace™ 560 mg on Days 1-28.	Study subjects will receive matching placebo on Days 1-28.
Overall Number of Participants Analyzed	24	10	19	9
Mean (Standard Deviation) Unit of Measure: score on a scale				
Day 14 change from Day 1	-4.024 (8.558)	-6.350 (8.756)	-6.101 (12.164)	-2.807 (7.256)
Day 28 change from Day 1	-6.205 (13.661)	-5.812 (12.039)	-6.200 (11.855)	-8.304 (12.993)
Day 42 change from Day 1	-7.611 (13.274)	-6.130 (14.271)	-8.196 (12.332)	0.242 (5.818)
Day 56 change from Day 1	-7.937 (16.281)	-7.371 (11.270)	-9.282 (10.302)	-1.637 (15.161)

10. Secondary Outcome

Title	To Evaluate the Use of Systemic Antipseudomonal Rescue Therapy
▼ Description	[Not Specified]
Time Frame	Screening to Day 56.

▼ Outcome Measure Data

▼ Analysis Population Description

The analysis population is the mITT population, defined as all randomized patients who received at least one dose of study medication

Arm/Group Title	Arikace™ 280 mg	Matching Placebo (280mg)	Arikace™ 560 mg	Matching Placebo (560 mg)
▼ Arm/Group Description:	Study subjects will receive Arikace™ 280 mg on Days 1-28.	Study subjects will receive matching placebo on Days 1-28.	Study subjects will receive Arikace™ 560 mg on Days 1-28.	Study subjects will receive matching placebo on Days 1-28.
Overall Number of Participants Analyzed	24	10	19	9
Measure Type: Count of Participants Unit of Measure: Participants				
Rescue Medication Initiation by Day 28	0 0.0%	0 0.0%	0 0.0%	1 11.1%
Rescue Medication Initiation by Day 56	0 0.0%	0 0.0%	0 0.0%	1 11.1%
No Rescue Medication Initiation	24 100.0%	10 100.0%	19 100.0%	7 77.8%

Adverse Events

Go to ▼

Time Frame	TEAEs were assessed at Baseline and all subsequent study visits up to day 56

Adverse Event Reporting Description	[Not Specified]

Arm/Group Title	Arikace at 280 mg	Matching Placebo (280 mg)	Arikace at 560 mg	Matching Placebo (560 mg)
▼ Arm/Group Description	Study subjects will receive Arikace™ 280 mg on Days 1-28.	Study subjects will receive matching placebo on Days 1-28.	Study subjects will receive Arikace™ 560 mg on Days 1-28.	Study subjects will receive matching placebo on Days 1-28.

All-Cause Mortality

	Arikace at 280 mg		Matching Placebo (280 mg)		Arikace at 560 mg		Matching Placebo (560 mg)	
	Affected / at Risk (%)		Affected / at Risk (%)		Affected / at Risk (%)		Affected / at Risk (%)	
Total	0/24 (0.00%)		0/10 (0.00%)		0/19 (0.00%)		0/9 (0.00%)	

▼ Serious Adverse Events

	Arikace at 280 mg		Matching Placebo (280 mg)		Arikace at 560 mg		Matching Placebo (560 mg)	
	Affected / at Risk (%)	# Events	Affected / at Risk (%)	# Events	Affected / at Risk (%)	# Events	Affected / at Risk (%)	# Events
Total	1/24 (4.17%)		0/10 (0.00%)		1/19 (5.26%)		1/9 (11.11%)	
Pregnancy, puerperium and perinatal conditions								
Abortion Incomplete † [1]	0/24 (0.00%)	0	0/10 (0.00%)	0	1/19 (5.26%)	1	0/9 (0.00%)	0

Respiratory, thoracic and mediastinal disorders								
Chronic Obstructive Pulmonary Disease † [1]	1/24 (4.17%)	1	0/10 (0.00%)	0	0/19 (0.00%)	0	0/9 (0.00%)	0
Lung Abscess † [1]	0/24 (0.00%)	0	0/10 (0.00%)	0	0/19 (0.00%)	0	1/9 (11.11%)	1

1 Term from vocabulary, MedDRA (11.1)

† Indicates events were collected by systematic assessment

Other (Not Including Serious) Adverse Events

Frequency Threshold for Reporting Other Adverse Events	5%

	Arikace at 280 mg		Matching Placebo (280 mg)		Arikace at 560 mg		Matching Placebo (560 mg)	
	Affected / at Risk (%)	# Events	Affected / at Risk (%)	# Events	Affected / at Risk (%)	# Events	Affected / at Risk (%)	# Events
Total	11/24 (45.83%)		5/10 (50.00%)		11/19 (57.89%)		6/9 (66.67%)	
Cardiac disorders								
Palpitations † [1]	0/24 (0.00%)	0	0/10 (0.00%)	0	1/19 (5.26%)	1	0/9 (0.00%)	0
Sinus Bradycardia † [1]	0/24 (0.00%)	0	1/10 (10.00%)	1	0/19 (0.00%)	0	0/9 (0.00%)	0
Gastrointestinal disorders								
Aphthous	0/24 (0.00%)	0	1/10 (10.00%)	1	0/19 (0.00%)	0	0/9 (0.00%)	0

Stomatitis [†1]								
Constipation [†1]	0/24 (0.00%)	0	0/10 (0.00%)	0	0/19 (0.00%)	0	1/9 (11.11%)	1
Nausea [†1]	0/24 (0.00%)	0	0/10 (0.00%)	0	1/19 (5.26%)	1	0/9 (0.00%)	0
General disorders								
Pyrexia [†1]	2/24 (8.33%)	2	1/10 (10.00%)	1	1/19 (5.26%)	1	2/9 (22.22%)	3
Fatigue [†1]	0/24 (0.00%)	0	0/10 (0.00%)	0	1/19 (5.26%)	1	1/9 (11.11%)	1
Infections and infestations								
Nasopharyngitis [†1]	1/24 (4.17%)	1	1/10 (10.00%)	1	0/19 (0.00%)	0	1/9 (11.11%)	1
Bronchiectasis [†1]	0/24 (0.00%)	0	0/10 (0.00%)	0	1/19 (5.26%)	1	1/9 (11.11%)	1
Laryngitis [†1]	0/24 (0.00%)	0	0/10 (0.00%)	0	1/19 (5.26%)	1	0/9 (0.00%)	0
Respiratory Tract Infection [†1]	0/24 (0.00%)	0	0/10 (0.00%)	0	1/19 (5.26%)	1	0/9 (0.00%)	0
Investigations								
Blood Creatinine Increased [†1]	0/24 (0.00%)	0	0/10 (0.00%)	0	1/19 (5.26%)	1	0/9 (0.00%)	0
Heart Rate Increased [†1]	0/24 (0.00%)	0	0/10 (0.00%)	0	0/19 (0.00%)	0	1/9 (11.11%)	1
Metabolism and nutrition disorders								
Anorexia [†1]	0/24 (0.00%)	0	0/10 (0.00%)	0	1/19 (5.26%)	1	1/9 (11.11%)	1
Nervous system disorders								
Headache [†1]	1/24 (4.17%)	1	1/10 (10.00%)	3	4/19 (21.05%)	4	1/9 (11.11%)	2
Dizziness [†1]	0/24 (0.00%)	0	1/10 (10.00%)	21	1/19 (5.26%)	1	0/9 (0.00%)	0
Cervicobrachial Syndrome [†1]	0/24 (0.00%)	0	1/10 (10.00%)	1	0/19 (0.00%)	0	0/9 (0.00%)	0
Psychiatric disorders								

Insomnia † [1]	0/24 (0.00%)	0	0/10 (0.00%)	0	1/19 (5.26%)	1	1/9 (11.11%)	1
Respiratory, thoracic and mediastinal disorders								
Productive Cough † [1]	2/24 (8.33%)	2	3/10 (30.00%)	4	2/19 (10.53%)	3	3/9 (33.33%)	3
Cough † [1]	1/24 (4.17%)	1	2/10 (20.00%)	4	5/19 (26.32%)	11	0/9 (0.00%)	0
Dyspnoea † [1]	0/24 (0.00%)	0	2/10 (20.00%)	3	3/19 (15.79%)	3	1/9 (11.11%)	1
Bronchial Disorder † [1]	3/24 (12.50%)	4	0/10 (0.00%)	0	1/19 (5.26%)	1	0/9 (0.00%)	0
Haemoptysis † [1]	2/24 (8.33%)	2	1/10 (10.00%)	1	1/19 (5.26%)	1	0/9 (0.00%)	0
Wheezing † [1]	1/24 (4.17%)	1	2/10 (20.00%)	3	1/19 (5.26%)	1	0/9 (0.00%)	0
Dysphonia † [1]	1/24 (4.17%)	1	0/10 (0.00%)	0	2/19 (10.53%)	2	0/9 (0.00%)	0
Rhinorrhoea † [1]	0/24 (0.00%)	0	1/10 (10.00%)	1	0/19 (0.00%)	0	1/9 (11.11%)	1
Sneezing † [1]	0/24 (0.00%)	0	2/10 (20.00%)	3	0/19 (0.00%)	0	1/9 (11.11%)	1
Skin and subcutaneous tissue disorders								
Pruritus † [1]	0/24 (0.00%)	0	1/10 (10.00%)	5	0/19 (0.00%)	0	0/9 (0.00%)	0
Rash † [1]	0/24 (0.00%)	0	1/10 (10.00%)	1	0/19 (0.00%)	0	0/9 (0.00%)	0

1 Term from vocabulary, MedDRA (11.1)

† Indicates events were collected by systematic assessment

Limitations and Caveats

Go to

[Not Specified]

More Information

Go to

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.

Results Point of Contact

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