BUILD 3: Bosentan Use in Interstitial Lung Disease (BUILD 3)

This study has been completed.

Sponsor:
Actelion

Information provided by (Responsible Party):
Actelion

ClinicalTrials.gov Identifier:
NCT00391443

First received: October 20, 2006
Last updated: September 9, 2015
Last verified: August 2015
History of Changes

Results First Received: April 25, 2012

Study Type:	Interven ional
Study Design:	Allocation: Randomized; Endpoint Classification: Safety/Efficacy Study; Intervention Model: Parallel Assignment; Masking: Double Blind (Subject, Caregiver, Investigator, Outcomes Assessor); Primary Purpose: Treatment
Condition:	Idiopathic Pulmonary Fibrosis
Interventions:	Drug: Bosentan Drug: Placebo

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
Placebo	Initial dose: 62.5 mg twice daily (b.i.d) for 4 weeks. Target dose: - body weight > 40 kg (90 lb): 125 mg b.i.d., (if the initial dose is well tolerated); - body weight < 40 kg (90 lb): 62.5 mg b.i.d.
Bosentan	Initial dose: 62.5 mg twice daily (b.i.d) for 4 weeks. Target dose: - body weight > 40 kg (90 lb): 125 mg b.i.d., (if the initial dose is well tolerated); - body weight < 40 kg (90 lb): 62.5 mg b.i.d.

Participant Flow: Overall Study

	Placebo	Bosentan
STARTED	209 [1]	407
COMPLETED	209	407
NOT COMPLETED	0	0

[1] 1 patient in the bosentan arm did not receive treatment & was excluded from he Safety Population.

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
Placebo	Initial dose: 62.5 mg twice daily (b.i.d) for 4 weeks. Target dose: - body weight > 40 kg (90 lb): 125 mg b.i.d., (if the initial dose is well tolerated); - body weight < 40 kg (90 lb): 62.5 mg b.i.d.
Bosentan	Initial dose: 62.5 mg twice daily (b.i.d) for 4 weeks. Target dose: - body weight > 40 kg (90 lb): 125 mg b.i.d., (if the initial dose is well tolerated); - body weight < 40 kg (90 lb): 62.5 mg b.i.d.
Total	Total of all reporting groups

Baseline Measures

	Placebo	Bosentan	Total
Number of Participants [units: participants]	209	407	616
Age [units: years] Mean (Standard Deviation)	63.2 (9.1)	63.8 (8.4)	63.6 (8.6)
Age, Customized [units: participants]			
Between 18 and 40 years	4	5	9
Between 41 and 60 years	74	119	193
Between 61 and 70 years	87	195	282
> 70 years	44	88	132
Gender [units: participants]			
Female	76	111	187
Male	133	296	429
Region of Enrollment [units: participants]			
United States	99	185	284
Serbia	2	0	2
Spain	7	15	22
Ireland	2	2	4
Austria	3	4	7
Israel	7	16	23
Switzerland	5	8	13
Italy	8	14	22
United Kingdom	3	7	10
France	9	14	23
Czech Republic	5	9	14
Canada	14	30	44
Belgium	1	2	3
Croatia	0	2	2
Australia	11	22	33
Germany	10	26	36
Netherlands	0	2	2

Japan	14	26	40
Korea, Republic of	9	23	32

Outcome Measures

Hide All Outcome Measures

1. Primary: Time to Occurrence of Disease Worsening or Death up to End of Study. [Time Frame: 36 months]

Measure Type	Primary
Measure Title	Time to Occurrence of Disease Worsening or Dea h up to End of Study.
Measure Description	Disease worsening was defined as an event of worsening of pulmonary function tests (PFT) or acute exacerbation of idiopathic pulmonary fibrosis (IPF).
Time Frame	36 months
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 primary analysis was performed on the Intent To Treat (ITT) population.

Reporting Groups

	Description
Placebo	Initial dose: 62.5 mg twice daily (b.i.d) for 4 weeks. Target dose: - body weight > 40 kg (90 lb): 125 mg b.i.d., (if the initial dose is well tolerated); - body weight < 40 kg (90 lb): 62.5 mg b.i.d.
Bosentan	Initial dose: 62.5 mg twice daily (b.i.d) for 4 weeks. Target dose: - body weight > 40 kg (90 lb): 125 mg b.i.d., (if the initial dose is well tolerated); - body weight < 40 kg (90 lb): 62.5 mg b.i.d.

Measured Values

	Placebo	Bosentan
Number of Participants Analyzed [units: participants]	**209**	**407**
Time to Occurrence of Disease Worsening or Death up to End of Study. [units: participants with event]		
month 4 (122 days)	**10**	**18**
month 8 (244 days)	**22**	**40**
month12 (366 days)	**43**	**74**
month 18 (549 days)	**74**	**117**
month 24 (732 days)	**88**	**145**
month 30 (915 days)	**94**	**156**
month 36 (1098 days)	**94**	**158**

Statistical Analysis 1 for Time to Occurrence of Disease Worsening or Death up to End of Study.

Groups [1]	All groups
Method [2]	Log Rank
P Value [3]	0.2110
Hazard Ratio (HR) [4]	0.850
95% Confidence Interval	0.658 to 1.097

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.

[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional informa ion, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estima ion information:
	No text entered.

2. Secondary: Percentage of Patients Who Experienced Either Disease Worsening or Death at 1 Year. [Time Frame: 12 months]

Measure Type	Secondary
Measure Title	Percentage of Patients Who Experienced Either Disease Worsening or Death at 1 Year.
Measure Description	Disease worsening was defined as an event of worsening of pulmonary function tests (PFT) or acute exacerbation of idiopathic pulmonary fibrosis (IPF).
Time Frame	12 months
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.
ITT population

Reporting Groups

	Description
Placebo	Initial dose: 62.5 mg twice daily (b.i.d) for 4 weeks. Target dose: - body weight > 40 kg (90 lb): 125 mg b.i.d., (if the initial dose is well tolerated); - body weight < 40 kg (90 lb): 62.5 mg b.i.d.
Bosentan	Initial dose: 62.5 mg twice daily (b.i.d) for 4 weeks. Target dose: - body weight > 40 kg (90 lb): 125 mg b.i.d., (if the initial dose is well tolerated); - body weight < 40 kg (90 lb): 62.5 mg b.i.d.

Measured Values

	Placebo	Bosentan
Number of Participants Analyzed [units: participants]	**209**	**407**
Percentage of Patients Who Experienced Either Disease Worsening or Death at 1 Year. [units: percentage of participants with event] Number (95% Confidence Interval)	**23.9 (18.3 to 30.3)**	**19.9 (16.1 to 24.1)**

Statistical Analysis 1 for Percentage of Patients Who Experienced Either Disease Worsening or Death at 1 Year.

Groups [1]	All groups
Method [2]	Fisher Exact
P Value [3]	0.2542
Relative risk reduction [4]	0.17
95% Confidence Interval	-0.13 to 0.39

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional informa ion, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:

	No text entered.
[4]	Other relevant estima ion information:
	No text entered.

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	All treatment-emergent adverse events occurring after the start of study treatment and within 24 hours after the end of study treatment
Additional Description	One subject who did not receive study treatment (bosentan) was excluded from the safety population. Events listed as idiopathic pulmonary fibrosis were reported as worsening of idiopathic pulmonary fibrosis.

Reporting Groups

	Description
Placebo	Initial dose: 62.5 mg twice daily (b.i.d) for 4 weeks. Target dose: - body weight > 40 kg (90 lb): 125 mg b.i.d., (if the initial dose is well tolerated); - body weight < 40 kg (90 lb): 62.5 mg b.i.d.
Bosentan	Initial dose: 62.5 mg twice daily (b.i.d) for 4 weeks. Target dose: - body weight > 40 kg (90 lb): 125 mg b.i.d., (if the initial dose is well tolerated); - body weight < 40 kg (90 lb): 62.5 mg b.i.d.

Serious Adverse Events

	Placebo	Bosentan
Total, serious adverse events		
# participants affected / at risk	74/209 (35.41%)	129/406 (31.77%)
Blood and lymphatic system disorders		
ANAEMIA [†1]		
# participants affected / at risk	0/209 (0.00%)	1/406 (0.25%)
LYMPHADENOPATHY [†1]		
# participants affected / at risk	0/209 (0.00%)	1/406 (0.25%)
Cardiac disorders		
CORONARY ARTERY DISEASE [†1]		
# participants affected / at risk	1/209 (0.48%)	6/406 (1.48%)
MYOCARDIAL INFARCTION [†1]		
# participants affected / at risk	1/209 (0.48%)	4/406 (0.99%)
ATRIAL FIBRILLATION [†1]		
# participants affected / at risk	0/209 (0.00%)	3/406 (0.74%)
ANGINA UNSTABLE [†1]		
# participants affected / at risk	0/209 (0.00%)	2/406 (0.49%)
CARDIAC FAILURE CONGESTIVE [†1]		
# participants affected / at risk	3/209 (1.44%)	1/406 (0.25%)
CORONARY ARTERY STENOSIS [†1]		
# participants affected / at risk	1/209 (0.48%)	1/406 (0.25%)
ACUTE CORONARY SYNDROME [†1]		
# participants affected / at risk	0/209 (0.00%)	1/406 (0.25%)
ATRIAL FLUTTER [†1]		
# participants affected / at risk	0/209 (0.00%)	1/406 (0.25%)
CARDIAC ARREST [†1]		
# participants affected / at risk	0/209 (0.00%)	1/406 (0.25%)
SUPRAVENTRICULAR TACHYCARDIA [†1]		
# participants affected / at risk	0/209 (0.00%)	1/406 (0.25%)
ANGINA PECTORIS [†1]		

# participants affected / at risk	4/209 (1.91%)	0/406 (0.00%)
CARDIAC FAILURE [†1]		
# participants affected / at risk	1/209 (0.48%)	0/406 (0.00%)
VENTRICULAR HYPOKINESIA [†1]		
# participants affected / at risk	1/209 (0.48%)	0/406 (0.00%)
Ear and labyrinth disorders		
MENIERE'S DISEASE [†1]		
# participants affected / at risk	0/209 (0.00%)	1/406 (0.25%)
VERTIGO [†1]		
# participants affected / at risk	0/209 (0.00%)	1/406 (0.25%)
Endocrine disorders		
GOITRE [†1]		
# participants affected / at risk	1/209 (0.48%)	0/406 (0.00%)
Gastrointestinal disorders		
COLITIS [†1]		
# participants affected / at risk	0/209 (0.00%)	1/406 (0.25%)
COLONIC POLYP [†1]		
# participants affected / at risk	0/209 (0.00%)	1/406 (0.25%)
GASTRITIS [†1]		
# participants affected / at risk	0/209 (0.00%)	1/406 (0.25%)
VOMITING [†1]		
# participants affected / at risk	0/209 (0.00%)	1/406 (0.25%)
ANAL HAEMORRHAGE [†1]		
# participants affected / at risk	1/209 (0.48%)	0/406 (0.00%)
DIVERTICULUM INTESTINAL HAEMORRHAGIC [†1]		
# participants affected / at risk	1/209 (0.48%)	0/406 (0.00%)
DYSKINESIA OESOPHAGEAL [†1]		
# participants affected / at risk	1/209 (0.48%)	0/406 (0.00%)
INGUINAL HERNIA [†1]		
# participants affected / at risk	1/209 (0.48%)	0/406 (0.00%)
INTESTINAL OBSTRUCTION [†1]		
# participants affected / at risk	1/209 (0.48%)	0/406 (0.00%)
LOWER GASTROINTESTINAL HAEMORRHAGE [†1]		
# participants affected / at risk	1/209 (0.48%)	0/406 (0.00%)
MESENTERIC ARTERIOSCLEROSIS [†1]		
# participants affected / at risk	1/209 (0.48%)	0/406 (0.00%)
PERITONITIS [†1]		
# participants affected / at risk	1/209 (0.48%)	0/406 (0.00%)
General disorders		
CHEST PAIN [†1]		
# participants affected / at risk	2/209 (0.96%)	2/406 (0.49%)
PYREXIA [†1]		
# participants affected / at risk	1/209 (0.48%)	2/406 (0.49%)
GENERAL PHYSICAL HEALTH DETERIORATION [†1]		
# participants affected / at risk	0/209 (0.00%)	1/406 (0.25%)
IMPAIRED HEALING [†1]		
# participants affected / at risk	0/209 (0.00%)	1/406 (0.25%)
CHEST DISCOMFORT [†1]		
# participants affected / at risk	1/209 (0.48%)	0/406 (0.00%)
INFLUENZA LIKE ILLNESS [†1]		

# participants affected / at risk	1/209 (0.48%)	0/406 (0.00%)
Hepatobiliary disorders		
BILE DUCT STONE [†1]		
# participants affected / at risk	0/209 (0.00%)	1/406 (0.25%)
CHOLELITHIASIS [†1]		
# participants affected / at risk	0/209 (0.00%)	1/406 (0.25%)
HEPATITIS ACUTE [†1]		
# participants affected / at risk	0/209 (0.00%)	1/406 (0.25%)
CHOLECYSTITIS [†1]		
# participants affected / at risk	2/209 (0.96%)	0/406 (0.00%)
CHOLECYSTITIS ACUTE [†1]		
# participants affected / at risk	1/209 (0.48%)	0/406 (0.00%)
Immune system disorders		
ALLERGIC OEDEMA [†1]		
# participants affected / at risk	0/209 (0.00%)	1/406 (0.25%)
DRUG HYPERSENSITIVITY [†1]		
# participants affected / at risk	0/209 (0.00%)	1/406 (0.25%)
Infections and infestations		
PNEUMONIA [†1]		
# participants affected / at risk	10/209 (4.78%)	16/406 (3.94%)
LOWER RESPIRATORY TRACT INFECTION [†1]		
# participants affected / at risk	5/209 (2.39%)	7/406 (1.72%)
BRONCHITIS [†1]		
# participants affected / at risk	3/209 (1.44%)	2/406 (0.49%)
CLOSTRIDIUM DIFFICILE COLITIS [†1]		
# participants affected / at risk	1/209 (0.48%)	2/406 (0.49%)
APPENDICITIS [†1]		
# participants affected / at risk	2/209 (0.96%)	1/406 (0.25%)
DEVICE RELATED INFECTION [†1]		
# participants affected / at risk	0/209 (0.00%)	1/406 (0.25%)
DIVERTICULITIS [†1]		
# participants affected / at risk	0/209 (0.00%)	1/406 (0.25%)
HERPES ZOSTER OPHTHALMIC [†1]		
# participants affected / at risk	0/209 (0.00%)	1/406 (0.25%)
PILONIDAL CYST [†1]		
# participants affected / at risk	0/209 (0.00%)	1/406 (0.25%)
PYELONEPHRITIS [†1]		
# participants affected / at risk	0/209 (0.00%)	1/406 (0.25%)
UROSEPSIS [†1]		
# participants affected / at risk	0/209 (0.00%)	1/406 (0.25%)
VIRAL UPPER RESPIRATORY TRACT INFECTION [†1]		
# participants affected / at risk	0/209 (0.00%)	1/406 (0.25%)
UPPER RESPIRATORY TRACT INFECTION [†1]		
# participants affected / at risk	3/209 (1.44%)	0/406 (0.00%)
LOBAR PNEUMONIA [†1]		
# participants affected / at risk	2/209 (0.96%)	0/406 (0.00%)
ANAL ABSCESS [†1]		
# participants affected / at risk	1/209 (0.48%)	0/406 (0.00%)
ARTHRITIS BACTERIAL [†1]		
# participants affected / at risk	1/209 (0.48%)	0/406 (0.00%)

CELLULITIS [†1]		
# participants affected / at risk	1/209 (0.48%)	0/406 (0.00%)
HERPES ZOSTER OTICUS [†1]		
# participants affected / at risk	1/209 (0.48%)	0/406 (0.00%)
TRACHEOBRONCHITIS [†1]		
# participants affected / at risk	1/209 (0.48%)	0/406 (0.00%)
URINARY TRACT INFECTION [†1]		
# participants affected / at risk	1/209 (0.48%)	0/406 (0.00%)
VIRAL LABYRINTHITIS [†1]		
# participants affected / at risk	1/209 (0.48%)	0/406 (0.00%)
Injury, poisoning and procedural complications		
ROAD TRAFFIC ACCIDENT [†1]		
# participants affected / at risk	0/209 (0.00%)	2/406 (0.49%)
FALL [†1]		
# participants affected / at risk	1/209 (0.48%)	1/406 (0.25%)
ANKLE FRACTURE [†1]		
# participants affected / at risk	0/209 (0.00%)	1/406 (0.25%)
EXCORIATION [†1]		
# participants affected / at risk	0/209 (0.00%)	1/406 (0.25%)
LUMBAR VERTEBRAL FRACTURE [†1]		
# participants affected / at risk	0/209 (0.00%)	1/406 (0.25%)
RIB FRACTURE [†1]		
# participants affected / at risk	0/209 (0.00%)	1/406 (0.25%)
TENDON RUPTURE [†1]		
# participants affected / at risk	0/209 (0.00%)	1/406 (0.25%)
UPPER LIMB FRACTURE [†1]		
# participants affected / at risk	0/209 (0.00%)	1/406 (0.25%)
CONTUSION [†1]		
# participants affected / at risk	1/209 (0.48%)	0/406 (0.00%)
HIP FRACTURE [†1]		
# participants affected / at risk	1/209 (0.48%)	0/406 (0.00%)
Investigations		
LIVER FUNCTION TEST ABNORMAL [†1]		
# participants affected / at risk	0/209 (0.00%)	4/406 (0.99%)
PULMONARY FUNCTION TEST DECREASED [†1]		
# participants affected / at risk	0/209 (0.00%)	2/406 (0.49%)
Metabolism and nutrition disorders		
DEHYDRATION [†1]		
# participants affected / at risk	1/209 (0.48%)	1/406 (0.25%)
HYPOVOLAEMIA [†1]		
# participants affected / at risk	0/209 (0.00%)	1/406 (0.25%)
Musculoskeletal and connective tissue disorders		
BACK PAIN [†1]		
# participants affected / at risk	3/209 (1.44%)	3/406 (0.74%)
OSTEOARTHRITIS [†1]		
# participants affected / at risk	1/209 (0.48%)	2/406 (0.49%)
ARTHRALGIA [†1]		
# participants affected / at risk	0/209 (0.00%)	1/406 (0.25%)
ROTATOR CUFF SYNDROME [†1]		
# participants affected / at risk	0/209 (0.00%)	1/406 (0.25%)

SJOGREN'S SYNDROME [†1]		
# participants affected / at risk	0/209 (0.00%)	1/406 (0.25%)
BURSITIS [†1]		
# participants affected / at risk	1/209 (0.48%)	0/406 (0.00%)
COSTOCHONDRITIS [†1]		
# participants affected / at risk	1/209 (0.48%)	0/406 (0.00%)
FRACTURE NONUNION [†1]		
# participants affected / at risk	1/209 (0.48%)	0/406 (0.00%)
JOINT EFFUSION [†1]		
# participants affected / at risk	1/209 (0.48%)	0/406 (0.00%)
POLYARTHRITIS [†1]		
# participants affected / at risk	1/209 (0.48%)	0/406 (0.00%)
SPINAL COLUMN STENOSIS [†1]		
# participants affected / at risk	1/209 (0.48%)	0/406 (0.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		
PROSTATE CANCER [†1]		
# participants affected / at risk	0/209 (0.00%)	4/406 (0.99%)
BLADDER CANCER [†1]		
# participants affected / at risk	0/209 (0.00%)	2/406 (0.49%)
COLON CANCER [†1]		
# participants affected / at risk	0/209 (0.00%)	1/406 (0.25%)
LUNG ADENOCARCINOMA [†1]		
# participants affected / at risk	0/209 (0.00%)	1/406 (0.25%)
LUNG NEOPLASM [†1]		
# participants affected / at risk	0/209 (0.00%)	1/406 (0.25%)
NON-HODGKIN'S LYMPHOMA [†1]		
# participants affected / at risk	0/209 (0.00%)	1/406 (0.25%)
SQUAMOUS CELL CARCINOMA OF SKIN [†1]		
# participants affected / at risk	0/209 (0.00%)	1/406 (0.25%)
LUNG NEOPLASM MALIGNANT [†1]		
# participants affected / at risk	1/209 (0.48%)	0/406 (0.00%)
Nervous system disorders		
SYNCOPE [†1]		
# participants affected / at risk	2/209 (0.96%)	1/406 (0.25%)
DIZZINESS [†1]		
# participants affected / at risk	1/209 (0.48%)	1/406 (0.25%)
CEREBRAL HAEMORRHAGE [†1]		
# participants affected / at risk	0/209 (0.00%)	1/406 (0.25%)
TRANSIENT ISCHAEMIC ATTACK [†1]		
# participants affected / at risk	0/209 (0.00%)	1/406 (0.25%)
CAROTID ARTERY OCCLUSION [†1]		
# participants affected / at risk	1/209 (0.48%)	0/406 (0.00%)
DEMENTIA [†1]		
# participants affected / at risk	1/209 (0.48%)	0/406 (0.00%)
HAEMORRHAGIC STROKE [†1]		
# participants affected / at risk	1/209 (0.48%)	0/406 (0.00%)
NEUROPATHY PERIPHERAL [†1]		
# participants affected / at risk	1/209 (0.48%)	0/406 (0.00%)
SOMNOLENCE [†1]		
# participants affected / at risk	1/209 (0.48%)	0/406 (0.00%)

Psychiatric disorders		
ANXIETY [†1]		
# participants affected / at risk	0/209 (0.00%)	1/406 (0.25%)
DEPRESSION [†1]		
# participants affected / at risk	0/209 (0.00%)	1/406 (0.25%)
PANIC DISORDER [†1]		
# participants affected / at risk	0/209 (0.00%)	1/406 (0.25%)
Renal and urinary disorders		
HAEMATURIA [†1]		
# participants affected / at risk	0/209 (0.00%)	3/406 (0.74%)
RENAL MASS [†1]		
# participants affected / at risk	0/209 (0.00%)	1/406 (0.25%)
RENAL FAILURE ACUTE [†1]		
# participants affected / at risk	1/209 (0.48%)	0/406 (0.00%)
Reproductive system and breast disorders		
BENIGN PROSTATIC HYPERPLASIA [†1]		
# participants affected / at risk	0/209 (0.00%)	1/406 (0.25%)
PROSTATISM [†1]		
# participants affected / at risk	1/209 (0.48%)	0/406 (0.00%)
Respiratory, thoracic and mediastinal disorders		
IDIOPATHIC PULMONARY FIBROSIS [†1]		
# participants affected / at risk	17/209 (8.13%)	41/406 (10.10%)
DYSPNOEA [†1]		
# participants affected / at risk	0/209 (0.00%)	6/406 (1.48%)
PULMONARY EMBOLISM [†1]		
# participants affected / at risk	1/209 (0.48%)	4/406 (0.99%)
RESPIRATORY FAILURE [†1]		
# participants affected / at risk	1/209 (0.48%)	4/406 (0.99%)
ACUTE RESPIRATORY FAILURE [†1]		
# participants affected / at risk	0/209 (0.00%)	2/406 (0.49%)
PULMONARY HYPERTENSION [†1]		
# participants affected / at risk	0/209 (0.00%)	2/406 (0.49%)
ACUTE RESPIRATORY DISTRESS SYNDROME [†1]		
# participants affected / at risk	1/209 (0.48%)	1/406 (0.25%)
COUGH [†1]		
# participants affected / at risk	1/209 (0.48%)	1/406 (0.25%)
ACUTE INTERSTITIAL PNEUMONITIS [†1]		
# participants affected / at risk	0/209 (0.00%)	1/406 (0.25%)
BRONCHOSPASM [†1]		
# participants affected / at risk	0/209 (0.00%)	1/406 (0.25%)
DYSPNOEA EXERTIONAL [†1]		
# participants affected / at risk	0/209 (0.00%)	1/406 (0.25%)
HAEMOPTYSIS [†1]		
# participants affected / at risk	0/209 (0.00%)	1/406 (0.25%)
NASAL CONGESTION [†1]		
# participants affected / at risk	0/209 (0.00%)	1/406 (0.25%)
PLEURAL EFFUSION [†1]		
# participants affected / at risk	0/209 (0.00%)	1/406 (0.25%)
PULMONARY OEDEMA [†1]		
# participants affected / at risk	0/209 (0.00%)	1/406 (0.25%)

PNEUMOTHORAX †1		
# participants affected / at risk	2/209 (0.96%)	0/406 (0.00%)
HYPOXIA †1		
# participants affected / at risk	1/209 (0.48%)	0/406 (0.00%)
Skin and subcutaneous tissue disorders		
PRURITUS ALLERGIC †1		
# participants affected / at risk	0/209 (0.00%)	1/406 (0.25%)
Surgical and medical procedures		
CHOLECYSTECTOMY †1		
# participants affected / at risk	0/209 (0.00%)	1/406 (0.25%)
TRANSURETHRAL PROSTATECTOMY †1		
# participants affected / at risk	0/209 (0.00%)	1/406 (0.25%)
LUNG TRANSPLANT †1		
# participants affected / at risk	1/209 (0.48%)	0/406 (0.00%)
Vascular disorders		
DEEP VEIN THROMBOSIS †1		
# participants affected / at risk	1/209 (0.48%)	2/406 (0.49%)
HYPOTENSION †1		
# participants affected / at risk	1/209 (0.48%)	1/406 (0.25%)
INTERMITTENT CLAUDICATION †1		
# participants affected / at risk	0/209 (0.00%)	1/406 (0.25%)
ORTHOSTATIC HYPOTENSION †1		
# participants affected / at risk	0/209 (0.00%)	1/406 (0.25%)
HYPERTENSION †1		
# participants affected / at risk	1/209 (0.48%)	0/406 (0.00%)
TEMPORAL ARTERITIS †1		
# participants affected / at risk	1/209 (0.48%)	0/406 (0.00%)
VASCULITIS †1		
# participants affected / at risk	1/209 (0.48%)	0/406 (0.00%)

† Events were collected by systematic assessment
1 Term from vocabulary, MedDRA (12.0)

Other Adverse Events

Hide Other Adverse Events

Time Frame	All treatment-emergent adverse events occurring after the start of study treatment and within 24 hours after the end of study treatment
Additional Description	One subject who did not receive study treatment (bosentan) was excluded from the safety population. Events listed as idiopathic pulmonary fibrosis were reported as worsening of idiopathic pulmonary fibrosis.

Frequency Threshold

Threshold above which other adverse events are reported	5

Reporting Groups

	Description
Placebo	Initial dose: 62.5 mg twice daily (b.i.d) for 4 weeks. Target dose: - body weight > 40 kg (90 lb): 125 mg b.i.d., (if the initial dose is well tolerated); - body weight < 40 kg (90 lb): 62.5 mg b.i.d.
Bosentan	Initial dose: 62.5 mg twice daily (b.i.d) for 4 weeks. Target dose: - body weight > 40 kg (90 lb): 125 mg b.i.d., (if the initial dose is well tolerated); - body weight < 40 kg (90 lb): 62.5 mg b.i.d.

Other Adverse Events

	Placebo	Bosentan
Total, other (not including serious) adverse events		
# participants affected / at risk	200/209 (95.69%)	386/406 (95.07%)
Gastrointestinal disorders		
NAUSEA [†1]		
# participants affected / at risk	15/209 (7.18%)	27/406 (6.65%)
General disorders		
FATIGUE [†1]		
# participants affected / at risk	15/209 (7.18%)	46/406 (11.33%)
OEDEMA PERIPHERAL [†1]		
# participants affected / at risk	23/209 (11.00%)	37/406 (9.11%)
CHEST PAIN [†1]		
# participants affected / at risk	12/209 (5.74%)	24/406 (5.91%)
Infections and infestations		
UPPER RESPIRATORY TRACT INFECTION [†1]		
# participants affected / at risk	59/209 (28.23%)	114/406 (28.08%)
BRONCHITIS [†1]		
# participants affected / at risk	28/209 (13.40%)	44/406 (10.84%)
NASOPHARYNGITIS [†1]		
# participants affected / at risk	22/209 (10.53%)	40/406 (9.85%)
SINUSITIS [†1]		
# participants affected / at risk	18/209 (8.61%)	38/406 (9.36%)
LOWER RESPIRATORY TRACT INFECTION [†1]		
# participants affected / at risk	18/209 (8.61%)	26/406 (6.40%)
Investigations		
ALANINE AMINOTRANSFERASE INCREASED [†1]		
# participants affected / at risk	7/209 (3.35%)	27/406 (6.65%)
LIVER FUNCTION TEST ABNORMAL [†1]		
# participants affected / at risk	0/209 (0.00%)	26/406 (6.40%)
ASPARTATE AMINOTRANSFERASE INCREASED [†1]		
# participants affected / at risk	6/209 (2.87%)	23/406 (5.67%)
Musculoskeletal and connective tissue disorders		
ARTHRALGIA [†1]		
# participants affected / at risk	17/209 (8.13%)	30/406 (7.39%)
BACK PAIN [†1]		
# participants affected / at risk	16/209 (7.66%)	24/406 (5.91%)
Nervous system disorders		
HEADACHE [†1]		
# participants affected / at risk	22/209 (10.53%)	44/406 (10.84%)
DIZZINESS [†1]		
# participants affected / at risk	17/209 (8.13%)	24/406 (5.91%)
Respiratory, thoracic and mediastinal disorders		
IDIOPATHIC PULMONARY FIBROSIS [†1]		
# participants affected / at risk	59/209 (28.23%)	92/406 (22.66%)
COUGH [†1]		
# participants affected / at risk	51/209 (24.40%)	78/406 (19.21%)
DYSPNOEA [†1]		
# participants affected / at risk	24/209 (11.48%)	57/406 (14.04%)

† Events were collected by systematic assessment

1 Term from vocabulary, MedDRA (12.0)

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:** Actelion, wi h steering committee, shall complete the review and provide any modifications required to protect Actelion's patent rights and confidential information within sixty (60) days of receipt of the proposed publication. During this period, Investigator shall not permit publication. If Actelion reasonably anticipates filing a patent application claiming an invention arising out of the Study, such publication shall be delayed until after the application is filed.

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