Bosentan in Digital Ulcers (RAPIDS 2 OL)

This study has been completed.

Sponsor:
Actelion

Information provided by (Responsible Party):
Actelion

ClinicalTrials.gov Identifier:
NCT00319696

First received: April 27, 2006
Last updated: September 27, 2012
Last verified: September 2012
History of Changes

Results First Received: June 29, 2012

Study Type:	Interventional
Study Design:	Allocation: Non-Randomized; Endpoint Classification: Safety/Efficacy Study; Intervention Model: Single Group Assignment; Masking: Open Label; Primary Purpose: Treatment
Conditions:	Systemic Sclerosis Digital Ulcers
Intervention:	Drug: bosentan

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
Patients were enrolled at 33 centers in 7 countries (Canada, France, Germany, Italy, Switzerland, UK, and USA. The first patient enrolled and started treatment on 8 July 2004 and the last patient enrolled and started treatment on 20 October 2005.

Pre-Assignment Details

Significant events and approaches for the overall study following participant enrollment, but prior to group assignment
Patients who completed RAPIDS-2 and who still had digital ulcers (DUs) or developed a new digital ulcer (DU) after the last follow-up visit were eligible. After release of the RAPIDS-2 results, patients who were prematurely discontinued from RAPIDS-2 for treatment failure or, if on placebo, for an adverse event and had DUs were also eligible.

Reporting Groups

	Description
Bosentan	Initial dose: bosentan 62.5 mg twice daily (b.i.d.) for the first 4 weeks. Target dose: bosentan 125 mg b.i.d. thereafter

Participant Flow: Overall Study

	Bosentan
STARTED	116

COMPLETED	56
NOT COMPLETED	60
Adverse Event	36
withdrawal of consent	14
administrative	7
Lost to Follow-up	3

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
Bosentan	Initial dose: bosentan 62.5 mg twice daily (b.i.d.) for the first 4 weeks. Target dose: bosentan 125 mg b.i.d. thereafter

Baseline Measures

	Bosentan
Overall Participants [units: participants]	**116**
Age [units: years] Mean (Standard Deviation)	**49.3 (12.0)**
Age, Customized [units: participants]	
Between 24 and 79 years	**116**
Gender [units: participants]	
Female	**87**
Male	**29**
Region of Enrollment [units: participants]	
Austria	**0**
Canada	**11**
France	**10**
Germany	**9**
Italy	**9**
Switzerland	**4**
United Kingdom	**6**
United States	**67**
Scleroderma Health Assessment Questionnaire (SHAQ) Individual Domain Score [1] [units: score on a scale] Mean (Standard Deviation)	
Dressing	**1.3 (0.9)**
Arising	**0.5 (0.8)**

Eating	**1.5 (1.0)**
Walking	**0.5 (0.7)**
Hygiene	**0.9 (1.0)**
Reach	**1.1 (0.9)**
Grip	**1.1 (0.8)**
Activity	**1.0 (0.9)**

[1] SHAQ evaluates physical disability. Patients were instructed to rate their capacity to perform activities of daily living within the previous 7 days by checking one of the following descriptors: “without any difficulty”, “with some difficulty,” “with much difficulty,” or “unable to do,” equivalent to scores of 0, 1, 2, and 3, respectively. Items were categorized into 8 domains: dressing/grooming, arising, eating, walking, hygiene, reach, grip, and activities.

Overall hand pain [1] [units: mm] Mean (Standard Deviation)	**58.62 (29.80)**

[1] Overall hand pain related to finger ulcers was assessed by the patient using a Visual Analogue Scale. Patients were instructed to score their pain by marking on the continuous 10-cm scale, where 0 (left) was no pain and 100 (right) very severe pain, in response to the question, “How much pain have you had because of your finger ulcers in the past week?” The investigator measured the distance in millimeters between 0 and the patient mark with the ruler provided and recorded the distance.

United Kingdom Scleroderma Functional Score (UKFS) [1] [units: score on a scale] Mean (Standard Deviation)	**11.06 (7.50)**

[1] UKFS relates to upper and lower extremity function and muscle weakness. For each item, the patient indicated the responses that best described their current ability: “able to perform in a normal manner,” “able to perform with alteration in style,” “can only manage with difficulty,” and “impossible to achieve.” Each response was given an integer from 0 (able to perform in a normal manner) to 3 (impossible to achieve), and the sum of individual responses provided an overall score of 0 to 33. Missing values were replaced with the worst value the patient reported on the other items at that visit.

Outcome Measures

Hide All Outcome Measures

1. Primary: Total Number of New Digital Ulcers (DUs) Per Patient Observed by the Investigator at Planned Visits [Time Frame: At planned visits up to week 80]

Measure Type	Primary
Measure Title	Total Number of New Digital Ulcers (DUs) Per Patient Observed by the Investigator at Planned Visits
Measure Description	The total number of new DUs per patient observed by the investigator at planned visits and new transient DUs recorded in the patient diary (a patient diary was used to record DUs that might appear and disappear between two planned visits)were assessed at each clinic visit
Time Frame	At planned visits up to week 80
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.
One patient did not have a DU at baseline (number of patients assessed at Weeks 0-4,4-8,8-16,16-24,24-32,32-40,40-48,48-56,56-64,64-72, and 72-80 were 114, 107, 103, 100, 97, 94, 88, 87, 86, 86, and 83, respectively.

Reporting Groups

	Description
0 New Ulcers	Number of new DUs includes the new number at each visit and the transient ulcers between visits.
At Least 1 New Ulcer	Number of new DUs includes the new number at each visit and the transient ulcers between visits.

At Least 2 New Ulcers	Number of new DUs includes the new number at each visit and the transient ulcers between visits.
At Least 3 New Ulcers	Number of new DUs includes the new number at each visit and the transient ulcers between visits.
At Least 4 New Ulcers	Number of new DUs includes the new number at each visit and the transient ulcers between visits.
At Least 5 New Ulcers	Number of new DUs includes the new number at each visit and the transient ulcers between visits.

Measured Values

	0 New Ulcers	At Least 1 New Ulcer	At Least 2 New Ulcers	At Least 3 New Ulcers	At Least 4 New Ulcers	At Least 5 New Ulcers
Overall Participants [units: participants]	**115**	**115**	**115**	**115**	**115**	**115**
Total Number of New Digital Ulcers (DUs) Per Patient Observed by the Investigator at Planned Visits [units: number of new digital ulcers]						
Week 0-4	**85**	**29**	**17**	**6**	**4**	**3**
Week 4-8	**73**	**34**	**15**	**6**	**4**	**3**
Week 8-16	**63**	**40**	**22**	**9**	**7**	**5**
Week 16-24	**64**	**36**	**17**	**11**	**4**	**2**
Week 24-32	**56**	**41**	**22**	**12**	**8**	**4**
Week 32-40	**59**	**35**	**15**	**7**	**5**	**4**
Week 40-48	**52**	**36**	**20**	**11**	**5**	**3**
Week 48-56	**50**	**37**	**18**	**13**	**7**	**5**
Week 56-64	**48**	**38**	**14**	**7**	**4**	**3**
Week 64-72	**51**	**35**	**24**	**15**	**10**	**8**
Week 72-80	**51**	**32**	**18**	**9**	**4**	**2**

No statistical analysis provided for Total Number of New Digital Ulcers (DUs) Per Patient Observed by the Investigator at Planned Visits

2. Primary: Time to Complete Healing of Each Baseline DU [Time Frame: Baseline to healing]

Measure Type	Primary
Measure Title	Time to Complete Healing of Each Baseline DU
Measure Description	No text entered.
Time Frame	Baseline to healing
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.
Complete healing of each baseline was not calculated due to the lack of effect on healing variables seen in the previous placebo-controlled study (RAPIDS 2). In consequence, the endpoint on time to complete healing of baseline DUs was not evaluated.

Reporting Groups

	Description
Bosentan	Initial dose: bosentan 62.5 mg twice daily (b.i.d.) for the first 4 weeks. Target dose: bosentan 125 mg b.i.d. thereafter

Measured Values

	Bosentan

Overall Participants [units: participants]	**0**
Time to Complete Healing of Each Baseline DU	

No statistical analysis provided for Time to Complete Healing of Each Baseline DU

3. Primary: Time to Complete Healing of Each New DU [Time Frame: New DU occurence to healing]

Measure Type	Primary
Measure Title	Time to Complete Healing of Each New DU
Measure Description	No text entered.
Time Frame	New DU occurence to healing
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.
Complete healing of each new DU was not calculated due to the lack of effect on healing variables seen in the previous placebo-controlled study (RAPIDS 2). In consequence, the endpoint on DU healing originally planned time to complete healing of new DUs was not evaluated.

Reporting Groups

	Description
Bosentan	Initial dose: bosentan 62.5 mg twice daily (b.i.d.) for the first 4 weeks. Target dose: bosentan 125 mg b.i.d. thereafter

Measured Values

	Bosentan
Overall Participants [units: participants]	**0**
Time to Complete Healing of Each New DU	

No statistical analysis provided for Time to Complete Healing of Each New DU

4. Primary: Mean Change From Baseline at Each 16 Week Interval up to Week 80 in Scleroderma Health Assessment Questionnaire (SHAQ) Individual Domain Score: Dressing [Time Frame: 80 weeks]

Measure Type	Primary
Measure Title	Mean Change From Baseline at Each 16 Week Interval up to Week 80 in Scleroderma Health Assessment Questionnaire (SHAQ) Individual Domain Score: Dressing
Measure Description	SHAQ evaluates physical disability. Patients were instructed to rate their capacity to perform activities of daily living within the previous 7 days by checking one of the following descriptors: “without any difficulty”, “with some difficulty,” “with much difficulty,” or “unable to do,” equivalent to scores of 0, 1, 2, and 3, respectively. Items were categorized into 8 domains: dressing/grooming, arising, eating, walking, hygiene, reach, grip, and activities.
Time Frame	80 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.

number of participants at baseline, week 16, week 32, week 48, week 64, and week 80 was 116, 99, 93, 85, 82, and 78, respectively

Reporting Groups

	Description
Bosentan	Initial dose: bosentan 62.5 mg twice daily (b.i.d.) for the first 4 weeks. Target dose: bosentan 125 mg b.i.d. thereafter

Measured Values

	Bosentan
Overall Participants [units: participants]	**116**
Mean Change From Baseline at Each 16 Week Interval up to Week 80 in Scleroderma Health Assessment Questionnaire (SHAQ) Individual Domain Score: Dressing [units: scores on a scale] Mean (Standard Deviation)	
change from baseline to week 16	**-0.3 (0.6)**
change from baseline to week 32	**-0.2 (0.7)**
change from baseline to week 48	**-0.1 (0.7)**
change from baseline to week 64	**-0.1 (0.7)**
change from baseline to week 80	**-0.1 (0.7)**

No statistical analysis provided for Mean Change From Baseline at Each 16 Week Interval up to Week 80 in Scleroderma Health Assessment Questionnaire (SHAQ) Individual Domain Score: Dressing

5. Primary: Mean Change From Baseline at Each 16 Week Interval up to Week 80 in Scleroderma Health Assessment Questionnaire (SHAQ) Individual Domain Score: Arising [Time Frame: 80 weeks]

Measure Type	Primary
Measure Title	Mean Change From Baseline at Each 16 Week Interval up to Week 80 in Scleroderma Health Assessment Questionnaire (SHAQ) Individual Domain Score: Arising
Measure Description	SHAQ evaluates physical disability. Patients were instructed to rate their capacity to perform activities of daily living within the previous 7 days by checking one of the following descriptors: "without any difficulty", "with some difficulty," "with much difficulty," or "unable to do," equivalent to scores of 0, 1, 2, and 3, respectively. Items were categorized into 8 domains: dressing/grooming, arising, eating, walking, hygiene, reach, grip, and activities.
Time Frame	80 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.
number of participants at baseline, week 16, week 32, week 48, week 64, and week 80 was 116, 99, 93, 85, 82, and 78, respectively

Reporting Groups

	Description
Bosentan	Initial dose: bosentan 62.5 mg twice daily (b.i.d.) for the first 4 weeks. Target dose: bosentan 125 mg b.i.d. thereafter

Measured Values

	Bosentan
Overall Participants	

[units: participants]	**116**
Mean Change From Baseline at Each 16 Week Interval up to Week 80 in Scleroderma Health Assessment Questionnaire (SHAQ) Individual Domain Score: Arising [units: scores on a scale] Mean (Standard Deviation)	
change from baseline to week 16	**0.0 (0.6)**
change from baseline to week 32	**-0.0 (0.6)**
change from baseline to week 48	**0.1 (0.6)**
change from baseline to week 64	**0.1 (0.7)**
change from baseline to week 80	**0.1 (0.6)**

No statistical analysis provided for Mean Change From Baseline at Each 16 Week Interval up to Week 80 in Scleroderma Health Assessment Questionnaire (SHAQ) Individual Domain Score: Arising

6. Primary: Mean Change From Baseline at Each 16 Week Interval up to Week 80 in Scleroderma Health Assessment Questionnaire (SHAQ) Individual Domain Score: Eating [Time Frame: 80 weeks]

Measure Type	Primary
Measure Title	Mean Change From Baseline at Each 16 Week Interval up to Week 80 in Scleroderma Health Assessment Questionnaire (SHAQ) Individual Domain Score: Eating
Measure Description	SHAQ evaluates physical disability. Patients were instructed to rate their capacity to perform activities of daily living within the previous 7 days by checking one of the following descriptors: "without any difficulty", "with some difficulty," "with much difficulty," or "unable to do," equivalent to scores of 0, 1, 2, and 3, respectively. Items were categorized into 8 domains: dressing/grooming, arising, eating, walking, hygiene, reach, grip, and activities.
Time Frame	80 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.
number of participants at baseline, week 16, week 32, week 48, week 64, and week 80 was 116, 99, 93, 85, 82, and 78, respectively

Reporting Groups

	Description
Bosentan	Initial dose: bosentan 62.5 mg twice daily (b.i.d.) for the first 4 weeks. Target dose: bosentan 125 mg b.i.d. thereafter

Measured Values

	Bosentan
Overall Participants [units: participants]	**116**
Mean Change From Baseline at Each 16 Week Interval up to Week 80 in Scleroderma Health Assessment Questionnaire (SHAQ) Individual Domain Score: Eating [units: scores on a scale] Mean (Standard Deviation)	
change from baseline to week 16	**-0.2 (0.6)**
change from baseline to week 32	**-0.1 (0.7)**
change from baseline to week 48	**-0.2 (0.7)**
change from baseline to week 64	**-0.1 (0.6)**
change from baseline to week 80	**-0.1 (0.7)**

No statistical analysis provided for Mean Change From Baseline at Each 16 Week Interval up to Week 80 in Scleroderma Health Assessment Questionnaire (SHAQ) Individual Domain Score: Eating

7. Primary: Mean Change From Baseline at Each 16 Week Interval up to Week 80 in Scleroderma Health Assessment Questionnaire (SHAQ) Individual Domain Score: Walking [Time Frame: 80 weeks]

Measure Type	Primary
Measure Title	Mean Change From Baseline at Each 16 Week Interval up to Week 80 in Scleroderma Health Assessment Questionnaire (SHAQ) Individual Domain Score: Walking
Measure Description	SHAQ evaluates physical disability. Patients were instructed to rate their capacity to perform activities of daily living within the previous 7 days by checking one of the following descriptors: "without any difficulty", "with some difficulty," "with much difficulty," or "unable to do," equivalent to scores of 0, 1, 2, and 3, respectively. Items were categorized into 8 domains: dressing/grooming, arising, eating, walking, hygiene, reach, grip, and activities.
Time Frame	80 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.
number of participants at baseline, week 16, week 32, week 48, week 64, and week 80 was 116, 99, 93, 85, 82, and 78, respectively

Reporting Groups

	Description
Bosentan	Initial dose: bosentan 62.5 mg twice daily (b.i.d.) for the first 4 weeks. Target dose: bosentan 125 mg b.i.d. thereafter

Measured Values

	Bosentan
Overall Participants [units: participants]	**116**
Mean Change From Baseline at Each 16 Week Interval up to Week 80 in Scleroderma Health Assessment Questionnaire (SHAQ) Individual Domain Score: Walking [units: scores on a scale] Mean (Standard Deviation)	
change from baseline to week 16	**-0.1 (0.6)**
change from baseline to week 32	**0.0 (0.7)**
change from baseline to week 48	**0.1 (0.7)**
change from baseline to week 64	**0.1 (0.8)**
change from baseline to week 80	**0.1 (0.8)**

No statistical analysis provided for Mean Change From Baseline at Each 16 Week Interval up to Week 80 in Scleroderma Health Assessment Questionnaire (SHAQ) Individual Domain Score: Walking

8. Primary: Mean Change From Baseline at Each 16 Week Interval up to Week 80 in Scleroderma Health Assessment Questionnaire (SHAQ) Individual Domain Score: Hygiene [Time Frame: 80 weeks]

Measure Type	Primary
Measure Title	Mean Change From Baseline at Each 16 Week Interval up to Week 80 in Scleroderma Health Assessment Questionnaire (SHAQ) Individual Domain Score: Hygiene

Measure Description	SHAQ evaluates physical disability. Patients were instructed to rate their capacity to perform activities of daily living within the previous 7 days by checking one of the following descriptors: "without any difficulty", "with some difficulty," "with much difficulty," or "unable to do," equivalent to scores of 0, 1, 2, and 3, respectively. Items were categorized into 8 domains: dressing/grooming, arising, eating, walking, hygiene, reach, grip, and activities.
Time Frame	80 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.
number of participants at baseline, week 16, week 32, week 48, week 64, and week 80 was 116, 99, 93, 85, 82, and 78, respectively

Reporting Groups

	Description
Bosentan	Initial dose: bosentan 62.5 mg twice daily (b.i.d.) for the first 4 weeks. Target dose: bosentan 125 mg b.i.d. thereafter

Measured Values

	Bosentan
Overall Participants [units: participants]	**116**
Mean Change From Baseline at Each 16 Week Interval up to Week 80 in Scleroderma Health Assessment Questionnaire (SHAQ) Individual Domain Score: Hygiene [units: scores on a scale] Mean (Standard Deviation)	
change from baseline to week 16	**-0.0 (0.7)**
change from baseline to week 32	**-0.0 (0.8)**
change from baseline to week 48	**-0.0 (0.8)**
change from baseline to week 64	**0.1 (0.7)**
change from baseline to week 80	**0.2 (0.8)**

No statistical analysis provided for Mean Change From Baseline at Each 16 Week Interval up to Week 80 in Scleroderma Health Assessment Questionnaire (SHAQ) Individual Domain Score: Hygiene

9. Primary: Mean Change From Baseline at Each 16 Week Interval up to Week 80 in Scleroderma Health Assessment Questionnaire (SHAQ) Individual Domain Score: Reach [Time Frame: 80 weeks]

Measure Type	Primary
Measure Title	Mean Change From Baseline at Each 16 Week Interval up to Week 80 in Scleroderma Health Assessment Questionnaire (SHAQ) Individual Domain Score: Reach
Measure Description	SHAQ evaluates physical disability. Patients were instructed to rate their capacity to perform activities of daily living within the previous 7 days by checking one of the following descriptors: "without any difficulty", "with some difficulty," "with much difficulty," or "unable to do," equivalent to scores of 0, 1, 2, and 3, respectively. Items were categorized into 8 domains: dressing/grooming, arising, eating, walking, hygiene, reach, grip, and activities.
Time Frame	80 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.

number of participants at baseline, week 16, week 32, week 48, week 64, and week 80 was 116, 99, 93, 85, 82, and 78, respectively

Reporting Groups

	Description
Bosentan	Initial dose: bosentan 62.5 mg twice daily (b.i.d.) for the first 4 weeks. Target dose: bosentan 125 mg b.i.d. thereafter

Measured Values

	Bosentan
Overall Participants [units: participants]	**116**
Mean Change From Baseline at Each 16 Week Interval up to Week 80 in Scleroderma Health Assessment Questionnaire (SHAQ) Individual Domain Score: Reach [units: scores on a scale] Mean (Standard Deviation)	
change from baseline to week 16	**-0.1 (0.7)**
change from baseline to week 32	**0.0 (0.7)**
change from baseline to week 48	**0.0 (0.8)**
change from baseline to week 64	**0.1 (0.8)**
change from baseline to week 80	**0.0 (0.7)**

No statistical analysis provided for Mean Change From Baseline at Each 16 Week Interval up to Week 80 in Scleroderma Health Assessment Questionnaire (SHAQ) Individual Domain Score: Reach

10. Primary: Mean Change From Baseline at Each 16 Week Interval up to Week 80 in Scleroderma Health Assessment Questionnaire (SHAQ) Individual Domain Score: Grip [Time Frame: 80 weeks]

Measure Type	Primary
Measure Title	Mean Change From Baseline at Each 16 Week Interval up to Week 80 in Scleroderma Health Assessment Questionnaire (SHAQ) Individual Domain Score: Grip
Measure Description	SHAQ evaluates physical disability. Patients were instructed to rate their capacity to perform activities of daily living within the previous 7 days by checking one of the following descriptors: "without any difficulty", "with some difficulty," "with much difficulty," or "unable to do," equivalent to scores of 0, 1, 2, and 3, respectively. Items were categorized into 8 domains: dressing/grooming, arising, eating, walking, hygiene, reach, grip, and activities.
Time Frame	80 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.
number of participants at baseline, week 16, week 32, week 48, week 64, and week 80 was 116, 99, 93, 85, 82, and 78, respectively

Reporting Groups

	Description
Bosentan	Initial dose: bosentan 62.5 mg twice daily (b.i.d.) for the first 4 weeks. Target dose: bosentan 125 mg b.i.d. thereafter

Measured Values

	Bosentan
Overall Participants	

[units: participants]	**116**
Mean Change From Baseline at Each 16 Week Interval up to Week 80 in Scleroderma Health Assessment Questionnaire (SHAQ) Individual Domain Score: Grip [units: scores on a scale] Mean (Standard Deviation)	
change from baseline to week 16	**-0.1 (0.7)**
change from baseline to week 32	**-0.2 (0.7)**
change from baseline to week 48	**-0.1 (0.7)**
change from baseline to week 64	**-0.1 (0.7)**
change from baseline to week 80	**-0.1 (0.7)**

No statistical analysis provided for Mean Change From Baseline at Each 16 Week Interval up to Week 80 in Scleroderma Health Assessment Questionnaire (SHAQ) Individual Domain Score: Grip

11. Primary: Mean Change From Baseline at Each 16 Week Interval up to Week 80 in Scleroderma Health Assessment Questionnaire (SHAQ) Individual Domain Score: Activity [Time Frame: 80 weeks]

Measure Type	Primary
Measure Title	Mean Change From Baseline at Each 16 Week Interval up to Week 80 in Scleroderma Health Assessment Questionnaire (SHAQ) Individual Domain Score: Activity
Measure Description	SHAQ evaluates physical disability. Patients were instructed to rate their capacity to perform activities of daily living within the previous 7 days by checking one of the following descriptors: "without any difficulty", "with some difficulty," "with much difficulty," or "unable to do," equivalent to scores of 0, 1, 2, and 3, respectively. Items were categorized into 8 domains: dressing/grooming, arising, eating, walking, hygiene, reach, grip, and activities.
Time Frame	80 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.
number of participants at baseline, week 16, week 32, week 48, week 64, and week 80 was 116, 99, 93, 85, 82, and 78, respectively

Reporting Groups

	Description
Bosentan	Initial dose: bosentan 62.5 mg twice daily (b.i.d.) for the first 4 weeks. Target dose: bosentan 125 mg b.i.d. thereafter

Measured Values

	Bosentan
Overall Participants [units: participants]	**116**
Mean Change From Baseline at Each 16 Week Interval up to Week 80 in Scleroderma Health Assessment Questionnaire (SHAQ) Individual Domain Score: Activity [units: scores on a scale] Mean (Standard Deviation)	
change from baseline to week 16	**-0.2 (0.5)**
change from baseline to week 32	**-0.1 (0.7)**
change from baseline to week 48	**-0.1 (0.7)**
change from baseline to week 64	**-0.1 (0.7)**
change from baseline to week 80	**-0.1 (0.6)**

No statistical analysis provided for Mean Change From Baseline at Each 16 Week Interval up to Week 80 in Scleroderma Health Assessment Questionnaire (SHAQ) Individual Domain Score: Activity

12. Primary: Mean Changes From Baseline at Each 16 Week Interval up to Week 80 in Overall Hand Pain Related to Finger Ulcers [Time Frame: 80 weeks]

Measure Type	Primary
Measure Title	Mean Changes From Baseline at Each 16 Week Interval up to Week 80 in Overall Hand Pain Related to Finger Ulcers
Measure Description	Overall hand pain related to finger ulcers was assessed by the patient using a Visual Analogue Scale. Patients were instructed to score their pain by marking on the continuous 10-cm scale, where 0 (left) was no pain and 100 (right) very severe pain, in response to the question, “How much pain have you had because of your finger ulcers in the past week?” The investigator measured the distance in millimeters between 0 and the patient mark with the ruler provided and recorded the distance.
Time Frame	80 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.
number of participants at baseline, week 16, week 32, week 48, week 64, and week 80 was 110, 94, 89, 81, 76, and 73, respectively

Reporting Groups

	Description
Bosentan	Initial dose: bosentan 62.5 mg twice daily (b.i.d.) for the first 4 weeks. Target dose: bosentan 125 mg b.i.d. thereafter

Measured Values

	Bosentan
Overall Participants [units: participants]	**116**
Mean Changes From Baseline at Each 16 Week Interval up to Week 80 in Overall Hand Pain Related to Finger Ulcers [units: mm] Mean (Standard Deviation)	
change from baseline to week 16	**-21.59 (28.02)**
change from baseline to week 32	**-28.16 (32.64)**
change from baseline to week 48	**-21.90 (32.09)**
change from baseline to week 64	**-22.96 (33.27)**
change from baseline to week 80	**-24.29 (36.55)**

No statistical analysis provided for Mean Changes From Baseline at Each 16 Week Interval up to Week 80 in Overall Hand Pain Related to Finger Ulcers

13. Primary: Mean Change From Baseline at Each 16 Week Interval up to Week 80 in the UK Systemic Sclerosis Functional Score (UKFS) [Time Frame: 80 weeks]

Measure Type	Primary
Measure Title	Mean Change From Baseline at Each 16 Week Interval up to Week 80 in the UK Systemic Sclerosis Functional Score (UKFS)
Measure Description	UKFS relates to upper and lower extremity function and muscle weakness. For each item, the patient indicated the

	responses that best described their current ability: “able to perform in a normal manner,” “able to perform with alteration in style,” “can only manage with difficulty,” and “impossible to achieve.” Each response was given an integer from 0 (able to perform in a normal manner) to 3 (impossible to achieve), and the sum of individual responses provided an overall score of 0 to 33. Missing values were replaced with the worst value the patient reported on the other items at that visit.
Time Frame	80 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.
number of participants at baseline, week 16, week 32, week 48, week 64, and week 80 was 116, 98, 93, 84, 82, and 78, respectively

Reporting Groups

	Description
Bosentan	Initial dose: bosentan 62.5 mg twice daily (b.i.d.) for the first 4 weeks. Target dose: bosentan 125 mg b.i.d. thereafter

Measured Values

	Bosentan
Overall Participants [units: participants]	**116**
Mean Change From Baseline at Each 16 Week Interval up to Week 80 in the UK Systemic Sclerosis Functional Score (UKFS) [units: score on a scale] Mean (Standard Deviation)	
change from baseline to week 16	**-1.37 (3.64)**
change from baseline to week 32	**-1.25 (4.01)**
change from baseline to week 48	**-0.89 (4.98)**
change from baseline to week 64	**-1.17 (4.00)**
change from baseline to week 80	**-0.45 (4.66)**

No statistical analysis provided for Mean Change From Baseline at Each 16 Week Interval up to Week 80 in the UK Systemic Sclerosis Functional Score (UKFS)

14. Secondary: Adverse Events up to 24 Hours After Last Study Medication [Time Frame: 80 weeks]

Measure Type	Secondary
Measure Title	Adverse Events up to 24 Hours After Last Study Medication
Measure Description	Number of patients with at least one treatment-emergent adverse event. All adverse events that occurred after study drug initiation and up to 24 hours after study drug discontinuation were to be recorded.
Time Frame	80 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.
Study population

Reporting Groups

	Description

Bosentan	Initial dose: bosentan 62.5 mg twice daily (b.i.d.) for the first 4 weeks. Target dose: bosentan 125 mg b.i.d. thereafter

Measured Values

	Bosentan
Overall Participants [units: participants]	**116**
Adverse Events up to 24 Hours After Last Study Medication [units: participants]	**111**

No statistical analysis provided for Adverse Events up to 24 Hours After Last Study Medication

15. Secondary: Serious Adverse Events up to 28 Days After Last Study Medication [Time Frame: 80 weeks]

Measure Type	Secondary
Measure Title	Serious Adverse Events up to 28 Days After Last Study Medication
Measure Description	Number of patients with at least one treatment-emergent serious adverse event. Adverse events that occurred after study drug initiation and up to 28 days after study drug discontinuation.
Time Frame	80 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.
Study population

Reporting Groups

	Description
Bosentan	Initial dose: bosentan 62.5 mg twice daily (b.i.d.) for the first 4 weeks. Target dose: bosentan 125 mg b.i.d. thereafter

Measured Values

	Bosentan
Overall Participants [units: participants]	**116**
Serious Adverse Events up to 28 Days After Last Study Medication [units: participants]	**45**

No statistical analysis provided for Serious Adverse Events up to 28 Days After Last Study Medication

16. Secondary: Adverse Events Leading to Permanent Discontinuation of the Study Medication [Time Frame: 80 weeks]

Measure Type	Secondary
Measure Title	Adverse Events Leading to Permanent Discontinuation of the Study Medication
Measure Description	Number of patients with an adverse event leading to permanent discontinuation of the study treatment
Time Frame	80 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.
Study population

Reporting Groups

	Description
Bosentan	Initial dose: bosentan 62.5 mg twice daily (b.i.d.) for the first 4 weeks. Target dose: bosentan 125 mg b.i.d. thereafter

Measured Values

	Bosentan
Overall Participants [units: participants]	**116**
Adverse Events Leading to Permanent Discontinuation of the Study Medication [units: participants]	**36**

No statistical analysis provided for Adverse Events Leading to Permanent Discontinuation of the Study Medication

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	80 weeks
Additional Description	Treatment-emergent adverse events

Reporting Groups

	Description
Bosentan	Initial dose: bosentan 62.5 mg twice daily (b.i.d.) for the first 4 weeks. Target dose: bosentan 125 mg b.i.d. thereafter

Serious Adverse Events

	Bosentan
Total, serious adverse events	
# participants affected / at risk	**45/116 (38.79%)**
Blood and lymphatic system disorders	
ANAEMIA † 1	
# participants affected / at risk	**2/116 (1.72%)**
IRON DEFICIENCY ANAEMIA † 1	
# participants affected / at risk	**1/116 (0.86%)**
Cardiac disorders	
CARDIAC FAILURE CONGESTIVE † 1	
# participants affected / at risk	**2/116 (1.72%)**
ACUTE CORONARY SYNDROME † 1	
# participants affected / at risk	**1/116 (0.86%)**
ATRIAL FIBRILLATION † 1	
# participants affected / at risk	**1/116 (0.86%)**
CARDIAC ARREST † 1	
# participants affected / at risk	**1/116 (0.86%)**
MYOCARDIAL INFARCTION † 1	
# participants affected / at risk	**1/116 (0.86%)**

MYOCARDITIS † 1	
# participants affected / at risk	1/116 (0.86%)
Gastrointestinal disorders	
ABDOMINAL PAIN † 1	
# participants affected / at risk	2/116 (1.72%)
ABDOMINAL PAIN LOWER † 1	
# participants affected / at risk	1/116 (0.86%)
COLITIS ISCHAEMIC † 1	
# participants affected / at risk	1/116 (0.86%)
DIVERTICULUM INTESTINAL † 1	
# participants affected / at risk	1/116 (0.86%)
FAECALOMA † 1	
# participants affected / at risk	1/116 (0.86%)
GASTRITIS † 1	
# participants affected / at risk	1/116 (0.86%)
GASTROINTESTINAL MOTILITY DISORDER † 1	
# participants affected / at risk	1/116 (0.86%)
ILEUS † 1	
# participants affected / at risk	1/116 (0.86%)
INTESTINAL OBSTRUCTION † 1	
# participants affected / at risk	1/116 (0.86%)
NAUSEA † 1	
# participants affected / at risk	1/116 (0.86%)
OESOPHAGITIS HAEMORRHAGIC † 1	
# participants affected / at risk	1/116 (0.86%)
VOMITING † 1	
# participants affected / at risk	1/116 (0.86%)
General disorders	
ADVERSE DRUG REACTION † 1	
# participants affected / at risk	2/116 (1.72%)
CHEST PAIN † 1	
# participants affected / at risk	2/116 (1.72%)
DEVICE DISLOCATION † 1	
# participants affected / at risk	1/116 (0.86%)
DRUG WITHDRAWAL SYNDROME † 1	
# participants affected / at risk	1/116 (0.86%)
IMPAIRED HEALING † 1	
# participants affected / at risk	1/116 (0.86%)
PAIN † 1	
# participants affected / at risk	1/116 (0.86%)
SUPRAPUBIC PAIN † 1	
# participants affected / at risk	1/116 (0.86%)
Infections and infestations	
PNEUMONIA † 1	
# participants affected / at risk	6/116 (5.17%)
INFECTED SKIN ULCER † 1	
# participants affected / at risk	4/116 (3.45%)
CELLULITIS † 1	
# participants affected / at risk	2/116 (1.72%)

DEVICE RELATED INFECTION † 1	
# participants affected / at risk	2/116 (1.72%)
SEPSIS † 1	
# participants affected / at risk	2/116 (1.72%)
ABSCESS LIMB † 1	
# participants affected / at risk	1/116 (0.86%)
APPENDICITIS † 1	
# participants affected / at risk	1/116 (0.86%)
BRONCHITIS † 1	
# participants affected / at risk	1/116 (0.86%)
CATHETER SITE INFECTION † 1	
# participants affected / at risk	1/116 (0.86%)
DIVERTICULITIS † 1	
# participants affected / at risk	1/116 (0.86%)
GANGRENE † 1	
# participants affected / at risk	1/116 (0.86%)
GASTROENTERITIS † 1	
# participants affected / at risk	1/116 (0.86%)
HEPATITIS B † 1	
# participants affected / at risk	1/116 (0.86%)
HERPES ZOSTER † 1	
# participants affected / at risk	1/116 (0.86%)
INFLUENZA † 1	
# participants affected / at risk	1/116 (0.86%)
LOBAR PNEUMONIA † 1	
# participants affected / at risk	1/116 (0.86%)
LOCALISED INFECTION † 1	
# participants affected / at risk	1/116 (0.86%)
OSTEOMYELITIS † 1	
# participants affected / at risk	1/116 (0.86%)
VIRAL PERICARDITIS † 1	
# participants affected / at risk	1/116 (0.86%)
VIRAL UPPER RESPIRATORY TRACT INFECTION † 1	
# participants affected / at risk	1/116 (0.86%)
Injury, poisoning and procedural complications	
ASBESTOSIS † 1	
# participants affected / at risk	1/116 (0.86%)
JOINT INJURY † 1	
# participants affected / at risk	1/116 (0.86%)
PROCEDURAL PAIN † 1	
# participants affected / at risk	1/116 (0.86%)
VASCULAR GRAFT OCCLUSION † 1	
# participants affected / at risk	1/116 (0.86%)
Investigations	
HEPATIC ENZYME INCREASED † 1	
# participants affected / at risk	1/116 (0.86%)
Metabolism and nutrition disorders	
DEHYDRATION † 1	
# participants affected / at risk	1/116 (0.86%)

MALNUTRITION † 1	
# participants affected / at risk	1/116 (0.86%)
Musculoskeletal and connective tissue disorders	
INTERVERTEBRAL DISC PROTRUSION † 1	
# participants affected / at risk	2/116 (1.72%)
SCLERODERMA † 1	
# participants affected / at risk	2/116 (1.72%)
MUSCULAR WEAKNESS † 1	
# participants affected / at risk	1/116 (0.86%)
MYOSITIS † 1	
# participants affected / at risk	1/116 (0.86%)
OSTEOARTHRITIS † 1	
# participants affected / at risk	1/116 (0.86%)
PAIN IN EXTREMITY † 1	
# participants affected / at risk	1/116 (0.86%)
RHEUMATOID ARTHRITIS † 1	
# participants affected / at risk	1/116 (0.86%)
ROTATOR CUFF SYNDROME † 1	
# participants affected / at risk	1/116 (0.86%)
SYSTEMIC SCLEROSIS † 1	
# participants affected / at risk	1/116 (0.86%)
TENOSYNOVITIS † 1	
# participants affected / at risk	1/116 (0.86%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
CHRONIC LYMPHOCYTIC LEUKAEMIA † 1	
# participants affected / at risk	1/116 (0.86%)
Nervous system disorders	
CAROTID ARTERY STENOSIS † 1	
# participants affected / at risk	1/116 (0.86%)
CEREBROVASCULAR ACCIDENT † 1	
# participants affected / at risk	1/116 (0.86%)
DIZZINESS POSTURAL † 1	
# participants affected / at risk	1/116 (0.86%)
HYPOAESTHESIA † 1	
# participants affected / at risk	1/116 (0.86%)
LUMBAR RADICULOPATHY † 1	
# participants affected / at risk	1/116 (0.86%)
PARAESTHESIA † 1	
# participants affected / at risk	1/116 (0.86%)
Psychiatric disorders	
ALCOHOLIC PSYCHOSIS † 1	
# participants affected / at risk	1/116 (0.86%)
DEPRESSION † 1	
# participants affected / at risk	1/116 (0.86%)
Renal and urinary disorders	
SCLERODERMA RENAL CRISIS † 1	
# participants affected / at risk	2/116 (1.72%)
RENAL FAILURE ACUTE † 1	

# participants affected / at risk	1/116 (0.86%)
Respiratory, thoracic and mediastinal disorders	
DYSPNOEA † 1	
# participants affected / at risk	6/116 (5.17%)
PULMONARY FIBROSIS † 1	
# participants affected / at risk	2/116 (1.72%)
PULMONARY HYPERTENSION † 1	
# participants affected / at risk	2/116 (1.72%)
ACUTE RESPIRATORY FAILURE † 1	
# participants affected / at risk	1/116 (0.86%)
CHRONIC OBSTRUCTIVE PULMONARY DISEASE † 1	
# participants affected / at risk	1/116 (0.86%)
PLEURAL EFFUSION † 1	
# participants affected / at risk	1/116 (0.86%)
PNEUMONITIS † 1	
# participants affected / at risk	1/116 (0.86%)
PNEUMOTHORAX † 1	
# participants affected / at risk	1/116 (0.86%)
PULMONARY ARTERIAL HYPERTENSION † 1	
# participants affected / at risk	1/116 (0.86%)
Skin and subcutaneous tissue disorders	
SKIN ULCER † 1	
# participants affected / at risk	5/116 (4.31%)
PYODERMA GANGRENOSUM † 1	
# participants affected / at risk	1/116 (0.86%)
SKIN DISCOLOURATION † 1	
# participants affected / at risk	1/116 (0.86%)
SKIN NECROSIS † 1	
# participants affected / at risk	1/116 (0.86%)
Surgical and medical procedures	
ARTHRODESIS † 1	
# participants affected / at risk	1/116 (0.86%)
FINGER AMPUTATION † 1	
# participants affected / at risk	1/116 (0.86%)
FOOT AMPUTATION † 1	
# participants affected / at risk	1/116 (0.86%)
HIP ARTHROPLASTY † 1	
# participants affected / at risk	1/116 (0.86%)
LUNG TRANSPLANT † 1	
# participants affected / at risk	1/116 (0.86%)
REVISION OF INTERNAL FIXATION † 1	
# participants affected / at risk	1/116 (0.86%)
Vascular disorders	
PERIPHERAL ISCHAEMIA † 1	
# participants affected / at risk	4/116 (3.45%)
EXTREMITY NECROSIS † 1	
# participants affected / at risk	1/116 (0.86%)
FEMORAL ARTERY OCCLUSION † 1	
# participants affected / at risk	1/116 (0.86%)

HYPOTENSION † 1	
# participants affected / at risk	1/116 (0.86%)

† Events were collected by systematic assessment
1 Term from vocabulary, MedDRA (13.0)

Other Adverse Events

Hide Other Adverse Events

Time Frame	80 weeks
Additional Description	Treatment-emergent adverse events

Frequency Threshold

Threshold above which other adverse events are reported	5

Reporting Groups

	Description
Bosentan	Initial dose: bosentan 62.5 mg twice daily (b.i.d.) for the first 4 weeks. Target dose: bosentan 125 mg b.i.d. thereafter

Other Adverse Events

	Bosentan
Total, other (not including serious) adverse events	
# participants affected / at risk	111/116 (95.69%)
Blood and lymphatic system disorders	
ANAEMIA † 1	
# participants affected / at risk	11/116 (9.48%)
Gastrointestinal disorders	
DIARRHOEA † 1	
# participants affected / at risk	21/116 (18.10%)
NAUSEA † 1	
# participants affected / at risk	13/116 (11.21%)
DYSPHAGIA † 1	
# participants affected / at risk	11/116 (9.48%)
GASTROOESOPHAGEAL REFLUX DISEASE † 1	
# participants affected / at risk	8/116 (6.90%)
MOUTH ULCERATION † 1	
# participants affected / at risk	6/116 (5.17%)
General disorders	
OEDEMA PERIPHERAL † 1	
# participants affected / at risk	13/116 (11.21%)
FATIGUE † 1	
# participants affected / at risk	11/116 (9.48%)
PYREXIA † 1	
# participants affected / at risk	9/116 (7.76%)
ASTHENIA † 1	
# participants affected / at risk	6/116 (5.17%)
Infections and infestations	
UPPER RESPIRATORY TRACT INFECTION † 1	

# participants affected / at risk	24/116 (20.69%)
INFECTED SKIN ULCER † 1	
# participants affected / at risk	21/116 (18.10%)
LOCALISED INFECTION † 1	
# participants affected / at risk	17/116 (14.66%)
NASOPHARYNGITIS † 1	
# participants affected / at risk	13/116 (11.21%)
BRONCHITIS † 1	
# participants affected / at risk	10/116 (8.62%)
SINUSITIS † 1	
# participants affected / at risk	10/116 (8.62%)
INFLUENZA † 1	
# participants affected / at risk	9/116 (7.76%)
URINARY TRACT INFECTION † 1	
# participants affected / at risk	8/116 (6.90%)
CELLULITIS † 1	
# participants affected / at risk	7/116 (6.03%)
GASTROENTERITIS VIRAL † 1	
# participants affected / at risk	7/116 (6.03%)
HERPES ZOSTER † 1	
# participants affected / at risk	6/116 (5.17%)
Investigations	
LIVER FUNCTION TEST ABNORMAL † 1	
# participants affected / at risk	12/116 (10.34%)
ALANINE AMINOTRANSFERASE INCREASED † 1	
# participants affected / at risk	11/116 (9.48%)
ASPARTATE AMINOTRANSFERASE INCREASED † 1	
# participants affected / at risk	7/116 (6.03%)
HAEMOGLOBIN DECREASED † 1	
# participants affected / at risk	6/116 (5.17%)
WEIGHT DECREASED † 1	
# participants affected / at risk	6/116 (5.17%)
Musculoskeletal and connective tissue disorders	
ARTHRALGIA † 1	
# participants affected / at risk	22/116 (18.97%)
PAIN IN EXTREMITY † 1	
# participants affected / at risk	13/116 (11.21%)
TENDONITIS † 1	
# participants affected / at risk	8/116 (6.90%)
BACK PAIN † 1	
# participants affected / at risk	7/116 (6.03%)
Nervous system disorders	
HEADACHE † 1	
# participants affected / at risk	14/116 (12.07%)
DIZZINESS † 1	
# participants affected / at risk	6/116 (5.17%)
Psychiatric disorders	
INSOMNIA † 1	
# participants affected / at risk	10/116 (8.62%)

Respiratory, thoracic and mediastinal disorders	
COUGH † 1	
# participants affected / at risk	**15/116 (12.93%)**
DYSPNOEA † 1	
# participants affected / at risk	**10/116 (8.62%)**
Skin and subcutaneous tissue disorders	
SKIN ULCER † 1	
# participants affected / at risk	**26/116 (22.41%)**
RASH † 1	
# participants affected / at risk	**14/116 (12.07%)**
PRURITUS † 1	
# participants affected / at risk	**13/116 (11.21%)**

† Events were collected by systematic assessment
1 Term from vocabulary, MedDRA (13.0)

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: No text entered.

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Responsible Party: Actelion
ClinicalTrials.gov Identifier: NCT00319696 History of Changes
Other Study ID Numbers: **AC-052-333**
RAPIDS-2 OL

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Results First Received:	June 29, 2012
Last Updated:	September 27, 2012
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