Sponsor protocol code	AC-055-302
Full title of trial	SERAPHIN: Study with Endothelin Receptor Antagonist in Pulmonary arterial Hypertension to improve cliNical outcome: A multicente double-blind, randomized, placebo-controlled, parallel-group, event-driven, phase III study to assess the effects of macitentan on morbidity and mortality in patients with symptomatic pulmonary arterial hypertension

Additional study identifiers

ISRCTN number	
NCT number	NCT00660179
UTN number	

Sponsor details

Sponsor 1

Name of organisation	Actelion Pharmaceuticals Ltd.
Street address	Gewerbestrasse 16
Town/city	Allschwil
Postal code	4123
Country	Switzerland

SCIENTIFIC CONTACT POINT

Name of organisation	Actelion Pharmaceuticals Ltd.
Functional contact point name	Clinical Trials Disclosure Desk
Telephone number	+()
Email address	clinical-trials-disclosure@actelion.com

PUBLIC CONTACT POINT

Name of organisation	Actelion Pharmaceuticals Ltd.
Functional contact point name	Clinical Trials Disclosure Desk
Telephone number	+()
Email address	clinical-trials-disclosure@actelion.com

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	no
EMA paediatric investigation plan(s)	
Does article 45 of regulation (EC) no 1901/2006 apply yo this trial?	no
Does article 46 of regulation (EC) no 1901/2006 apply yo this trial?	no

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	2012-04-26
Is this the analysis of the primary completion data?	yes
Primary completion date	2012-03-15
Global end of trial date reached?	yes
Global end of trial date	2012-03-15
Was the trial ended prematurely?	no

General information about the trial

Main objective of the trial	To demonstrate that either dose (3 mg or 10 mg) of macitentan reduces the risk of morbidity and mortality in patients with sympto PAH.
Actual start date of recruitment	2008-05-25
Long term follow-up planned	no
Independent data monitoring committee (IMDC) involvement?	yes
Protection of trial subjects	Prior to the start of the trial, each study center consulted an Independent Ethics Committee (IEC) or Institutional Review Board (IRB i.e., a review panel that was responsible for ensuring the protection of the rights, safety and wellbeing of human subjects involved i clinical investigation. The protocol and any material provided to the patient (such as a patient information sheet or description of th study used to obtain informed consent) were reviewed and approved by the appropriate IEC or IRB before the study was started. Th study was conducted according to the principles of the 'Declaration of Helsinki' and with the laws and regulations of the country in which the research was conducted. Documentary evidence of adequate Good Clinical Practice (GCP) training of the investigator was collected. Both Actelion and the investigator had the right to terminate the study at any time, and in such a case, were responsible f protecting the patients' interests. The investigator was responsible for maintaining the confidentiality of patients' identities. Written informed consent was required to be obtained from each individual participating in the study prior to any study procedure and after adequate explanation of the aims, methods, objectives, and potential hazards of the study. It was made clear to each patient that he she was free to refuse to enter the study, or to withdraw from it at any time for any reason.
Background therapy	Treatment with oral diuretics was allowed if it had been ongoing at a stable dose for at least 1 month before randomization. Optimization of the dose of oral diuretics was allowed during the treatment period. The following treatments for PAH were allowed a concomitant medications if they had been taken by the patients at a stable dose for at least 3 months prior to randomization: inhaled prostanoids (e.g., beraprost, iloprost); Oral phosphodiesterase inhibitors (e.g., sildenafil); Calcium channel blockers; Any introduction of a new treatment for PAH without documented worsening of PAH was strongly discouraged during the study per If an additional PAH-specific therapy was started without a protocol-defined morbidity event, study drug was not to be discontinued (unless the additional therapy was an ERA), and patients were followed up to EOS according to the visit and assessment schedule.
Evidence for comparator(s)	IMPORTANT NOTE: Because of an error message generated by the system a value higher than the actual value had to be added in o the fields of the "Age Breakdown for Trial" shown below in the Section "Population of trial subjects". The ACTUAL NUMBER OF SUBJECTS ENROLLED for the category "From 65-84 years" is 104 (not 105). Although all patients were counted in the 'all-randomiz set', data obtained from 1 patient were not included in the tables for demographic characteristics (informed consent not signed).

Population of trial subjects

TRIAL COUNTRY	PLANNED NUMBER OF SUBJECTS	ACTUAL NUMBER OF SUBJECTS ENROLLED

Argentina	43
Australia	10
Austria	4
Belarus	23
Belgium	2
Bulgaria	6
Canada	16
Chile	28
China	87
Colombia	9
Croatia	1
Denmark	1
France	11
Germany	44
Hong Kong	4
Hungary	6
India	47
Israel	20
Italy	5
Malaysia	7
Mexico	40
Netherlands	1
Norway	2
Peru	7
Poland	21
Romania	16
Russian Federation	72
Serbia	16
Singapore	13
Slovakia	6
South Africa	24
Spain	15
Sweden	7
Taiwan	14
Thailand	25
Turkey	3
United Kingdom	5
United States	67
Ukraine	14
Total: worldwide	742
Total: EEA	153

AGE RANGE	PLANNED NUMBER OF SUBJECTS	ACTUAL NUMBER OF SUBJECTS ENRO
In utero		0
Preterm newborn infants (gestational age < 37 wks)		0
Newborns (0-27 days)		0
Infants and toddlers (28 days-23 months)		0
Children (2-11 years)		0
Adolescents (12-17 years)		20
Adults (18-64 years)		617
From 65-84 years		105
85 years and over		0

SUBJECT DISPOSITION **This section contains errors/warnings**

Details

Recruitment details	742 patients from 151 centers in 39 countries were randomized.
Screening details	A total of 955 patients were screened from 158 centers in 39 countries.

Pre-assignment period

MILESTONES	
Started	
Completed	
INTERMEDIATE MILESTONES	
REASONS FOR NON-COMPLETION	

Period 1

Period details

Period title	Overall study
Is this the baseline period	no
Allocation method	Randomised - controlled
Blinding type	Double Blind
Roles blinded	Subject, Investigator, Monitor, Data analyst
Blinding details	The two dose strengths of macitentan and placebo were indistinguishable and all study drug kits were packaged in the sa IMPORTANT NOTE: Because of an error message generated by the system (possibly due to a "conflict" with the change in the box "Are arms mutually exclusive" had to be left unticked for Period 1 (meaning: No). This is not correct: arms for Pe other periods) were mutually exclusive.
Are arms mutually exclusive	no
Subjects in period	742

Period arms

TITLE	TYPE	DESCRIPTION	PRODUCTS
Placebo			**Name**: Placebo **Code**: **Other names**:

Placebo	Comparator	Placebo once daily	**Dosage & administration**: Placebo once daily, tablet for oral use **Pharma forms**: [Tablet] **Route of Admin**: [Oral use]
ACT-064992 3 mg	Experimental	ACT-064992 3 mg once daily	**Name**: ACT-064992 3 mg **Code**: **Other names**: **Dosage & administration**: ACT-064992 3 mg once daily, tablet for oral **Pharma forms**: [Tablet] **Route of Admin**: [Oral use]
ACT-064992 10 mg	Experimental	ACT-064992 10 mg once daily	**Name**: ACT-064992 10 mg **Code**: **Other names**: **Dosage & administration**: ACT-064992 10 mg once daily, tablet for ora **Pharma forms**: [Tablet] **Route of Admin**: [Oral use]

Period milestone achievement

MILESTONE/REASON	PLACEBO	ACT-064992 3 MG	ACT-064992 10 MG
STARTED	250	250	242
COMPLETED	250	250	242
OTHER MILESTONES			
REASONS FOR NON-COMPLETION			
REASONS FOR SUBJECT JOINING			

Period 2

Period details

Period title	Patient demographics
Is this the baseline period	yes
Allocation method	Randomised - controlled
Blinding type	Double Blind
Roles blinded	Subject, Investigator, Monitor, Data analyst
Blinding details	This study was performed in a double-blind fashion. The two dose strengths of macitentan and placebo were indistinguis study drug kits were packaged in the same way. The investigator and study staff, the patients, the monitors, and Actelion and contractors remained blinded to the study drug allocation until database closure.
Are arms mutually exclusive	yes
Subjects in period	739

Period arms

TITLE	TYPE	DESCRIPTION	PRODUCTS
Placebo	Placebo Comparator	Placebo	**Name**: Placebo **Code**: **Other names**: **Dosage & administration**: Placebo once daily, tablet for oral use **Pharma forms**: [Tablet] **Route of Admin**: [Oral use]
ACT-064992 3 mg once daily	Experimental	ACT-064992 3 mg once daily	**Name**: ACT-064992 3 mg **Code**: **Other names**: **Dosage & administration**: ACT-064992 3 mg once daily, tablet for oral **Pharma forms**: [Tablet] **Route of Admin**: [Oral use]
ACT-064992 10 mg once daily	Experimental	ACT-064992 10 mg once daily	**Name**: ACT-064992 10 mg **Code**: **Other names**: **Dosage & administration**: ACT-064992 10 mg once daily, tablet for ora **Pharma forms**: [Tablet] **Route of Admin**: [Oral use]

Period milestone achievement

MILESTONE/REASON	PLACEBO	ACT-064992 3 MG ONCE DAILY	ACT-064992 10 MG ONCE DAILY
STARTED	249	248	242
COMPLETED	249	248	242
OTHER MILESTONES			
REASONS FOR NON-COMPLETION			
REASONS FOR SUBJECT JOINING			

Period 3

Period details

Period title	Reasons for discontinuation of treatment
Is this the baseline period	no
Allocation method	Randomised - controlled
Blinding type	Double Blind
Roles blinded	Subject, Investigator, Monitor, Data analyst
Blinding details	This study was performed in a double-blind fashion. The two dose strengths of macitentan and placebo were indistinguis study drug kits were packaged in the same way. The investigator and study staff, the patients, the monitors, and Actelion and contractors remained blinded to the study drug allocation until database closure.
Are arms mutually exclusive	no
Subjects in period	741

Period arms

TITLE	TYPE	DESCRIPTION	PRODUCTS
			Name: Placebo **Code**:

Placebo	Placebo Comparator	Placebo once daily	**Other names**: **Dosage & administration**: Placebo once daily, tablet for oral use **Pharma forms**: [Tablet] **Route of Admin**: [Oral use]
ACT-064992 3 mg	Experimental	ACT-064992 3 mg once daily	**Name**: ACT-064992 3 mg **Code**: **Other names**: **Dosage & administration**: ACT-064992 3 mg once daily, tablet for oral **Pharma forms**: [Tablet] **Route of Admin**: [Oral use]
ACT-064992 10 mg	Experimental	ACT-064992 10 mg once daily	**Name**: ACT-064992 10 mg **Code**: **Other names**: **Dosage & administration**: ACT-064992 10 mg once daily, tablet for ora **Pharma forms**: [Tablet] **Route of Admin**: [Oral use]

Period milestone achievement

MILESTONE/REASON	PLACEBO	ACT-064992 3 MG	ACT-064992 10 MG
STARTED	249	250	242
COMPLETED	101	132	135
OTHER MILESTONES REASONS FOR NON-COMPLETION			
ADVERSE EVENT, SERIOUS FATAL	12	10	10
CONSENT WITHDRAWN BY SUBJECT	1	3	4
LOST TO FOLLOW-UP	3	2	
OTHER: ADMINISTRATIVE REASON	5	2	5
OTHER: TREATMENT FAILURE	3	2	
OTHER: DIESEASE PROGRESSION LEADING TO OPEN-LABEL STUDY	80	57	50
ADVERSE EVENT, NON-FATAL	31	34	26
OTHER: ADMINISTRATION OF FORBIDDEN DRUG	2	1	
OTHER: WTIHDRAWAL FROM TREATMENT	11	7	12
REASONS FOR SUBJECT JOINING			

SUBJECT ANALYSIS SETS

TITLE	TYPE	DESCRIPTION	NUMBER
All randomized set	Intention-to-treat	This analysis set included all randomized patients, whether or not they received study drug.	
All treated set	Full analysis	This analysis set included all randomized patients who received study drug at least once.	
Per protocol set	Per protocol	This analysis set included all patients from the All-treated set who did not deviate from the protocol in a way that might affect the evaluation of the effect of the study drug on the primary endpoint, i.e., without any 'major protocol violations' as pre-defined in the SAP identified prior to unblinding.	

BASELINE CHARACTERISTICS

Baseline characteristics information

The baseline period is	Patient demographics
How are baseline characteristics reported?	Per Arm in the baseline period

Reporting groups

Reporting group 1

Title	Placebo
Subjects	249
Description	Placebo

Reporting group 2

Title	ACT-064992 3 mg once daily
Subjects	248
Description	ACT-064992 3 mg once daily

Reporting group 3

Title	ACT-064992 10 mg once daily
Subjects	242
Description	ACT-064992 10 mg once daily

Age characteristics

Age categorical characteristic

Characteristic title	Age Categorical
Units	Years
Description	Age categorical description
Categories	<=18 years, Between 18 and 65 years, >=65 years
Ready for collection values	yes
REPORTING GROUPS	

GROUP#	TITLE	<=18 YEARS	BETWEEN 18 AND 65 YEARS	>=
Group 1	Placebo	7	199	

Group 2	ACT-064992 3 mg once daily	7	208
Group 3	ACT-064992 10 mg once daily	6	209
Group 4	Category totals	20	616

SUBJECT ANALYSIS SETS

SET#	TITLE	<=18 YEARS	BETWEEN 18 AND 65 YEARS	>=
Set 1	All randomized set	20	616	
Set 2	All treated set			
Set 3	Per protocol set			

Age continuous characteristic

Characteristic title	Age Continuous
Units	Year
Description	Age continuous description
Central tendency type	Arithmetic mean
Dispersion type	Standard deviation
Ready for collection values	yes

REPORTING GROUPS

GROUP#	TITLE	TENDENCY	STANDARD DEVIATION
Group 1	Placebo	46.7	17.03
Group 2	ACT-064992 3 mg once daily	44.5	16.26
Group 3	ACT-064992 10 mg once daily	45.5	14.99

SUBJECT ANALYSIS SETS

SET#	TITLE	TENDENCY	STANDARD DEVIATION
Set 1	All randomized set	45.6	16.13
Set 2	All treated set		
Set 3	Per protocol set		

Gender characteristics

Characteristic title	Gender Categorical
Units	Subjects
Description	Gender categorical description
Categories	Female, Male
Ready for collection values	yes

REPORTING GROUPS

GROUP#	TITLE	FEMALE	MALE
Group 1	Placebo	184	65
Group 2	ACT-064992 3 mg once daily	187	61
Group 3	ACT-064992 10 mg once daily	194	48
Group 4	Category totals	565	174

SUBJECT ANALYSIS SETS

SET#	TITLE	FEMALE	MALE
Set 1	All randomized set	565	174
Set 2	All treated set		
Set 3	Per protocol set		

Study specific characteristics

Study categorical characteristic 1

Characteristic title	WHO classification of the functional status of patients with pulmonary hypertension
Units	Subjects
Description	Class I: no limitation of usual physical activity (PA) which does not increase dyspnea, fatigue, chest pain, or presyncope. limitation of PA. No discomfort at rest. Normal PA increases dyspnea, fatigue, chest pain, or presyncope. Class III: marked PA. No discomfort at rest. Less than ordinary activity increases dyspnea, fatigue, chest pain, or presyncope. Class IV: unal any PA and who may have signs of right ventricular failure. Dyspnea and/or fatigue may be present at rest and symptoms by almost any PA
Categories	Class I, Class II, Class III, Class IV
Ready for collection values	yes

REPORTING GROUPS

GROUP#	TITLE	CLASS I	CLASS II	CLASS III	C
Group 1	Placebo	0	129	116	
Group 2	ACT-064992 3 mg once daily	0	138	105	
Group 3	ACT-064992 10 mg once daily	1	120	116	
Group 4	Category totals	1	387	337	

SUBJECT ANALYSIS SETS

SET#	TITLE	CLASS I	CLASS II	CLASS III	C
Set 1	All randomized set	1	387	337	
Set 2	All treated set				
Set 3	Per protocol set				

END POINTS **This section contains errors/warnings**

End point 1

End point details

End point title	Time to first confirmed morbidity or mortality event (CEC adjudicated) up to the end of treatment + 7 days (Kaplan-Meier patients without a morbidity or mortality event) (data presented up to month 36)
Description	Morbidity or mortality events (CEC adjudicated) were defined as: a) Death due to any cause; b) Atrial septostomy; c) Lung transplantation; d) Initiation of intravenous (i.v.) or subcutaneous prostanoids, or; e) Other worsening of PAH. Other wor was defined by the combined occurrence of all the following 3 events: At least 15% decrease in the 6 minute walk distan baseline, confirmed by 2 tests performed on separate days, within 2 weeks. AND worsening of PAH symptoms including a the following: a) Increase in WHO Functional Class (WHO FC), or no change in patients in WHO FC IV at baseline; b) App worsening of signs of right heart failure that did not respond to optimized oral diuretic therapy AND need for new treatme

	that included the following: a) Oral or inhaled prostanoids; b) Oral phosphodiesterase inhibitors; c) Endothelin receptor a (only after discontinuation of study treatment; d) i.v. diuretics.
Timeframe	Up to end of double-blind treatment + 7 days NOTE: The number of patients at risk of experiencing an event at each tim decreases over time.
End point type	Primary
Countable/Measurable	Measurable
Measurable units	percentage of participants-Kaplan Meier
Measure type	Number
Precision/Dispersion type	Not applicable
Reporting groups	Overall study :Placebo, Overall study :ACT-064992 3 mg, Overall study :ACT-064992 10 mg
Subject analysis sets	All randomized set
Categories	Kaplan-Meier Estimate at Month 6, Kaplan-Meier Estimate at Month 12, Kaplan-Meier Estimate at Month 18, Kaplan-Meier E Month 24, Kaplan-Meier Estimate at Month 30, Kaplan-Meier Estimate at Month 36

KAPLAN-MEIER ESTIMATE AT MONTH 6

REPORTING GROUPS

PERIOD#	TITLE	SUBJECTS	MEASURE
Overall study	Placebo	250	80.1
Overall study	ACT-064992 3 mg	250	89.3
Overall study	ACT-064992 10 mg	242	92.7

SUBJECT ANALYSIS SETS

SET#	TITLE	SUBJECTS	MEASURE
Set 1	All randomized set	0	

KAPLAN-MEIER ESTIMATE AT MONTH 12

REPORTING GROUPS

PERIOD#	TITLE	SUBJECTS	MEASURE
Overall study	Placebo	250	71.4
Overall study	ACT-064992 3 mg	250	81.6
Overall study	ACT-064992 10 mg	242	85.5

SUBJECT ANALYSIS SETS

SET#	TITLE	SUBJECTS	MEASURE
Set 1	All randomized set	0	

KAPLAN-MEIER ESTIMATE AT MONTH 18

REPORTING GROUPS

PERIOD#	TITLE	SUBJECTS	MEASURE
Overall study	Placebo	250	61.5
Overall study	ACT-064992 3 mg	250	72.5
Overall study	ACT-064992 10 mg	242	79.9

SUBJECT ANALYSIS SETS

SET#	TITLE	SUBJECTS	MEASURE
Set 1	All randomized set	0	

KAPLAN-MEIER ESTIMATE AT MONTH 24

REPORTING GROUPS

PERIOD#	TITLE	SUBJECTS	MEASURE
Overall study	Placebo	250	57.3
Overall study	ACT-064992 3 mg	250	65.5
Overall study	ACT-064992 10 mg	242	74.3

SUBJECT ANALYSIS SETS

SET#	TITLE	SUBJECTS	MEASURE
Set 1	All randomized set	0	

KAPLAN-MEIER ESTIMATE AT MONTH 30

REPORTING GROUPS

PERIOD#	TITLE	SUBJECTS	MEASURE
Overall study	Placebo	250	50.2
Overall study	ACT-064992 3 mg	250	61.9
Overall study	ACT-064992 10 mg	242	70

SUBJECT ANALYSIS SETS

SET#	TITLE	SUBJECTS	MEASURE
Set 1	All randomized set	0	

KAPLAN-MEIER ESTIMATE AT MONTH 36

REPORTING GROUPS

PERIOD#	TITLE	SUBJECTS	MEASURE
Overall study	Placebo	250	47
Overall study	ACT-064992 3 mg	250	55
Overall study	ACT-064992 10 mg	242	63.2

SUBJECT ANALYSIS SETS

SET#	TITLE	SUBJECTS	MEASURE
Set 1	All randomized set	0	

Statistical analysis 1

Statistical analysis overview

Statistical analysis title	Statistical analysis 1
Analysis description	
Analysis type	Other
Analysis specification	Pre-specified
Arm comparison groups	Placebo, ACT-064992 3 mg
Subject analysis comparison groups	All randomized set
Primary analysis	no
Analysis type comment	

Statistical test of hypothesis

P-value	0.0108
Value equality relation	=
P-value comment	
Analysis method	Logrank

Method of estimation

Confidence interval	97.5
Number of sides	2-sided
Lower limit	0.516
Upper limit	0.96
Point estimate	0.704
Effect estimate	
Parameter	Hazard ratio (HR)
Dispersion type	
Dispersion value	

Statistical analysis 2

Statistical analysis overview

Statistical analysis title	Statistical analysis 2
Analysis description	
Analysis type	Other
Analysis specification	Pre-specified
Arm comparison groups	Placebo, ACT-064992 10 mg
Subject analysis comparison groups	All randomized set
Primary analysis	no
Analysis type comment	

Statistical test of hypothesis

P-value	0.0001
Value equality relation	<
P-value comment	
Analysis method	Logrank

Method of estimation

Confidence interval	97.5
Number of sides	2-sided
Lower limit	0.392
Upper limit	0.762
Point estimate	0.547
Effect estimate	
Parameter	Hazard ratio (HR)
Dispersion type	
Dispersion value	

End point 2

End point details

End point title	Time to death due to PAH or hospitalisation for PAH up to the end of treatment + 7 days (Kaplan-Meier estimate of patier event)
Description	Events of PAH or hospitalization for PAH up to the end of treatment included: death due to PAH, or onset of a treatment-adverse event with a fatal outcome due to PAH occurring up to 4 weeks after the end of treatment, or hospitalisation for end of treatment. Note that Month 36 is the last time point at which more than 10% of patients are still in follow-up. NO number of patients at risk of experiencing an event at each time point decreases over time.
Timeframe	Up to end of double-blind treatment + 7 days (data presented up to month 36)
End point type	Secondary
Countable/Measurable	Measurable
Measurable units	percentage of participants-Kaplan Meier
Measure type	Number
Precision/Dispersion type	Not applicable
Reporting groups	Overall study :ACT-064992 3 mg, Overall study :Placebo, Overall study :ACT-064992 10 mg
Subject analysis sets	All randomized set
Categories	Kaplan-Meier Estimate at Month 6, Kaplan-Meier Estimate at Month 12, Kaplan-Meier Estimate at Month 18, Kaplan-Meier E Month 24, Kaplan-Meier Estimate at Month 30, Kaplan-Meier Estimate at Month 36

KAPLAN-MEIER ESTIMATE AT MONTH 6

REPORTING GROUPS

PERIOD#	TITLE	SUBJECTS	MEASURE
Overall study	ACT-064992 3 mg	250	84.4
Overall study	Placebo	250	90.8
Overall study	ACT-064992 10 mg	242	94.6

SUBJECT ANALYSIS SETS

SET#	TITLE	SUBJECTS	MEASURE
Set 1	All randomized set	0	

KAPLAN-MEIER ESTIMATE AT MONTH 12

REPORTING GROUPS

PERIOD#	TITLE	SUBJECTS	MEASURE
Overall study	ACT-064992 3 mg	250	76.7
Overall study	Placebo	250	84.9
Overall study	ACT-064992 10 mg	242	89.8

SUBJECT ANALYSIS SETS

SET#	TITLE	SUBJECTS	MEASURE
Set 1	All randomized set	0	

KAPLAN-MEIER ESTIMATE AT MONTH 18

REPORTING GROUPS

PERIOD#	TITLE	SUBJECTS	MEASURE
Overall study	ACT-064992 3 mg	250	69
Overall study	Placebo	250	78.1
Overall study	ACT-064992 10 mg	242	84.8

SUBJECT ANALYSIS SETS

SET#	TITLE	SUBJECTS	MEASURE
Set 1	All randomized set	0	

KAPLAN-MEIER ESTIMATE AT MONTH 24

REPORTING GROUPS

PERIOD#	TITLE	SUBJECTS	MEASURE
Overall study	ACT-064992 3 mg	250	67.9
Overall study	Placebo	250	75.1
Overall study	ACT-064992 10 mg	242	81.7

SUBJECT ANALYSIS SETS

SET#	TITLE	SUBJECTS	MEASURE
Set 1	All randomized set	0	

KAPLAN-MEIER ESTIMATE AT MONTH 30

REPORTING GROUPS

PERIOD#	TITLE	SUBJECTS	MEASURE
Overall study	ACT-064992 3 mg	250	62
Overall study	Placebo	250	70.3
Overall study	ACT-064992 10 mg	242	77.9

SUBJECT ANALYSIS SETS

SET#	TITLE	SUBJECTS	MEASURE
Set 1	All randomized set	0	

KAPLAN-MEIER ESTIMATE AT MONTH 36

REPORTING GROUPS

PERIOD#	TITLE	SUBJECTS	MEASURE
Overall study	ACT-064992 3 mg	250	55.4
Overall study	Placebo	250	67.1
Overall study	ACT-064992 10 mg	242	70.6

SUBJECT ANALYSIS SETS

SET#	TITLE	SUBJECTS	MEASURE
Set 1	All randomized set	0	

Statistical analysis 1

Statistical analysis overview

Statistical analysis title	Statistical analysis 1
Analysis description	
Analysis type	Other
Analysis specification	Pre-specified
Arm comparison groups	ACT-064992 3 mg, Placebo
Subject analysis comparison groups	All randomized set
Primary analysis	no
Analysis type comment	

Statistical test of hypothesis

P-value	0.0146
Value equality relation	=
P-value comment	
Analysis method	Logrank

Method of estimation

Confidence interval	97.5
Number of sides	2-sided
Lower limit	0.462
Upper limit	0.97
Point estimate	0.669
Effect estimate	
Parameter	Hazard ratio (HR)
Dispersion type	
Dispersion value	

Statistical analysis 2

Statistical analysis overview

Statistical analysis title	Statistical analysis 2
Analysis description	
Analysis type	Other
Analysis specification	Pre-specified
Arm comparison groups	Placebo, ACT-064992 10 mg
Subject analysis comparison groups	All randomized set
Primary analysis	no
Analysis type comment	

Statistical test of hypothesis

P-value	0.0001

Value equality relation	<
P-value comment	
Analysis method	Logrank

Method of estimation

Confidence interval	97.5
Number of sides	2-sided
Lower limit	0.335
Upper limit	0.747
Point estimate	0.5
Effect estimate	
Parameter	Hazard ratio (HR)
Dispersion type	
Dispersion value	

End point 3

End point details

End point title	Time to death due to any cause up to the end of treatment (Kaplan-Meier estimate of patients without an event)
Description	Events of death due to any cause up to the end of treatment (plus 7 days) NOTE: The number of patients at risk of experi event at each time point decreases over time
Timeframe	Up to end of double-blind treatment + 7 days (data presented up to month 36)
End point type	Secondary
Countable/Measurable	Measurable
Measurable units	percentage of participants-Kaplan Meier
Measure type	Number
Precision/Dispersion type	Not applicable
Reporting groups	Overall study :Placebo, Overall study :ACT-064992 3 mg, Overall study :ACT-064992 10 mg
Subject analysis sets	All randomized set
Categories	Kaplan-Meier Estimate at Month 6, Kaplan-Meier Estimate at Month 12, Kaplan-Meier Estimate at Month18, Kaplan-Meier E Month 24, Kaplan-Meier Estimate at Month 30, Kaplan-Meier Estimate at Month 36

KAPLAN-MEIER ESTIMATE AT MONTH 6

REPORTING GROUPS

PERIOD#	TITLE	SUBJECTS	MEASURE
Overall study	Placebo	250	95.2
Overall study	ACT-064992 3 mg	250	97.1
Overall study	ACT-064992 10 mg	242	97.4

SUBJECT ANALYSIS SETS

SET#	TITLE	SUBJECTS	MEASURE
Set 1	All randomized set	0	

KAPLAN-MEIER ESTIMATE AT MONTH 12

REPORTING GROUPS

PERIOD#	TITLE	SUBJECTS	MEASURE
Overall study	Placebo	250	93.6
Overall study	ACT-064992 3 mg	250	95.6
Overall study	ACT-064992 10 mg	242	96.4

SUBJECT ANALYSIS SETS

SET#	TITLE	SUBJECTS	MEASURE
Set 1	All randomized set	0	

KAPLAN-MEIER ESTIMATE AT MONTH18

REPORTING GROUPS

PERIOD#	TITLE	SUBJECTS	MEASURE
Overall study	Placebo	250	92.4
Overall study	ACT-064992 3 mg	250	94.6
Overall study	ACT-064992 10 mg	242	94.8

SUBJECT ANALYSIS SETS

SET#	TITLE	SUBJECTS	MEASURE
Set 1	All randomized set	0	

KAPLAN-MEIER ESTIMATE AT MONTH 24

REPORTING GROUPS

PERIOD#	TITLE	SUBJECTS	MEASURE
Overall study	Placebo	250	91.7
Overall study	ACT-064992 3 mg	250	91.7
Overall study	ACT-064992 10 mg	242	94.8

SUBJECT ANALYSIS SETS

SET#	TITLE	SUBJECTS	MEASURE
Set 1	All randomized set	0	

KAPLAN-MEIER ESTIMATE AT MONTH 30

REPORTING GROUPS

PERIOD#	TITLE	SUBJECTS	MEASURE
Overall study	Placebo	250	89.8
Overall study	ACT-064992 3 mg	250	89.9
Overall study	ACT-064992 10 mg	242	93.3

SUBJECT ANALYSIS SETS

SET#	TITLE	SUBJECTS	MEASURE
Set 1	All randomized set	0	

KAPLAN-MEIER ESTIMATE AT MONTH 36

REPORTING GROUPS

PERIOD#	TITLE	SUBJECTS	MEASURE
Overall study	Placebo	250	89.8
Overall study	ACT-064992 3 mg	250	87.3
Overall study	ACT-064992 10 mg	242	93.3

SUBJECT ANALYSIS SETS

SET#	TITLE	SUBJECTS	MEASURE
Set 1	All randomized set	0	

Statistical analysis 1

Statistical analysis overview

Statistical analysis title	Statistical analysis 1
Analysis description	
Analysis type	Other
Analysis specification	Pre-specified
Arm comparison groups	Placebo, ACT-064992 3 mg
Subject analysis comparison groups	All randomized set
Primary analysis	no
Analysis type comment	

Statistical test of hypothesis

P-value	0.9249
Value equality relation	=
P-value comment	
Analysis method	Logrank

Method of estimation

Confidence interval	97.5
Number of sides	2-sided
Lower limit	0.477
Upper limit	1.976
Point estimate	0.971
Effect estimate	
Parameter	Hazard ratio (HR)
Dispersion type	
Dispersion value	

Statistical analysis 2

Statistical analysis overview

Statistical analysis title	Statistical analysis 2
Analysis description	
Analysis type	Other
Analysis specification	Pre-specified
Arm comparison groups	Placebo, ACT-064992 10 mg
Subject analysis comparison groups	All randomized set
Primary analysis	no
Analysis type comment	

Statistical test of hypothesis

P-value	0.2037
Value equality relation	=
P-value comment	
Analysis method	Logrank

Method of estimation

Confidence interval	97.5
Number of sides	2-sided
Lower limit	0.287
Upper limit	1.418
Point estimate	0.638
Effect estimate	
Parameter	Hazard ratio (HR)
Dispersion type	
Dispersion value	

End point 4

End point details

End point title	Time to death due to any cause up to the end of study (Kaplan-Meier estimate of patients without an event)
Description	Events of death due to any cause up to the end of study (EOS). The initiation of EOS procedure occurred when the targe was expected to have been achieved (30 January 2012). NOTE: The number of patients at risk of experiencing an event a point decreases over time.
Timeframe	Up to end of study (data presented up to month 36)
End point type	Secondary
Countable/Measurable	Measurable
Measurable units	Number of events
Measure type	Number
Precision/Dispersion type	Not applicable

Reporting groups	Overall study :Placebo, Overall study :ACT-064992 3 mg, Overall study :ACT-064992 10 mg
Subject analysis sets	All randomized set
Categories	Kaplan-Meier Estimate at Month 6, Kaplan-Meier Estimate at Month 12, Kaplan-Meier Estimate at Month 18, Kaplan-Meier E Month 24, Kaplan-Meier Estimate at Month 30, Kaplan-Meier Estimate at Month 36

KAPLAN-MEIER ESTIMATE AT MONTH 6

REPORTING GROUPS

PERIOD#	TITLE	SUBJECTS	MEASURE
Overall study	Placebo	250	94.7
Overall study	ACT-064992 3 mg	250	96.4
Overall study	ACT-064992 10 mg	242	96.3

SUBJECT ANALYSIS SETS

SET#	TITLE	SUBJECTS	MEASURE
Set 1	All randomized set	0	

KAPLAN-MEIER ESTIMATE AT MONTH 12

REPORTING GROUPS

PERIOD#	TITLE	SUBJECTS	MEASURE
Overall study	Placebo	250	91.4
Overall study	ACT-064992 3 mg	250	93.9
Overall study	ACT-064992 10 mg	242	95

SUBJECT ANALYSIS SETS

SET#	TITLE	SUBJECTS	MEASURE
Set 1	All randomized set	0	

KAPLAN-MEIER ESTIMATE AT MONTH 18

REPORTING GROUPS

PERIOD#	TITLE	SUBJECTS	MEASURE
Overall study	Placebo	250	89.3
Overall study	ACT-064992 3 mg	250	91.4
Overall study	ACT-064992 10 mg	242	93.3

SUBJECT ANALYSIS SETS

SET#	TITLE	SUBJECTS	MEASURE
Set 1	All randomized set	0	

KAPLAN-MEIER ESTIMATE AT MONTH 24

REPORTING GROUPS

PERIOD#	TITLE	SUBJECTS	MEASURE
Overall study	Placebo	250	87.2
Overall study	ACT-064992 3 mg	250	87.3
Overall study	ACT-064992 10 mg	242	89.1

SUBJECT ANALYSIS SETS

SET#	TITLE	SUBJECTS	MEASURE
Set 1	All randomized set	0	

KAPLAN-MEIER ESTIMATE AT MONTH 30

REPORTING GROUPS

PERIOD#	TITLE	SUBJECTS	MEASURE
Overall study	Placebo	250	82.6
Overall study	ACT-064992 3 mg	250	83.4
Overall study	ACT-064992 10 mg	242	86.9

SUBJECT ANALYSIS SETS

SET#	TITLE	SUBJECTS	MEASURE
Set 1	All randomized set	0	

KAPLAN-MEIER ESTIMATE AT MONTH 36

REPORTING GROUPS

PERIOD#	TITLE	SUBJECTS	MEASURE
Overall study	Placebo	250	80.7
Overall study	ACT-064992 3 mg	250	80
Overall study	ACT-064992 10 mg	242	82.9

SUBJECT ANALYSIS SETS

SET#	TITLE	SUBJECTS	MEASURE
Set 1	All randomized set	0	

Statistical analysis 1

Statistical analysis overview

Statistical analysis title	Statistical analysis 1
Analysis description	
Analysis type	Other
Analysis specification	Pre-specified
Arm comparison groups	Placebo, ACT-064992 3 mg
Subject analysis comparison groups	All randomized set
Primary analysis	no
Analysis type comment	

Statistical test of hypothesis

P-value	0.8312
Value equality relation	=
P-value comment	
Analysis method	Logrank

Method of estimation

Confidence interval	97.5
Number of sides	2-sided
Lower limit	0.653
Upper limit	1.673
Point estimate	1.046
Effect estimate	
Parameter	Hazard ratio (HR)

Dispersion type	
Dispersion value	

Statistical analysis 2

Statistical analysis overview

Statistical analysis title	Statistical analysis 2
Analysis description	
Analysis type	Other
Analysis specification	Pre-specified
Arm comparison groups	Placebo, ACT-064992 10 mg
Subject analysis comparison groups	All randomized set
Primary analysis	no
Analysis type comment	

Statistical test of hypothesis

P-value	0.2509
Value equality relation	=
P-value comment	
Analysis method	Logrank

Method of estimation

Confidence interval	97.5
Number of sides	2-sided
Lower limit	0.464
Upper limit	1.282
Point estimate	0.771
Effect estimate	
Parameter	Hazard ratio (HR)
Dispersion type	
Dispersion value	

End point 5

End point details

End point title	Change from baseline to Month 6 in 6-minute walk distance
Description	The 6-minute walk test (6MWT) is a non-encouraged test, performed in a 30 m long flat corridor, where the patient is ins as far as possible, back and forth around two cones, with the permission to slow down, rest, or stop if needed. These gu provided to all sites. For patients who had never performed a 6MWT previously, a training test was required before the qu for inclusion were performed.
Timeframe	Baseline to Month 6
End point type	Secondary
Countable/Measurable	Measurable
Measurable units	metres
Measure type	Arithmetic mean
Precision/Dispersion type	Standard deviation
Reporting groups	Overall study :Placebo, Overall study :ACT-064992 3 mg, Overall study :ACT-064992 10 mg
Subject analysis sets	All randomized set
Categories	Baseline, Change from baseline at Month 6

BASELINE

REPORTING GROUPS

PERIOD#	TITLE	SUBJECTS	MEASURE	STANDARD DEVIAT
Overall study	Placebo	249	352	110.6
Overall study	ACT-064992 3 mg	248	364	95.5
Overall study	ACT-064992 10 mg	242	363	93.2

SUBJECT ANALYSIS SETS

SET#	TITLE	SUBJECTS	MEASURE	STANDARD DEVIAT
Set 1	All randomized set	0		

CHANGE FROM BASELINE AT MONTH 6

REPORTING GROUPS

PERIOD#	TITLE	SUBJECTS	MEASURE	STANDARD DEVIAT
Overall study	Placebo	249	-9.4	100.59
Overall study	ACT-064992 3 mg	248	7.4	93.15
Overall study	ACT-064992 10 mg	242	12.5	83.54

SUBJECT ANALYSIS SETS

SET#	TITLE	SUBJECTS	MEASURE	STANDARD DEVIAT
Set 1	All randomized set	0		

End point 6

End point details

End point title	Number of patients with improvements in World Health Organization functional class from baseline to Month 6
Description	Class I: no limitation of usual physical activity (PA) which does not increase dyspnea, fatigue, chest pain, or presyncope. limitation of PA. No discomfort at rest. Normal PA increases dyspnea, fatigue, chest pain, or presyncope. Class III: markec PA. No discomfort at rest. Less than ordinary activity increases dyspnea, fatigue, chest pain, or presyncope. Class IV: unal any PA and who may have signs of right ventricular failure. Dyspnea and/or fatigue may be present at rest and symptoms by almost any PA.
Timeframe	Baseline to month 6

End point type	Secondary
Countable/Measurable	Countable
Countable units	participants
Reporting groups	Overall study :Placebo, Overall study :ACT-064992 3 mg, Overall study :ACT-064992 10 mg
Subject analysis sets	All randomized set
Categories	

REPORTING GROUPS

PERIOD#	TITLE	SUBJECTS	COUNT
Overall study	Placebo	249	32
Overall study	ACT-064992 3 mg	248	49
Overall study	ACT-064992 10 mg	242	54

SUBJECT ANALYSIS SETS

SET#	TITLE	SUBJECTS	COUNT
Set 1	All randomized set	0 **Comments:** Not applicable	

End point 7

End point details

End point title	Pulmonary vascular resistance at baseline and month 6 (without using imputation rules at month 6)
Description	In a sub-study, hemodynamic variables were assessed at baseline and Month 6 (without using imputation rules at month patient had undergone a right heart catheterization during the 3 months prior to randomization, these results were to be baseline values, if the background therapy had not changed during the intervening period.
Timeframe	Baseline to month 6
End point type	Other pre-specified
Countable/Measurable	Measurable
Measurable units	(dyn*sec/cm^5)
Measure type	Arithmetic mean
Precision/Dispersion type	Full range (min-max)
Reporting groups	Overall study :Placebo, Overall study :ACT-064992 3 mg, Overall study :ACT-064992 10 mg
Subject analysis sets	All randomized set
Categories	Baseline, Month 6

BASELINE

REPORTING GROUPS

PERIOD#	TITLE	SUBJECTS	MEASURE	FULL RANGE (MI
Overall study	Placebo	50	886	259 to 339
Overall study	ACT-064992 3 mg	47	945	250 to 231
Overall study	ACT-064992 10 mg	48	907	254 to 277

SUBJECT ANALYSIS SETS

SET#	TITLE	SUBJECTS	MEASURE	FULL R.
Set 1	All randomized set	0		

MONTH 6

REPORTING GROUPS

PERIOD#	TITLE	SUBJECTS	MEASURE	FULL RANGE (MI
Overall study	Placebo	50	1042	164 to 340
Overall study	ACT-064992 3 mg	47	736	71 to 230
Overall study	ACT-064992 10 mg	48	680	158 to 281

SUBJECT ANALYSIS SETS

SET#	TITLE	SUBJECTS	MEASURE	FULL R.
Set 1	All randomized set	0		

End point 8

End point details

End point title	Cardiac index at baseline and month 6 (without using imputation rules at month 6)
Description	In a sub-study, hemodynamic variables were assessed at baseline and Month 6 (without using imputation rules at month patient had undergone a right heart catheterization during the 3 months prior to randomization, these results were to be baseline values, if the background therapy had not changed during the intervening period.
Timeframe	Baseline to month 6
End point type	Other pre-specified
Countable/Measurable	Measurable
Measurable units	L/min/m^2
Measure type	Arithmetic mean
Precision/Dispersion type	Full range (min-max)
Reporting groups	Overall study :Placebo, Overall study :ACT-064992 3 mg, Overall study :ACT-064992 10 mg
Subject analysis sets	All randomized set
Categories	Baseline, Month 6, Change from Baseline to Month 6

BASELINE

REPORTING GROUPS

PERIOD#	TITLE	SUBJECTS	MEASURE	FULL RANGE (MI
Overall study	Placebo	50	2.54	1.31 to 4
Overall study	ACT-064992 3 mg	47	2.34	1.13 to 5
Overall study	ACT-064992 10 mg	48	2.63	1.2 to 6

SUBJECT ANALYSIS SETS

SET#	TITLE	SUBJECTS	MEASURE	FULL R.
Set 1	All randomized set	0		

MONTH 6

REPORTING GROUPS

PERIOD#	TITLE	SUBJECTS	MEASURE	FULL RANGE (MI
Overall study	Placebo	50	2.21	1.06 to 3
Overall study	ACT-064992 3 mg	47	2.69	1.26 to 5
Overall study	ACT-064992 10 mg	48	2.93	1.46 to 5

SUBJECT ANALYSIS SETS

SET#	TITLE	SUBJECTS	MEASURE	FULL R.
Set 1	All randomized set	0		

CHANGE FROM BASELINE TO MONTH 6

REPORTING GROUPS

PERIOD#	TITLE	SUBJECTS	MEASURE	FULL RANGE (MI
Overall study	Placebo	50	-0.33	-2.53 to (
Overall study	ACT-064992 3 mg	47	0.36	-0.81 to 1
Overall study	ACT-064992 10 mg	48	0.3	-2.97 to 1

SUBJECT ANALYSIS SETS

SET#	TITLE	SUBJECTS	MEASURE	FULL R.
Set 1	All randomized set	0		

End point 9

End point details

End point title	Summary of the first causes of morbidity or mortality
Description	Morbidity or mortality events were defined as: a) Death; b) Atrial septostomy; c) Lung transplantation; d) Initiation of intr or subcutaneous prostanoids, or; e) Other worsening of pulmonary arterial hypertension (PAH). Other worsening of PAH v the combined occurrence of all the following 3 events: At least 15% decrease in the 6 minute walk distance from baselin 2 tests performed on separate days, within 2 weeks. AND worsening of PAH symptoms including at least one of the follov Increase in WHO Functional Class (WHO FC), or no change in patients in WHO FC IV at baseline; b) Appearance or worser right heart failure that did not respond to optimized oral diuretic therapy AND need for new treatment(s) for PAH that inc following: a) Oral or inhaled prostanoids; b) Oral phosphodiesterase inhibitors; c) Endothelin receptor antagonists (only a discontinuation of study treatment; d) i.v. diuretics
Timeframe	Up to end of double-blind treatment + 7 days
End point type	Other pre-specified
Countable/Measurable	Countable
Countable units	participants
Reporting groups	Overall study :Placebo, Overall study :ACT-064992 3 mg, Overall study :ACT-064992 10 mg
Subject analysis sets	All randomized set
Categories	Other worsening of PAH, Death, Prostanoid initiation (i.v. or s.c.), Lung transplantation

REPORTING GROUPS

PERIOD#	TITLE	SUBJECTS	OTHER WORSENING OF PAH	DEATH	PROSTANOID INITIATION (I.V. OR S.C.)	TRA
Overall study	Placebo	250	93	17	6	
Overall study	ACT-064992 3 mg	250	72	21	1	
Overall study	ACT-064992 10 mg	242	59	16	1	

SUBJECT ANALYSIS SETS

SET#	TITLE	SUBJECTS	OTHER WORSENING OF PAH	DEATH	PROSTANOID INITIATION (I.V. OR S.C.)	TRA
Set 1	All randomized set	0 **Comments:** Not applicable				

ADVERSE EVENTS

Adverse events information

Timeframe for adverse event reporting	Up to end of treatment plus 28 days
Adverse event reporting additional description	One patient in the placebo group never received study treatment and was not included in the analysis. Note that relations study drug (as assessed by the Investigator) is derived from the relationship of serious adverse event with outcome death
Assessment type	systematic
Frequency threshold for reporting non-serious adverse events	5
Dictionary name	MedDRA
Version	14.0

Adverse events reporting groups

Adverse event reporting group 1

Reporting group title	Placebo
Reporting group description	Matching ACT-064992 placebo tablet, once daily
Subjects exposed	249
Subjects affected by serious adverse events	137
Subjects affected by non-serious adverse events	219
Total number of deaths (all causes)	21
Total number of deaths resulting from adverse events	0

Adverse event reporting group 2

Reporting group title	ACT-064992 3 mg
Reporting group description	ACT-064992 tablet, 3 mg, once daily
Subjects exposed	250
Subjects affected by serious adverse events	130
Subjects affected by non-serious adverse events	227
Total number of deaths (all causes)	22
Total number of deaths resulting from adverse events	1

Adverse event reporting group 3

Reporting group title	ACT-064992 10 mg
Reporting group description	ACT-064992 tablet, 10 mg, once daily
Subjects exposed	242
Subjects affected by serious adverse events	109
Subjects affected by non-serious adverse events	222
Total number of deaths (all causes)	16
Total number of deaths resulting from adverse events	0

Serious adverse events

Serious adverse event 1

SERIOUS ADVERSE EVENT DETAILS

System organ class	Respiratory, thoracic and mediastinal disorders
Event term	PULMONARY ARTERIAL HYPERTENSION
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PE… REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I… TREATMENT, NU…
Placebo	56	249	61	1	0	0
ACT-064992 3 mg	48	250	49	1	0	0
ACT-064992 10 mg	32	242	32	0	0	0

Serious adverse event 2

SERIOUS ADVERSE EVENT DETAILS

System organ class	Respiratory, thoracic and mediastinal disorders
Event term	HAEMOPTYSIS
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PE… REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I… TREATMENT, NU…
Placebo	4	249	5	0	0	0
ACT-064992 3 mg	4	250	5	0	0	0
ACT-064992 10 mg	3	242	4	0	0	0

Serious adverse event 3

SERIOUS ADVERSE EVENT DETAILS

System organ class	Respiratory, thoracic and mediastinal disorders
Event term	RESPIRATORY FAILURE
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PE… REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I… TREATMENT, NU…
Placebo	2	249	2	0	0	0
ACT-064992 3 mg	3	250	3	0	0	0
ACT-064992	3	242	3	1	0	0

10 mg

Serious adverse event 4

SERIOUS ADVERSE EVENT DETAILS

System organ class	Respiratory, thoracic and mediastinal disorders
Event term	DYSPNOEA
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PE... REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	1	249	1	0	0	0
ACT-064992 3 mg	2	250	2	0	0	0
ACT-064992 10 mg	2	242	2	0	0	0

Serious adverse event 5

SERIOUS ADVERSE EVENT DETAILS

System organ class	Respiratory, thoracic and mediastinal disorders
Event term	PULMONARY EMBOLISM
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PE... REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	1	249	1	0	0	0
ACT-064992 3 mg	1	250	1	0	0	0
ACT-064992 10 mg	2	242	2	0	0	0

Serious adverse event 6

SERIOUS ADVERSE EVENT DETAILS

System organ class	Respiratory, thoracic and mediastinal disorders
Event term	CHRONIC OBSTRUCTIVE PULMONARY DISEASE
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PE... REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	0	249	0	0	0	0
ACT-064992 3 mg	3	250	3	0	0	0
ACT-064992 10 mg	0	242	0	0	0	0

Serious adverse event 7

SERIOUS ADVERSE EVENT DETAILS

System organ class	Respiratory, thoracic and mediastinal disorders
Event term	ACUTE RESPIRATORY FAILURE
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA

Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PER REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	1	249	1	0	0	0
ACT-064992 3 mg	2	250	2	0	0	0
ACT-064992 10 mg	0	242	0	0	0	0

Serious adverse event 8

SERIOUS ADVERSE EVENT DETAILS

System organ class	Respiratory, thoracic and mediastinal disorders
Event term	EPISTAXIS
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PER REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	0	249	0	0	0	0
ACT-064992 3 mg	1	250	1	0	0	0
ACT-064992 10 mg	1	242	1	0	0	0

Serious adverse event 9

SERIOUS ADVERSE EVENT DETAILS

System organ class	Respiratory, thoracic and mediastinal disorders
Event term	PULMONARY FIBROSIS
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PER REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	0	249	0	0	0	0
ACT-064992 3 mg	1	250	1	0	0	0
ACT-064992 10 mg	1	242	1	0	0	0

Serious adverse event 10

SERIOUS ADVERSE EVENT DETAILS

System organ class	Respiratory, thoracic and mediastinal disorders
Event term	PLEURAL EFFUSION
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PER REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	1	249	1	0	0	0
ACT-064992 3 mg	0	250	0	0	0	0
ACT-064992 10 mg	1	242	1	0	0	0

Serious adverse event 11

SERIOUS ADVERSE EVENT DETAILS

System organ class	Respiratory, thoracic and mediastinal disorders

Event term	HYPOXIA
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PER REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	0	249	0	0	0	0
ACT-064992 3 mg	0	250	0	0	0	0
ACT-064992 10 mg	1	242	1	0	0	0

Serious adverse event 12

SERIOUS ADVERSE EVENT DETAILS

System organ class	Respiratory, thoracic and mediastinal disorders
Event term	INTERSTITIAL LUNG DISEASE
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PER REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	0	249	0	0	0	0
ACT-064992 3 mg	1	250	1	0	0	0
ACT-064992 10 mg	0	242	0	0	0	0

Serious adverse event 13

SERIOUS ADVERSE EVENT DETAILS

System organ class	Respiratory, thoracic and mediastinal disorders
Event term	LUNG INFILTRATION
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PER REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	0	249	0	0	0	0
ACT-064992 3 mg	0	250	0	0	0	0
ACT-064992 10 mg	1	242	1	0	0	0

Serious adverse event 14

SERIOUS ADVERSE EVENT DETAILS

System organ class	Respiratory, thoracic and mediastinal disorders
Event term	PHARYNGEAL CYST
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PER REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	0	249	0	0	0	0

ACT-064992 3 mg	0	250	0	0	0	0
ACT-064992 10 mg	1	242	1	0	0	0

Serious adverse event 15

SERIOUS ADVERSE EVENT DETAILS

System organ class	Respiratory, thoracic and mediastinal disorders
Event term	PLEURITIC PAIN
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PER REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	0	249	0	0	0	0
ACT-064992 3 mg	1	250	1	0	0	0
ACT-064992 10 mg	0	242	0	0	0	0

Serious adverse event 16

SERIOUS ADVERSE EVENT DETAILS

System organ class	Respiratory, thoracic and mediastinal disorders
Event term	PNEUMONIA ASPIRATION
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PER REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	0	249	0	0	0	0
ACT-064992 3 mg	1	250	1	0	0	0
ACT-064992 10 mg	0	242	0	0	0	0

Serious adverse event 17

SERIOUS ADVERSE EVENT DETAILS

System organ class	Respiratory, thoracic and mediastinal disorders
Event term	TACHYPNOEA
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PER REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	0	249	0	0	0	0
ACT-064992 3 mg	1	250	1	0	0	0
ACT-064992 10 mg	0	242	0	0	0	0

Serious adverse event 18

SERIOUS ADVERSE EVENT DETAILS

System organ class	Respiratory, thoracic and mediastinal disorders
Event term	PNEUMOTHORAX
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA

Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PER REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	1	249	2	0	0	0
ACT-064992 3 mg	0	250	0	0	0	0
ACT-064992 10 mg	0	242	0	0	0	0

Serious adverse event 19

SERIOUS ADVERSE EVENT DETAILS

System organ class	Respiratory, thoracic and mediastinal disorders
Event term	SLEEP APNOEA SYNDROME
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PER REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	1	249	1	0	0	0
ACT-064992 3 mg	0	250	0	0	0	0
ACT-064992 10 mg	0	242	0	0	0	0

Serious adverse event 20

SERIOUS ADVERSE EVENT DETAILS

System organ class	Cardiac disorders
Event term	RIGHT VENTRICULAR FAILURE
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PER REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	40	249	47	0	0	0
ACT-064992 3 mg	21	250	25	2	1	1
ACT-064992 10 mg	23	242	25	0	0	0

Serious adverse event 21

SERIOUS ADVERSE EVENT DETAILS

System organ class	Cardiac disorders
Event term	ATRIAL FLUTTER
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PER REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	2	249	2	0	0	0
ACT-064992 3 mg	2	250	3	0	0	0
ACT-064992 10 mg	4	242	6	1	0	0

Serious adverse event 22

SERIOUS ADVERSE EVENT DETAILS

System organ class	Cardiac disorders
Event term	CARDIAC ARREST
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PER REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	1	249	1	0	0	0
ACT-064992 3 mg	3	250	3	0	0	0
ACT-064992 10 mg	0	242	0	0	0	0

Serious adverse event 23

SERIOUS ADVERSE EVENT DETAILS

System organ class	Cardiac disorders
Event term	SUPRAVENTRICULAR TACHYCARDIA
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PER REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	0	249	0	0	0	0
ACT-064992 3 mg	1	250	2	0	0	0
ACT-064992 10 mg	2	242	5	0	0	0

Serious adverse event 24

SERIOUS ADVERSE EVENT DETAILS

System organ class	Cardiac disorders
Event term	ACUTE MYOCARDIAL INFARCTION
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PER REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	1	249	1	0	0	0
ACT-064992 3 mg	1	250	1	0	0	0
ACT-064992 10 mg	1	242	1	0	0	0

Serious adverse event 25

SERIOUS ADVERSE EVENT DETAILS

System organ class	Cardiac disorders
Event term	ATRIAL TACHYCARDIA
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PER REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	0	249	0	0	0	0
ACT-064992 3 mg	1	250	1	0	0	0
ACT-064992 10 mg	1	242	1	0	0	0

Serious adverse event 26

SERIOUS ADVERSE EVENT DETAILS

System organ class	Cardiac disorders
Event term	BRADYCARDIA
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PE REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	0	249	0	0	0	0
ACT-064992 3 mg	1	250	1	0	0	0
ACT-064992 10 mg	1	242	1	0	0	0

Serious adverse event 27

SERIOUS ADVERSE EVENT DETAILS

System organ class	Cardiac disorders
Event term	CARDIO-RESPIRATORY ARREST
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PE REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	0	249	0	0	0	0
ACT-064992 3 mg	1	250	1	0	0	0
ACT-064992 10 mg	1	242	1	0	0	0

Serious adverse event 28

SERIOUS ADVERSE EVENT DETAILS

System organ class	Cardiac disorders
Event term	ATRIAL FIBRILLATION
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PE REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	3	249	4	0	0	0
ACT-064992 3 mg	1	250	1	0	0	0
ACT-064992 10 mg	0	242	0	0	0	0

Serious adverse event 29

SERIOUS ADVERSE EVENT DETAILS

System organ class	Blood and lymphatic system disorders
Event term	LEFT VENTRICULAR FAILURE
Additional description	
Assessment type	systematic

Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PE.. REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	3	249	4	0	0	0
ACT-064992 3 mg	0	250	0	0	0	0
ACT-064992 10 mg	1	242	1	0	0	0

Serious adverse event 30

SERIOUS ADVERSE EVENT DETAILS

System organ class	Cardiac disorders
Event term	ACUTE RIGHT VENTRICULAR FAILURE
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PE.. REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	1	249	1	0	0	0
ACT-064992 3 mg	1	250	1	0	0	0
ACT-064992 10 mg	0	242	0	0	0	0

Serious adverse event 31

SERIOUS ADVERSE EVENT DETAILS

System organ class	Cardiac disorders
Event term	ANGINA PECTORIS
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PE.. REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	1	249	2	0	0	0
ACT-064992 3 mg	1	250	1	0	0	0
ACT-064992 10 mg	0	242	0	0	0	0

Serious adverse event 32

SERIOUS ADVERSE EVENT DETAILS

System organ class	Cardiac disorders
Event term	CARDIOGENIC SHOCK
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PE.. REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	1	249	1	0	0	0
ACT-064992 3 mg	0	250	0	0	0	0
ACT-064992 10 mg	1	242	1	1	0	0

Serious adverse event 33

SERIOUS ADVERSE EVENT DETAILS

System organ class	Cardiac disorders
Event term	CORONARY ARTERY DISEASE
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PER REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	1	249	1	0	0	0
ACT-064992 3 mg	1	250	1	0	0	0
ACT-064992 10 mg	0	242	0	0	0	0

Serious adverse event 34

SERIOUS ADVERSE EVENT DETAILS

System organ class	Cardiac disorders
Event term	ARRHYTHMIA
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PER REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	0	249	0	0	0	0
ACT-064992 3 mg	0	250	0	0	0	0
ACT-064992 10 mg	1	242	1	0	0	0

Serious adverse event 35

SERIOUS ADVERSE EVENT DETAILS

System organ class	Cardiac disorders
Event term	ATRIOVENTRICULAR BLOCK
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PER REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	0	249	0	0	0	0
ACT-064992 3 mg	0	250	0	0	0	0
ACT-064992 10 mg	1	242	1	0	0	0

Serious adverse event 36

SERIOUS ADVERSE EVENT DETAILS

System organ class	Cardiac disorders
Event term	ATRIOVENTRICULAR BLOCK COMPLETE
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA

Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PER REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	0	249	0	0	0	0
ACT-064992 3 mg	1	250	1	0	0	0
ACT-064992 10 mg	0	242	0	0	0	0

Serious adverse event 37

SERIOUS ADVERSE EVENT DETAILS

System organ class	Cardiac disorders
Event term	PALPITATIONS
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PER REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	0	249	0	0	0	0
ACT-064992 3 mg	1	250	1	0	0	0
ACT-064992 10 mg	0	242	0	0	0	0

Serious adverse event 38

SERIOUS ADVERSE EVENT DETAILS

System organ class	Cardiac disorders
Event term	RIGHT VENTRICULAR DYSFUNCTION
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PER REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	0	249	0	0	0	0
ACT-064992 3 mg	0	250	0	0	0	0
ACT-064992 10 mg	1	242	1	0	0	0

Serious adverse event 39

SERIOUS ADVERSE EVENT DETAILS

System organ class	Cardiac disorders
Event term	TACHYCARDIA
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PER REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	0	249	0	0	0	0
ACT-064992 3 mg	0	250	0	0	0	0
ACT-064992 10 mg	1	242	1	0	0	0

Serious adverse event 40

SERIOUS ADVERSE EVENT DETAILS

System organ class	Cardiac disorders
Event term	VENTRICULAR TACHYCARDIA

Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PE… REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I… TREATMENT, NU…
Placebo	0	249	0	0	0	0
ACT-064992 3 mg	0	250	0	0	0	0
ACT-064992 10 mg	1	242	1	0	0	0

Serious adverse event 41

SERIOUS ADVERSE EVENT DETAILS

System organ class	Cardiac disorders
Event term	ACUTE CORONARY SYNDROME
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PE… REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I… TREATMENT, NU…
Placebo	1	249	1	0	0	0
ACT-064992 3 mg	0	250	0	0	0	0
ACT-064992 10 mg	0	242	0	0	0	0

Serious adverse event 42

SERIOUS ADVERSE EVENT DETAILS

System organ class	Cardiac disorders
Event term	ACUTE LEFT VENTRICULAR FAILURE
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PE… REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I… TREATMENT, NU…
Placebo	1	249	1	0	0	0
ACT-064992 3 mg	0	250	0	0	0	0
ACT-064992 10 mg	0	242	0	0	0	0

Serious adverse event 43

SERIOUS ADVERSE EVENT DETAILS

System organ class	Cardiac disorders
Event term	CARDIAC FAILURE CONGESTIVE
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PE… REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I… TREATMENT, NU…
Placebo	1	249	1	0	0	0
ACT-064992 3						

mg	0	250	0	0	0	0
ACT-064992 10 mg	0	242	0	0	0	0

Serious adverse event 44

SERIOUS ADVERSE EVENT DETAILS

System organ class	Cardiac disorders
Event term	CARDIOPULMONARY FAILURE
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PE… REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I… TREATMENT, NU…
Placebo	1	249	1	0	0	0
ACT-064992 3 mg	0	250	0	0	0	0
ACT-064992 10 mg	0	242	0	0	0	0

Serious adverse event 45

SERIOUS ADVERSE EVENT DETAILS

System organ class	Cardiac disorders
Event term	LEFT VENTRICULAR DYSFUNCTION
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PE… REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I… TREATMENT, NU…
Placebo	1	249	1	0	0	0
ACT-064992 3 mg	0	250	0	0	0	0
ACT-064992 10 mg	0	242	0	0	0	0

Serious adverse event 46

SERIOUS ADVERSE EVENT DETAILS

System organ class	Cardiac disorders
Event term	PERICARDIAL EFFUSION
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PE… REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I… TREATMENT, NU…
Placebo	1	249	1	0	0	0
ACT-064992 3 mg	0	250	0	0	0	0
ACT-064992 10 mg	0	242	0	0	0	0

Serious adverse event 47

SERIOUS ADVERSE EVENT DETAILS

System organ class	Cardiac disorders
Event term	TACHYARRHYTHMIA
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse	no

event?

Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PE... REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I... TREATMENT, NU...
Placebo	1	249	1	0	0	0
ACT-064992 3 mg	0	250	0	0	0	0
ACT-064992 10 mg	0	242	0	0	0	0

Serious adverse event 48

SERIOUS ADVERSE EVENT DETAILS

System organ class	Infections and infestations
Event term	PNEUMONIA
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PE... REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I... TREATMENT, NU...
Placebo	8	249	9	0	0	0
ACT-064992 3 mg	7	250	9	0	0	0
ACT-064992 10 mg	4	242	4	0	0	0

Serious adverse event 49

SERIOUS ADVERSE EVENT DETAILS

System organ class	Infections and infestations
Event term	GASTROENTERITIS
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PE... REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I... TREATMENT, NU...
Placebo	2	249	2	0	0	0
ACT-064992 3 mg	3	250	3	0	0	0
ACT-064992 10 mg	2	242	2	0	0	0

Serious adverse event 50

SERIOUS ADVERSE EVENT DETAILS

System organ class	Infections and infestations
Event term	BRONCHITIS
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PE... REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I... TREATMENT, NU...
Placebo	1	249	1	0	0	0
ACT-064992 3 mg	2	250	2	0	0	0
ACT-064992 10 mg	1	242	1	0	0	0

Serious adverse event 51

SERIOUS ADVERSE EVENT DETAILS

System organ class	Infections and infestations
Event term	UPPER RESPIRATORY TRACT INFECTION
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PER REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	1	249	1	0	0	0
ACT-064992 3 mg	3	250	3	0	0	0
ACT-064992 10 mg	0	242	0	0	0	0

Serious adverse event 52

SERIOUS ADVERSE EVENT DETAILS

System organ class	Infections and infestations
Event term	URINARY TRACT INFECTION
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PER REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	3	249	3	0	0	0
ACT-064992 3 mg	0	250	0	0	0	0
ACT-064992 10 mg	2	242	2	0	0	0

Serious adverse event 53

SERIOUS ADVERSE EVENT DETAILS

System organ class	Infections and infestations
Event term	RESPIRATORY TRACT INFECTION
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PER REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	2	249	2	0	0	0
ACT-064992 3 mg	0	250	0	0	0	0
ACT-064992 10 mg	2	242	2	0	0	0

Serious adverse event 54

SERIOUS ADVERSE EVENT DETAILS

System organ class	Infections and infestations
Event term	LOWER RESPIRATORY TRACT INFECTION
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PER REPORTING GROUP

REPORTING	SUBJECTS AFFECTED	SUBJECTS EXPOSED	OCCURRENCES ALL	OCCURENCES CAUSALLY RELATED TO	FATALITIES,	FATALITIES CAUSALLY I

GROUPS	NUMBER	NUMBER	NUMBER	TREATMENT, NUMBER	NUMBER	TREATMENT, NU
Placebo	1	249	2	0	0	0
ACT-064992 3 mg	2	250	2	0	0	0
ACT-064992 10 mg	0	242	0	0	0	0

Serious adverse event 55

SERIOUS ADVERSE EVENT DETAILS

System organ class	Infections and infestations
Event term	ERYSIPELAS
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PER REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	0	249	0	0	0	0
ACT-064992 3 mg	2	250	2	0	0	0
ACT-064992 10 mg	0	242	0	0	0	0

Serious adverse event 56

SERIOUS ADVERSE EVENT DETAILS

System organ class	Infections and infestations
Event term	SEPSIS
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PER REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	4	249	4	0	0	0
ACT-064992 3 mg	0	250	0	0	0	0
ACT-064992 10 mg	1	242	1	0	0	0

Serious adverse event 57

SERIOUS ADVERSE EVENT DETAILS

System organ class	Infections and infestations
Event term	LUNG INFECTION
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PER REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	1	249	1	0	0	0
ACT-064992 3 mg	1	250	1	0	0	0
ACT-064992 10 mg	0	242	0	0	0	0

Serious adverse event 58

SERIOUS ADVERSE EVENT DETAILS

System organ class	Infections and infestations
Event term	SEPTIC SHOCK
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse	MedDRA

events in these results is

Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PER REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	1	249	1	0	0	0
ACT-064992 3 mg	1	250	1	0	0	0
ACT-064992 10 mg	0	242	0	0	0	0

Serious adverse event 59

SERIOUS ADVERSE EVENT DETAILS

System organ class	Infections and infestations
Event term	WOUND INFECTION
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PER REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	1	249	1	0	0	0
ACT-064992 3 mg	0	250	0	0	0	0
ACT-064992 10 mg	1	242	0	0	0	0

Serious adverse event 60

SERIOUS ADVERSE EVENT DETAILS

System organ class	Infections and infestations
Event term	BACTERIAL SEPSIS
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PER REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	0	249	0	0	0	0
ACT-064992 3 mg	0	250	0	0	0	0
ACT-064992 10 mg	1	242	1	0	0	0

Serious adverse event 61

SERIOUS ADVERSE EVENT DETAILS

System organ class	Infections and infestations
Event term	BRONCHITIS BACTERIAL
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PER REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	0	249	0	0	0	0
ACT-064992 3 mg	0	250	0	0	0	0
ACT-064992 10 mg	1	242	1	0	0	0

Serious adverse event 62

SERIOUS ADVERSE EVENT DETAILS

System organ class	Infections and infestations
Event term	DENGUE FEVER
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PER REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	0	249	0	0	0	0
ACT-064992 3 mg	1	250	1	0	0	0
ACT-064992 10 mg	0	242	0	0	0	0

Serious adverse event 63

SERIOUS ADVERSE EVENT DETAILS

System organ class	Blood and lymphatic system disorders
Event term	DIARRHOEA INFECTIOUS
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PER REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	0	249	0	0	0	0
ACT-064992 3 mg	1	250	1	0	0	0
ACT-064992 10 mg	0	242	0	0	0	0

Serious adverse event 64

SERIOUS ADVERSE EVENT DETAILS

System organ class	Infections and infestations
Event term	ENTEROCOCCAL SEPSIS
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PER REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	0	249	0	0	0	0
ACT-064992 3 mg	1	250	1	0	0	0
ACT-064992 10 mg	0	242	0	0	0	0

Serious adverse event 65

SERIOUS ADVERSE EVENT DETAILS

System organ class	Infections and infestations
Event term	HEPATITIS E
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PER REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	0	249	0	0	0	0
ACT-064992 3 mg	1	250	1	0	0	0
ACT-064992 10 mg	0	242	0	0	0	0

Serious adverse event 66

SERIOUS ADVERSE EVENT DETAILS

System organ class	Infections and infestations
Event term	LOBAR PNEUMONIA
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PER REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	0	249	0	0	0	0
ACT-064992 3 mg	1	250	1	0	0	0
ACT-064992 10 mg	0	242	0	0	0	0

Serious adverse event 67

SERIOUS ADVERSE EVENT DETAILS

System organ class	Infections and infestations
Event term	LUNG INFECTION PSEUDOMONAL
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PER REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	0	249	0	0	0	0
ACT-064992 3 mg	0	250	0	0	0	0
ACT-064992 10 mg	1	242	2	0	0	0

Serious adverse event 68

SERIOUS ADVERSE EVENT DETAILS

System organ class	Infections and infestations
Event term	NASOPHARYNGITIS
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PER REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	0	249	0	0	0	0
ACT-064992 3 mg	1	250	1	0	0	0
ACT-064992 10 mg	0	242	0	0	0	0

Serious adverse event 69

SERIOUS ADVERSE EVENT DETAILS

System organ class	Infections and infestations
Event term	OMPHALITIS
Additional description	

Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PER REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	0	249	0	0	0	0
ACT-064992 3 mg	0	250	0	0	0	0
ACT-064992 10 mg	1	242	1	0	0	0

Serious adverse event 70

SERIOUS ADVERSE EVENT DETAILS

System organ class	Infections and infestations
Event term	OVERGROWTH BACTERIAL
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PER REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	0	249	0	0	0	0
ACT-064992 3 mg	0	250	0	0	0	0
ACT-064992 10 mg	1	242	2	0	0	0

Serious adverse event 71

SERIOUS ADVERSE EVENT DETAILS

System organ class	Infections and infestations
Event term	PAROTID ABSCESS
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PER REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	0	249	0	0	0	0
ACT-064992 3 mg	0	250	0	0	0	0
ACT-064992 10 mg	1	242	1	0	0	0

Serious adverse event 72

SERIOUS ADVERSE EVENT DETAILS

System organ class	Infections and infestations
Event term	PNEUMONIA INFLUENZAL
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PER REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	0	249	0	0	0	0
ACT-064992 3 mg	1	250	1	0	0	0

ACT-064992 10 mg	0	242	0	0	0	0

Serious adverse event 73

SERIOUS ADVERSE EVENT DETAILS

System organ class	Infections and infestations
Event term	PNEUMONIA MORAXELLA
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PER REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	0	249	0	0	0	0
ACT-064992 3 mg	1	250	1	0	0	0
ACT-064992 10 mg	0	242	0	0	0	0

Serious adverse event 74

SERIOUS ADVERSE EVENT DETAILS

System organ class	Infections and infestations
Event term	PNEUMONIA NECROTISING
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PER REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	0	249	0	0	0	0
ACT-064992 3 mg	0	250	0	0	0	0
ACT-064992 10 mg	1	242	1	0	0	0

Serious adverse event 75

SERIOUS ADVERSE EVENT DETAILS

System organ class	Infections and infestations
Event term	PNEUMONIA PNEUMOCOCCAL
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PER REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	0	249	0	0	0	0
ACT-064992 3 mg	1	250	1	0	0	0
ACT-064992 10 mg	0	242	0	0	0	0

Serious adverse event 76

SERIOUS ADVERSE EVENT DETAILS

System organ class	Infections and infestations
Event term	POST PROCEDURAL CELLULITIS
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no

Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PER REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	0	249	0	0	0	0
ACT-064992 3 mg	1	250	1	0	0	0
ACT-064992 10 mg	0	242	0	0	0	0

Serious adverse event 77

SERIOUS ADVERSE EVENT DETAILS

System organ class	Infections and infestations
Event term	PYELONEPHRITIS
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PER REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	0	249	0	0	0	0
ACT-064992 3 mg	0	250	0	0	0	0
ACT-064992 10 mg	1	242	1	0	0	0

Serious adverse event 78

SERIOUS ADVERSE EVENT DETAILS

System organ class	Infections and infestations
Event term	SALPINGO-OOPHORITIS
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PER REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	0	249	0	0	0	0
ACT-064992 3 mg	0	250	0	0	0	0
ACT-064992 10 mg	1	242	1	0	0	0

Serious adverse event 79

SERIOUS ADVERSE EVENT DETAILS

System organ class	Infections and infestations
Event term	SIALOADENITIS
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PER REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	0	249	0	0	0	0
ACT-064992 3 mg	0	250	0	0	0	0
ACT-064992 10 mg	1	242	1	0	0	0

Serious adverse event 80

SERIOUS ADVERSE EVENT DETAILS

System organ class	Infections and infestations

Event term	TRACHEOBRONCHITIS
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PER REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	0	249	0	0	0	0
ACT-064992 3 mg	1	250	1	0	0	0
ACT-064992 10 mg	0	242	0	0	0	0

Serious adverse event 81

SERIOUS ADVERSE EVENT DETAILS

System organ class	Infections and infestations
Event term	VIRAL INFECTION
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PER REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	0	249	0	0	0	0
ACT-064992 3 mg	1	250	1	0	0	0
ACT-064992 10 mg	0	242	0	0	0	0

Serious adverse event 82

SERIOUS ADVERSE EVENT DETAILS

System organ class	Infections and infestations
Event term	VULVAL ABSCESS
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PER REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	0	249	0	0	0	0
ACT-064992 3 mg	0	250	0	0	0	0
ACT-064992 10 mg	1	242	1	0	0	0

Serious adverse event 83

SERIOUS ADVERSE EVENT DETAILS

System organ class	Infections and infestations
Event term	CELLULITIS
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PER REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	2	249	2	0	0	0

ACT-064992 3 mg	0	250	0	0	0	0
ACT-064992 10 mg	0	242	0	0	0	0

Serious adverse event 84

SERIOUS ADVERSE EVENT DETAILS

System organ class	Infections and infestations
Event term	ABSCESS INTESTINAL
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PE.. REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	1	249	1	0	0	0
ACT-064992 3 mg	0	250	0	0	0	0
ACT-064992 10 mg	0	242	0	0	0	0

Serious adverse event 85

SERIOUS ADVERSE EVENT DETAILS

System organ class	Infections and infestations
Event term	APPENDICITIS
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PE.. REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	1	249	1	0	0	0
ACT-064992 3 mg	0	250	0	0	0	0
ACT-064992 10 mg	0	242	0	0	0	0

Serious adverse event 86

SERIOUS ADVERSE EVENT DETAILS

System organ class	Infections and infestations
Event term	CUTANEOUS TUBERCULOSIS
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PE.. REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	1	249	1	0	0	0
ACT-064992 3 mg	0	250	0	0	0	0
ACT-064992 10 mg	0	242	0	0	0	0

Serious adverse event 87

SERIOUS ADVERSE EVENT DETAILS

System organ class	Infections and infestations
Event term	HERPES ZOSTER
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name	

and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PER REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	1	249	1	0	0	0
ACT-064992 3 mg	0	250	0	0	0	0
ACT-064992 10 mg	0	242	0	0	0	0

Serious adverse event 88

SERIOUS ADVERSE EVENT DETAILS

System organ class	Infections and infestations
Event term	INFECTED SKIN ULCER
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PER REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	1	249	1	0	0	0
ACT-064992 3 mg	0	250	0	0	0	0
ACT-064992 10 mg	0	242	0	0	0	0

Serious adverse event 89

SERIOUS ADVERSE EVENT DETAILS

System organ class	Infections and infestations
Event term	SINUSITIS
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PER REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	1	249	1	0	0	0
ACT-064992 3 mg	0	250	0	0	0	0
ACT-064992 10 mg	0	242	0	0	0	0

Serious adverse event 90

SERIOUS ADVERSE EVENT DETAILS

System organ class	Gastrointestinal disorders
Event term	PANCREATITIS ACUTE
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PER REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	0	249	0	0	0	0
ACT-064992 3 mg	3	250	3	0	0	0
ACT-064992 10 mg	1	242	1	1	0	0

Serious adverse event 91

SERIOUS ADVERSE EVENT DETAILS

System organ class	Gastrointestinal disorders
Event term	UPPER GASTROINTESTINAL HAEMORRHAGE
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PER REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	2	249	2	0	0	0
ACT-064992 3 mg	2	250	2	0	0	0
ACT-064992 10 mg	0	242	0	0	0	0

Serious adverse event 92

SERIOUS ADVERSE EVENT DETAILS

System organ class	Gastrointestinal disorders
Event term	DIARRHOEA
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PER REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	1	249	1	0	0	0
ACT-064992 3 mg	0	250	0	0	0	0
ACT-064992 10 mg	2	242	2	0	0	0

Serious adverse event 93

SERIOUS ADVERSE EVENT DETAILS

System organ class	Gastrointestinal disorders
Event term	GASTRIC ULCER HAEMORRHAGE
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PER REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	0	249	0	0	0	0
ACT-064992 3 mg	1	250	1	0	0	0
ACT-064992 10 mg	1	242	1	0	0	0

Serious adverse event 94

SERIOUS ADVERSE EVENT DETAILS

System organ class	Gastrointestinal disorders
Event term	HAEMATEMESIS
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PER REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	0	249	0	0	0	0
ACT-064992 3 mg	1	250	1	0	0	0
ACT-064992 10 mg	1	242	1	0	0	0

Serious adverse event 95

SERIOUS ADVERSE EVENT DETAILS

System organ class	Gastrointestinal disorders
Event term	ASCITES
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PER REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	1	249	1	1	0	0
ACT-064992 3 mg	1	250	1	0	0	0
ACT-064992 10 mg	0	242	0	0	0	0

Serious adverse event 96

SERIOUS ADVERSE EVENT DETAILS

System organ class	Gastrointestinal disorders
Event term	ABDOMINAL DISTENSION
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PER REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	0	249	0	0	0	0
ACT-064992 3 mg	1	250	1	0	0	0
ACT-064992 10 mg	0	242	0	0	0	0

Serious adverse event 97

SERIOUS ADVERSE EVENT DETAILS

System organ class	Gastrointestinal disorders
Event term	ABDOMINAL PAIN
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PER REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	0	249	0	0	0	0
ACT-064992 3 mg	0	250	0	0	0	0
ACT-064992 10 mg	1	242	2	0	0	0

Serious adverse event 98

SERIOUS ADVERSE EVENT DETAILS

System organ class	Gastrointestinal disorders
Event term	ANAL POLYP
Additional description	
Assessment type	systematic

Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PE... REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	0	249	0	0	0	0
ACT-064992 3 mg	0	250	0	0	0	0
ACT-064992 10 mg	1	242	1	0	0	0

Serious adverse event 99

SERIOUS ADVERSE EVENT DETAILS

System organ class	Blood and lymphatic system disorders
Event term	COLITIS ISCHAEMIC
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PE... REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	0	249	0	0	0	0
ACT-064992 3 mg	1	250	1	0	0	0
ACT-064992 10 mg	0	242	0	0	0	0

Serious adverse event 100

SERIOUS ADVERSE EVENT DETAILS

System organ class	Gastrointestinal disorders
Event term	DYSPHAGIA
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PE... REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	0	249	0	0	0	0
ACT-064992 3 mg	0	250	0	0	0	0
ACT-064992 10 mg	1	242	1	0	0	0

Serious adverse event 101

SERIOUS ADVERSE EVENT DETAILS

System organ class	Gastrointestinal disorders
Event term	GASTROINTESTINAL MOTILITY DISORDER
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PE... REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	0	249	0	0	0	0
ACT-064992 3 mg	0	250	0	0	0	0
ACT-064992 10 mg	1	242	2	0	0	0

Serious adverse event 102

SERIOUS ADVERSE EVENT DETAILS

System organ class	Gastrointestinal disorders
Event term	GINGIVAL BLEEDING
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PE... REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I... TREATMENT, NU...
Placebo	0	249	0	0	0	0
ACT-064992 3 mg	1	250	1	0	0	0
ACT-064992 10 mg	0	242	0	0	0	0

Serious adverse event 103

SERIOUS ADVERSE EVENT DETAILS

System organ class	Gastrointestinal disorders
Event term	INTESTINAL OBSTRUCTION
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PE... REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I... TREATMENT, NU...
Placebo	0	249	0	0	0	0
ACT-064992 3 mg	1	250	1	0	0	0
ACT-064992 10 mg	0	242	0	0	0	0

Serious adverse event 104

SERIOUS ADVERSE EVENT DETAILS

System organ class	Gastrointestinal disorders
Event term	MALABSORPTION
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PE... REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I... TREATMENT, NU...
Placebo	0	249	0	0	0	0
ACT-064992 3 mg	0	250	0	0	0	0
ACT-064992 10 mg	1	242	1	0	0	0

Serious adverse event 105

SERIOUS ADVERSE EVENT DETAILS

System organ class	Gastrointestinal disorders
Event term	NAUSEA
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA

Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PER REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	0	249	0	0	0	0
ACT-064992 3 mg	1	250	1	0	0	0
ACT-064992 10 mg	0	242	0	0	0	0

Serious adverse event 106

SERIOUS ADVERSE EVENT DETAILS

System organ class	Gastrointestinal disorders
Event term	OESOPHAGEAL VARICES HAEMORRHAGE
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PER REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	0	249	0	0	0	0
ACT-064992 3 mg	1	250	1	0	0	0
ACT-064992 10 mg	0	242	0	0	0	0

Serious adverse event 107

SERIOUS ADVERSE EVENT DETAILS

System organ class	Gastrointestinal disorders
Event term	PANCREATITIS RELAPSING
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PER REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	0	249	0	0	0	0
ACT-064992 3 mg	0	250	0	0	0	0
ACT-064992 10 mg	1	242	1	1	0	0

Serious adverse event 108

SERIOUS ADVERSE EVENT DETAILS

System organ class	Gastrointestinal disorders
Event term	PEPTIC ULCER
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PER REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	0	249	0	0	0	0
ACT-064992 3 mg	0	250	0	0	0	0
ACT-064992 10 mg	1	242	1	0	0	0

Serious adverse event 109

SERIOUS ADVERSE EVENT DETAILS

System organ class	Gastrointestinal disorders

Event term	TONGUE HAEMORRHAGE
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PER REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	0	249	0	0	0	0
ACT-064992 3 mg	1	250	1	0	0	0
ACT-064992 10 mg	0	242	0	0	0	0

Serious adverse event 110

SERIOUS ADVERSE EVENT DETAILS

System organ class	Gastrointestinal disorders
Event term	VOMITING
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PER REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	0	249	0	0	0	0
ACT-064992 3 mg	1	250	1	0	0	0
ACT-064992 10 mg	0	242	0	0	0	0

Serious adverse event 111

SERIOUS ADVERSE EVENT DETAILS

System organ class	Gastrointestinal disorders
Event term	ILEUS
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PER REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	1	249	1	0	0	0
ACT-064992 3 mg	0	250	0	0	0	0
ACT-064992 10 mg	0	242	0	0	0	0

Serious adverse event 112

SERIOUS ADVERSE EVENT DETAILS

System organ class	Gastrointestinal disorders
Event term	INGUINAL HERNIA
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PER REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU

Placebo	1	249	1	0	0	0
ACT-064992 3 mg	0	250	0	0	0	0
ACT-064992 10 mg	0	242	0	0	0	0

Serious adverse event 113

SERIOUS ADVERSE EVENT DETAILS

System organ class	Gastrointestinal disorders
Event term	PANCREATIC MASS
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PER REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	1	249	1	0	0	0
ACT-064992 3 mg	0	250	0	0	0	0
ACT-064992 10 mg	0	242	0	0	0	0

Serious adverse event 114

SERIOUS ADVERSE EVENT DETAILS

System organ class	Gastrointestinal disorders
Event term	PERITONITIS
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PER REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	1	249	1	0	0	0
ACT-064992 3 mg	0	250	0	0	0	0
ACT-064992 10 mg	0	242	0	0	0	0

Serious adverse event 115

SERIOUS ADVERSE EVENT DETAILS

System organ class	Gastrointestinal disorders
Event term	RECTAL HAEMORRHAGE
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PER REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	1	249	1	1	0	0
ACT-064992 3 mg	0	250	0	0	0	0
ACT-064992 10 mg	0	242	0	0	0	0

Serious adverse event 116

SERIOUS ADVERSE EVENT DETAILS

System organ class	General disorders and administration site conditions
Event term	CHEST PAIN
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA

Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PER REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	1	249	1	0	0	0
ACT-064992 3 mg	4	250	4	0	0	0
ACT-064992 10 mg	3	242	3	0	0	0

Serious adverse event 117

SERIOUS ADVERSE EVENT DETAILS

System organ class	General disorders and administration site conditions
Event term	SUDDEN DEATH
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PER REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	0	249	0	0	0	0
ACT-064992 3 mg	1	250	1	0	0	0
ACT-064992 10 mg	2	242	2	0	0	0

Serious adverse event 118

SERIOUS ADVERSE EVENT DETAILS

System organ class	General disorders and administration site conditions
Event term	SUDDEN CARDIAC DEATH
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PER REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	2	249	2	0	0	0
ACT-064992 3 mg	1	250	1	0	0	0
ACT-064992 10 mg	1	242	1	0	0	0

Serious adverse event 119

SERIOUS ADVERSE EVENT DETAILS

System organ class	General disorders and administration site conditions
Event term	GENERAL PHYSICAL HEALTH DETERIORATION
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PER REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	0	249	0	0	0	0
ACT-064992 3 mg	1	250	1	0	0	0
ACT-064992 10 mg	1	242	1	0	0	0

Serious adverse event 120

SERIOUS ADVERSE EVENT DETAILS

System organ class	General disorders and administration site conditions
Event term	PYREXIA
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PE… REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I… TREATMENT, NU…
Placebo	0	249	0	0	0	0
ACT-064992 3 mg	2	250	2	0	0	0
ACT-064992 10 mg	0	242	0	0	0	0

Serious adverse event 121

SERIOUS ADVERSE EVENT DETAILS

System organ class	General disorders and administration site conditions
Event term	ADVERSE DRUG REACTION
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PE… REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I… TREATMENT, NU…
Placebo	1	249	1	0	0	0
ACT-064992 3 mg	1	250	1	1	0	0
ACT-064992 10 mg	0	242	0	0	0	0

Serious adverse event 122

SERIOUS ADVERSE EVENT DETAILS

System organ class	General disorders and administration site conditions
Event term	DEATH
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PE… REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I… TREATMENT, NU…
Placebo	1	249	1	0	0	0
ACT-064992 3 mg	0	250	0	0	0	0
ACT-064992 10 mg	1	242	1	0	0	0

Serious adverse event 123

SERIOUS ADVERSE EVENT DETAILS

System organ class	General disorders and administration site conditions
Event term	CHEST DISCOMFORT
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PE… REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	0	249	0	0	0	0
ACT-064992 3 mg	1	250	1	0	0	0
ACT-064992 10 mg	0	242	0	0	0	0

Serious adverse event 124

SERIOUS ADVERSE EVENT DETAILS

System organ class	General disorders and administration site conditions
Event term	DEVICE MALFUNCTION
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PE REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	0	249	0	0	0	0
ACT-064992 3 mg	0	250	0	0	0	0
ACT-064992 10 mg	1	242	1	0	0	0

Serious adverse event 125

SERIOUS ADVERSE EVENT DETAILS

System organ class	General disorders and administration site conditions
Event term	FATIGUE
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PE REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	0	249	0	0	0	0
ACT-064992 3 mg	0	250	0	0	0	0
ACT-064992 10 mg	1	242	1	0	0	0

Serious adverse event 126

SERIOUS ADVERSE EVENT DETAILS

System organ class	General disorders and administration site conditions
Event term	MULTI-ORGAN DISORDER
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PE REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	0	249	0	0	0	0
ACT-064992 3 mg	1	250	1	0	0	0
ACT-064992 10 mg	0	242	0	0	0	0

Serious adverse event 127

SERIOUS ADVERSE EVENT DETAILS

System organ class	Blood and lymphatic system disorders
Event term	MULTI-ORGAN FAILURE
Additional description	
Assessment type	systematic

Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PER REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	0	249	0	0	0	0
ACT-064992 3 mg	0	250	0	0	0	0
ACT-064992 10 mg	1	242	1	0	0	0

Serious adverse event 128

SERIOUS ADVERSE EVENT DETAILS

System organ class	General disorders and administration site conditions
Event term	DEVICE DISLOCATION
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PER REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	1	249	1	0	0	0
ACT-064992 3 mg	0	250	0	0	0	0
ACT-064992 10 mg	0	242	0	0	0	0

Serious adverse event 129

SERIOUS ADVERSE EVENT DETAILS

System organ class	General disorders and administration site conditions
Event term	OEDEMA PERIPHERAL
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PER REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	1	249	1	0	0	0
ACT-064992 3 mg	0	250	0	0	0	0
ACT-064992 10 mg	0	242	0	0	0	0

Serious adverse event 130

SERIOUS ADVERSE EVENT DETAILS

System organ class	Nervous system disorders
Event term	SYNCOPE
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PER REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	6	249	8	0	0	0
ACT-064992 3 mg	7	250	9	0	0	0
ACT-064992 10 mg	4	242	5	0	0	0

Serious adverse event 131

SERIOUS ADVERSE EVENT DETAILS

System organ class	Nervous system disorders
Event term	CARPAL TUNNEL SYNDROME
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PE... REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	0	249	0	0	0	0
ACT-064992 3 mg	1	250	1	0	0	0
ACT-064992 10 mg	0	242	0	0	0	0

Serious adverse event 132

SERIOUS ADVERSE EVENT DETAILS

System organ class	Nervous system disorders
Event term	HEADACHE
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PE... REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	0	249	0	0	0	0
ACT-064992 3 mg	0	250	0	0	0	0
ACT-064992 10 mg	1	242	1	0	0	0

Serious adverse event 133

SERIOUS ADVERSE EVENT DETAILS

System organ class	Nervous system disorders
Event term	ISCHAEMIC STROKE
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PE... REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	0	249	0	0	0	0
ACT-064992 3 mg	0	250	0	0	0	0
ACT-064992 10 mg	1	242	1	0	0	0

Serious adverse event 134

SERIOUS ADVERSE EVENT DETAILS

System organ class	Nervous system disorders
Event term	SCIATICA
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA

version 14.0

VALUES FOR SERIOUS ADVERSE EVENT PER REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	0	249	0	0	0	0
ACT-064992 3 mg	1	250	1	0	0	0
ACT-064992 10 mg	0	242	0	0	0	0

Serious adverse event 135

SERIOUS ADVERSE EVENT DETAILS

System organ class	Nervous system disorders
Event term	SUBARACHNOID HAEMORRHAGE
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PER REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	0	249	0	0	0	0
ACT-064992 3 mg	1	250	1	0	0	0
ACT-064992 10 mg	0	242	0	0	0	0

Serious adverse event 136

SERIOUS ADVERSE EVENT DETAILS

System organ class	Nervous system disorders
Event term	PRESYNCOPE
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PER REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	2	249	2	0	0	0
ACT-064992 3 mg	0	250	0	0	0	0
ACT-064992 10 mg	0	242	0	0	0	0

Serious adverse event 137

SERIOUS ADVERSE EVENT DETAILS

System organ class	Nervous system disorders
Event term	CEREBRAL INFARCTION
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PER REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	1	249	1	0	0	0
ACT-064992 3 mg	0	250	0	0	0	0
ACT-064992 10 mg	0	242	0	0	0	0

Serious adverse event 138

SERIOUS ADVERSE EVENT DETAILS

System organ class	Nervous system disorders
Event term	CEREBROVASCULAR ACCIDENT

Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PER REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	1	249	1	0	0	0
ACT-064992 3 mg	0	250	0	0	0	0
ACT-064992 10 mg	0	242	0	0	0	0

Serious adverse event 139

SERIOUS ADVERSE EVENT DETAILS

System organ class	Nervous system disorders
Event term	TRIGEMINAL NEURALGIA
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PER REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	1	249	1	0	0	0
ACT-064992 3 mg	0	250	0	0	0	0
ACT-064992 10 mg	0	242	0	0	0	0

Serious adverse event 140

SERIOUS ADVERSE EVENT DETAILS

System organ class	Blood and lymphatic system disorders
Event term	ANAEMIA
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PER REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	1	249	1	0	0	0
ACT-064992 3 mg	5	250	6	1	0	0
ACT-064992 10 mg	6	242	6	2	0	0

Serious adverse event 141

SERIOUS ADVERSE EVENT DETAILS

System organ class	Blood and lymphatic system disorders
Event term	THROMBOCYTOPENIA
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PER REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	1	249	1	1	0	0

ACT-064992 3 mg	0	250	0	0	0	0
ACT-064992 10 mg	1	242	1	0	0	0

Serious adverse event 142

SERIOUS ADVERSE EVENT DETAILS

System organ class	Blood and lymphatic system disorders
Event term	COAGULOPATHY
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PER REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	0	249	0	0	0	0
ACT-064992 3 mg	1	250	1	0	0	0
ACT-064992 10 mg	0	242	0	0	0	0

Serious adverse event 143

SERIOUS ADVERSE EVENT DETAILS

System organ class	Blood and lymphatic system disorders
Event term	HAEMOLYTIC ANAEMIA
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PER REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	0	249	0	0	0	0
ACT-064992 3 mg	0	250	0	0	0	0
ACT-064992 10 mg	1	242	1	0	0	0

Serious adverse event 144

SERIOUS ADVERSE EVENT DETAILS

System organ class	Blood and lymphatic system disorders
Event term	HAEMORRHAGIC ANAEMIA
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PER REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	0	249	0	0	0	0
ACT-064992 3 mg	0	250	0	0	0	0
ACT-064992 10 mg	1	242	1	0	0	0

Serious adverse event 145

SERIOUS ADVERSE EVENT DETAILS

System organ class	Blood and lymphatic system disorders
Event term	HYPOCOAGULABLE STATE
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name	

and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PER REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	0	249	0	0	0	0
ACT-064992 3 mg	1	250	1	0	0	0
ACT-064992 10 mg	0	242	0	0	0	0

Serious adverse event 146

SERIOUS ADVERSE EVENT DETAILS

System organ class	Blood and lymphatic system disorders
Event term	ANAEMIA MEGALOBLASTIC
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PER REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	1	249	1	0	0	0
ACT-064992 3 mg	0	250	0	0	0	0
ACT-064992 10 mg	0	242	0	0	0	0

Serious adverse event 147

SERIOUS ADVERSE EVENT DETAILS

System organ class	Neoplasms benign, malignant and unspecified (incl cysts and polyps)
Event term	COLON CANCER
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PER REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	0	249	0	0	0	0
ACT-064992 3 mg	2	250	2	0	0	0
ACT-064992 10 mg	0	242	0	0	0	0

Serious adverse event 148

SERIOUS ADVERSE EVENT DETAILS

System organ class	Neoplasms benign, malignant and unspecified (incl cysts and polyps)
Event term	OVARIAN NEOPLASM
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PER REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	0	249	0	0	0	0
ACT-064992 3 mg	1	250	1	0	0	0
ACT-064992 10 mg	1	242	1	0	0	0

Serious adverse event 149

SERIOUS ADVERSE EVENT DETAILS

System organ class	Neoplasms benign, malignant and unspecified (incl cysts and polyps)
Event term	UTERINE LEIOMYOMA
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PER REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	0	249	0	0	0	0
ACT-064992 3 mg	1	250	1	0	0	0
ACT-064992 10 mg	1	242	1	0	0	0

Serious adverse event 150

SERIOUS ADVERSE EVENT DETAILS

System organ class	Blood and lymphatic system disorders
Event term	BREAST CANCER
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PER REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	1	249	1	0	0	0
ACT-064992 3 mg	1	250	1	0	0	0
ACT-064992 10 mg	0	242	0	0	0	0

Serious adverse event 151

SERIOUS ADVERSE EVENT DETAILS

System organ class	Neoplasms benign, malignant and unspecified (incl cysts and polyps)
Event term	ANGIOSARCOMA
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PER REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	0	249	0	0	0	0
ACT-064992 3 mg	1	250	1	0	0	0
ACT-064992 10 mg	0	242	0	0	0	0

Serious adverse event 152

SERIOUS ADVERSE EVENT DETAILS

System organ class	Neoplasms benign, malignant and unspecified (incl cysts and polyps)
Event term	METASTATIC NEOPLASM
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PE

REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	0	249	0	0	0	0
ACT-064992 3 mg	1	250	1	0	0	0
ACT-064992 10 mg	0	242	0	0	0	0

Serious adverse event 153

SERIOUS ADVERSE EVENT DETAILS

System organ class	Neoplasms benign, malignant and unspecified (incl cysts and polyps)
Event term	RECTOSIGMOID CANCER
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PER REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	0	249	0	0	0	0
ACT-064992 3 mg	1	250	1	0	0	0
ACT-064992 10 mg	0	242	0	0	0	0

Serious adverse event 154

SERIOUS ADVERSE EVENT DETAILS

System organ class	Neoplasms benign, malignant and unspecified (incl cysts and polyps)
Event term	TONGUE NEOPLASM BENIGN
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PER REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	0	249	0	0	0	0
ACT-064992 3 mg	1	250	1	0	0	0
ACT-064992 10 mg	0	242	0	0	0	0

Serious adverse event 155

SERIOUS ADVERSE EVENT DETAILS

System organ class	Neoplasms benign, malignant and unspecified (incl cysts and polyps)
Event term	RECTAL CANCER
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PER REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	1	249	1	0	0	0
ACT-064992 3 mg	0	250	0	0	0	0
ACT-064992 10 mg	0	242	0	0	0	0

Serious adverse event 156

SERIOUS ADVERSE EVENT DETAILS

System organ class	Reproductive system and breast disorders
Event term	MENORRHAGIA
Additional description	

Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PE... REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	0	249	0	0	0	0
ACT-064992 3 mg	2	250	2	0	0	0
ACT-064992 10 mg	1	242	1	0	0	0

Serious adverse event 157

SERIOUS ADVERSE EVENT DETAILS

System organ class	Reproductive system and breast disorders
Event term	DYSFUNCTIONAL UTERINE BLEEDING
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PE... REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	0	249	0	0	0	0
ACT-064992 3 mg	2	250	2	0	0	0
ACT-064992 10 mg	0	242	0	0	0	0

Serious adverse event 158

SERIOUS ADVERSE EVENT DETAILS

System organ class	Reproductive system and breast disorders
Event term	OVARIAN CYST
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PE... REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	0	249	0	0	0	0
ACT-064992 3 mg	1	250	1	0	0	0
ACT-064992 10 mg	1	242	1	0	0	0

Serious adverse event 159

SERIOUS ADVERSE EVENT DETAILS

System organ class	Reproductive system and breast disorders
Event term	METRORRHAGIA
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PE... REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	0	249	0	0	0	0
ACT-064992 3 mg	1	250	1	0	0	0
ACT-064992						

10 mg	0	242	0	0	0	0

Serious adverse event 160

SERIOUS ADVERSE EVENT DETAILS

System organ class	Reproductive system and breast disorders
Event term	PELVIC FLUID COLLECTION
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PE... REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	0	249	0	0	0	0
ACT-064992 3 mg	0	250	0	0	0	0
ACT-064992 10 mg	1	242	1	0	0	0

Serious adverse event 161

SERIOUS ADVERSE EVENT DETAILS

System organ class	Reproductive system and breast disorders
Event term	POSTMENOPAUSAL HAEMORRHAGE
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PE... REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	0	249	0	0	0	0
ACT-064992 3 mg	0	250	0	0	0	0
ACT-064992 10 mg	1	242	1	0	0	0

Serious adverse event 162

SERIOUS ADVERSE EVENT DETAILS

System organ class	Reproductive system and breast disorders
Event term	VAGINAL HAEMORRHAGE
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PE... REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	0	249	0	0	0	0
ACT-064992 3 mg	0	250	0	0	0	0
ACT-064992 10 mg	1	242	2	0	0	0

Serious adverse event 163

SERIOUS ADVERSE EVENT DETAILS

System organ class	Reproductive system and breast disorders
Event term	UTERINE HAEMORRHAGE
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no

Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PER REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	1	249	1	0	0	0
ACT-064992 3 mg	0	250	0	0	0	0
ACT-064992 10 mg	0	242	0	0	0	0

Serious adverse event 164

SERIOUS ADVERSE EVENT DETAILS

System organ class	Investigations
Event term	ALANINE AMINOTRANSFERASE INCREASED
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PER REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	1	249	1	1	0	0
ACT-064992 3 mg	0	250	0	0	0	0
ACT-064992 10 mg	2	242	2	2	0	0

Serious adverse event 165

SERIOUS ADVERSE EVENT DETAILS

System organ class	Investigations
Event term	ASPARTATE AMINOTRANSFERASE INCREASED
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PER REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	1	249	1	1	0	0
ACT-064992 3 mg	0	250	0	0	0	0
ACT-064992 10 mg	2	242	2	2	0	0

Serious adverse event 166

SERIOUS ADVERSE EVENT DETAILS

System organ class	Investigations
Event term	LIVER FUNCTION TEST ABNORMAL
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PER REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	1	249	1	0	0	0
ACT-064992 3 mg	0	250	0	0	0	0
ACT-064992 10 mg	2	242	2	2	0	0

Serious adverse event 167

SERIOUS ADVERSE EVENT DETAILS

System organ class	Investigations
Event term	HEPATIC ENZYME INCREASED
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PE… REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I… TREATMENT, NU…
Placebo	0	249	0	0	0	0
ACT-064992 3 mg	1	250	2	1	0	0
ACT-064992 10 mg	1	242	1	0	0	0

Serious adverse event 168

SERIOUS ADVERSE EVENT DETAILS

System organ class	Investigations
Event term	HAEMOGLOBIN DECREASED
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PE… REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I… TREATMENT, NU…
Placebo	0	249	0	0	0	0
ACT-064992 3 mg	1	250	1	0	0	0
ACT-064992 10 mg	0	242	0	0	0	0

Serious adverse event 169

SERIOUS ADVERSE EVENT DETAILS

System organ class	Investigations
Event term	HEPATITIS B VIRUS TEST POSITIVE
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PE… REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I… TREATMENT, NU…
Placebo	0	249	0	0	0	0
ACT-064992 3 mg	0	250	0	0	0	0
ACT-064992 10 mg	1	242	1	0	0	0

Serious adverse event 170

SERIOUS ADVERSE EVENT DETAILS

System organ class	Investigations
Event term	HIV TEST POSITIVE
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PE… REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I… TREATMENT, NU…

Placebo	0	249	0	0	0	0
ACT-064992 3 mg	0	250	0	0	0	0
ACT-064992 10 mg	1	242	1	0	0	0

Serious adverse event 171

SERIOUS ADVERSE EVENT DETAILS

System organ class	Investigations
Event term	INTERNATIONAL NORMALISED RATIO DECREASED
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PER REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	0	249	0	0	0	0
ACT-064992 3 mg	1	250	1	0	0	0
ACT-064992 10 mg	0	242	0	0	0	0

Serious adverse event 172

SERIOUS ADVERSE EVENT DETAILS

System organ class	Investigations
Event term	TRANSAMINASES INCREASED
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PER REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	0	249	0	0	0	0
ACT-064992 3 mg	1	250	1	1	0	0
ACT-064992 10 mg	0	242	0	0	0	0

Serious adverse event 173

SERIOUS ADVERSE EVENT DETAILS

System organ class	Investigations
Event term	GAMMA-GLUTAMYLTRANSFERASE INCREASED
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PER REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	1	249	1	1	0	0
ACT-064992 3 mg	0	250	0	0	0	0
ACT-064992 10 mg	0	242	0	0	0	0

Serious adverse event 174

SERIOUS ADVERSE EVENT DETAILS

System organ class	Injury, poisoning and procedural complications
Event term	SUBDURAL HAEMATOMA
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA

Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PER REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	2	249	2	0	0	0
ACT-064992 3 mg	1	250	1	0	0	0
ACT-064992 10 mg	1	242	1	0	0	0

Serious adverse event 175

SERIOUS ADVERSE EVENT DETAILS

System organ class	Injury, poisoning and procedural complications
Event term	ANKLE FRACTURE
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PER REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	0	249	0	0	0	0
ACT-064992 3 mg	0	250	0	0	0	0
ACT-064992 10 mg	1	242	1	0	0	0

Serious adverse event 176

SERIOUS ADVERSE EVENT DETAILS

System organ class	Injury, poisoning and procedural complications
Event term	FEMUR FRACTURE
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PER REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	0	249	0	0	0	0
ACT-064992 3 mg	1	250	1	0	0	0
ACT-064992 10 mg	0	242	0	0	0	0

Serious adverse event 177

SERIOUS ADVERSE EVENT DETAILS

System organ class	Injury, poisoning and procedural complications
Event term	LUMBAR VERTEBRAL FRACTURE
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PER REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	0	249	0	0	0	0
ACT-064992 3 mg	1	250	1	0	0	0
ACT-064992 10 mg	0	242	0	0	0	0

Serious adverse event 178

SERIOUS ADVERSE EVENT DETAILS

System organ class	Injury, poisoning and procedural complications
Event term	ROAD TRAFFIC ACCIDENT
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PE… REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I… TREATMENT, NU…
Placebo	0	249	0	0	0	0
ACT-064992 3 mg	1	250	1	0	0	0
ACT-064992 10 mg	0	242	0	0	0	0

Serious adverse event 179

SERIOUS ADVERSE EVENT DETAILS

System organ class	Injury, poisoning and procedural complications
Event term	THORACIC VERTEBRAL FRACTURE
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PE… REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I… TREATMENT, NU…
Placebo	0	249	0	0	0	0
ACT-064992 3 mg	0	250	0	0	0	0
ACT-064992 10 mg	1	242	1	0	0	0

Serious adverse event 180

SERIOUS ADVERSE EVENT DETAILS

System organ class	Injury, poisoning and procedural complications
Event term	UPPER LIMB FRACTURE
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PE… REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I… TREATMENT, NU…
Placebo	0	249	0	0	0	0
ACT-064992 3 mg	1	250	1	0	0	0
ACT-064992 10 mg	0	242	0	0	0	0

Serious adverse event 181

SERIOUS ADVERSE EVENT DETAILS

System organ class	Injury, poisoning and procedural complications
Event term	BRAIN CONTUSION
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PE…

REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	1	249	1	0	0	0
ACT-064992 3 mg	0	250	0	0	0	0
ACT-064992 10 mg	0	242	0	0	0	0

Serious adverse event 182

SERIOUS ADVERSE EVENT DETAILS

System organ class	Injury, poisoning and procedural complications
Event term	BRAIN HERNIATION
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PE REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	1	249	1	0	0	0
ACT-064992 3 mg	0	250	0	0	0	0
ACT-064992 10 mg	0	242	0	0	0	0

Serious adverse event 183

SERIOUS ADVERSE EVENT DETAILS

System organ class	Injury, poisoning and procedural complications
Event term	PATELLA FRACTURE
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PE REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	1	249	1	0	0	0
ACT-064992 3 mg	0	250	0	0	0	0
ACT-064992 10 mg	0	242	0	0	0	0

Serious adverse event 184

SERIOUS ADVERSE EVENT DETAILS

System organ class	Blood and lymphatic system disorders
Event term	POST PROCEDURAL HAEMORRHAGE
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PE REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	1	249	1	0	0	0
ACT-064992 3 mg	0	250	0	0	0	0
ACT-064992 10 mg	0	242	0	0	0	0

Serious adverse event 185

SERIOUS ADVERSE EVENT DETAILS

System organ class	Injury, poisoning and procedural complications
Event term	SKULL FRACTURE
Additional description	

Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PER REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	1	249	1	0	0	0
ACT-064992 3 mg	0	250	0	0	0	0
ACT-064992 10 mg	0	242	0	0	0	0

Serious adverse event 186

SERIOUS ADVERSE EVENT DETAILS

System organ class	Blood and lymphatic system disorders
Event term	TRAUMATIC BRAIN INJURY
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PER REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	1	249	1	0	0	0
ACT-064992 3 mg	0	250	0	0	0	0
ACT-064992 10 mg	0	242	0	0	0	0

Serious adverse event 187

SERIOUS ADVERSE EVENT DETAILS

System organ class	Musculoskeletal and connective tissue disorders
Event term	SYSTEMIC LUPUS ERYTHEMATOSUS
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PER REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	1	249	1	0	0	0
ACT-064992 3 mg	1	250	1	0	0	0
ACT-064992 10 mg	1	242	1	0	0	0

Serious adverse event 188

SERIOUS ADVERSE EVENT DETAILS

System organ class	Musculoskeletal and connective tissue disorders
Event term	SYSTEMIC SCLEROSIS
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PER REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	0	249	0	0	0	0
ACT-064992 3 mg	0	250	0	0	0	0

ACT-064992 10 mg	2	242	2	0	0	0

Serious adverse event 189

SERIOUS ADVERSE EVENT DETAILS

System organ class	Musculoskeletal and connective tissue disorders
Event term	BACK PAIN
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PER REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	2	249	2	0	0	0
ACT-064992 3 mg	1	250	1	0	0	0
ACT-064992 10 mg	0	242	0	0	0	0

Serious adverse event 190

SERIOUS ADVERSE EVENT DETAILS

System organ class	Musculoskeletal and connective tissue disorders
Event term	OSTEOARTHRITIS
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PER REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	1	249	1	0	0	0
ACT-064992 3 mg	0	250	0	0	0	0
ACT-064992 10 mg	1	242	1	0	0	0

Serious adverse event 191

SERIOUS ADVERSE EVENT DETAILS

System organ class	Musculoskeletal and connective tissue disorders
Event term	COSTOCHONDRITIS
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PER REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	0	249	0	0	0	0
ACT-064992 3 mg	0	250	0	0	0	0
ACT-064992 10 mg	1	242	1	0	0	0

Serious adverse event 192

SERIOUS ADVERSE EVENT DETAILS

System organ class	Musculoskeletal and connective tissue disorders
Event term	MUSCULOSKELETAL PAIN
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no

Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PER REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	0	249	0	0	0	0
ACT-064992 3 mg	0	250	0	0	0	0
ACT-064992 10 mg	1	242	1	0	0	0

Serious adverse event 193

SERIOUS ADVERSE EVENT DETAILS

System organ class	Musculoskeletal and connective tissue disorders
Event term	ARTHRALGIA
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PER REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	1	249	1	0	0	0
ACT-064992 3 mg	0	250	0	0	0	0
ACT-064992 10 mg	0	242	0	0	0	0

Serious adverse event 194

SERIOUS ADVERSE EVENT DETAILS

System organ class	Musculoskeletal and connective tissue disorders
Event term	OSTEOPOROTIC FRACTURE
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PER REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	1	249	1	0	0	0
ACT-064992 3 mg	0	250	0	0	0	0
ACT-064992 10 mg	0	242	0	0	0	0

Serious adverse event 195

SERIOUS ADVERSE EVENT DETAILS

System organ class	Musculoskeletal and connective tissue disorders
Event term	PAIN IN EXTREMITY
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PER REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	1	249	1	0	0	0
ACT-064992 3 mg	0	250	0	0	0	0
ACT-064992 10 mg	0	242	0	0	0	0

Serious adverse event 196

SERIOUS ADVERSE EVENT DETAILS

System organ class	Renal and urinary disorders
Event term	RENAL FAILURE ACUTE
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PER REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	0	249	0	0	0	0
ACT-064992 3 mg	4	250	5	0	0	0
ACT-064992 10 mg	1	242	1	1	0	0

Serious adverse event 197

SERIOUS ADVERSE EVENT DETAILS

System organ class	Renal and urinary disorders
Event term	GLOMERULONEPHRITIS
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PER REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	0	249	0	0	0	0
ACT-064992 3 mg	0	250	0	0	0	0
ACT-064992 10 mg	1	242	1	0	0	0

Serious adverse event 198

SERIOUS ADVERSE EVENT DETAILS

System organ class	Renal and urinary disorders
Event term	LUPUS NEPHRITIS
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PER REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	0	249	0	0	0	0
ACT-064992 3 mg	0	250	0	0	0	0
ACT-064992 10 mg	1	242	1	0	0	0

Serious adverse event 199

SERIOUS ADVERSE EVENT DETAILS

System organ class	Renal and urinary disorders
Event term	NEPHROLITHIASIS
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PER REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	0	249	0	0	0	0
ACT-064992 3 mg	1	250	2	0	0	0
ACT-064992 10 mg	0	242	0	0	0	0

Serious adverse event 200

SERIOUS ADVERSE EVENT DETAILS

System organ class	Renal and urinary disorders
Event term	RENAL IMPAIRMENT
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PE REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	0	249	0	0	0	0
ACT-064992 3 mg	1	250	1	0	0	0
ACT-064992 10 mg	0	242	0	0	0	0

Serious adverse event 201

SERIOUS ADVERSE EVENT DETAILS

System organ class	Renal and urinary disorders
Event term	TUBULOINTERSTITIAL NEPHRITIS
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PE REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	0	249	0	0	0	0
ACT-064992 3 mg	1	250	1	0	0	0
ACT-064992 10 mg	0	242	0	0	0	0

Serious adverse event 202

SERIOUS ADVERSE EVENT DETAILS

System organ class	Renal and urinary disorders
Event term	CALCULUS URINARY
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PE REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	1	249	1	0	0	0
ACT-064992 3 mg	0	250	0	0	0	0
ACT-064992 10 mg	0	242	0	0	0	0

Serious adverse event 203

SERIOUS ADVERSE EVENT DETAILS

System organ class	Renal and urinary disorders
Event term	PROTEINURIA
Additional description	
Assessment type	systematic

Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PER REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	1	249	1	0	0	0
ACT-064992 3 mg	0	250	0	0	0	0
ACT-064992 10 mg	0	242	0	0	0	0

Serious adverse event 204

SERIOUS ADVERSE EVENT DETAILS

System organ class	Renal and urinary disorders
Event term	RENAL COLIC
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PER REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	1	249	1	0	0	0
ACT-064992 3 mg	0	250	0	0	0	0
ACT-064992 10 mg	0	242	0	0	0	0

Serious adverse event 205

SERIOUS ADVERSE EVENT DETAILS

System organ class	Renal and urinary disorders
Event term	RENAL FAILURE
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PER REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	1	249	1	0	0	0
ACT-064992 3 mg	0	250	0	0	0	0
ACT-064992 10 mg	0	242	0	0	0	0

Serious adverse event 206

SERIOUS ADVERSE EVENT DETAILS

System organ class	Hepatobiliary disorders
Event term	CHOLECYSTITIS
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PER REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	0	249	0	0	0	0
ACT-064992 3 mg	1	250	1	0	0	0
ACT-064992 10 mg	1	242	1	0	0	0

Serious adverse event 207

SERIOUS ADVERSE EVENT DETAILS

System organ class	Hepatobiliary disorders
Event term	CHOLELITHIASIS
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PER REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	0	249	0	0	0	0
ACT-064992 3 mg	1	250	1	0	0	0
ACT-064992 10 mg	1	242	1	0	0	0

Serious adverse event 208

SERIOUS ADVERSE EVENT DETAILS

System organ class	Hepatobiliary disorders
Event term	HEPATITIS
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PER REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	1	249	1	0	0	0
ACT-064992 3 mg	0	250	0	0	0	0
ACT-064992 10 mg	1	242	1	1	0	0

Serious adverse event 209

SERIOUS ADVERSE EVENT DETAILS

System organ class	Hepatobiliary disorders
Event term	JAUNDICE
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PER REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	1	249	1	0	0	0
ACT-064992 3 mg	1	250	1	1	0	0
ACT-064992 10 mg	0	242	0	0	0	0

Serious adverse event 210

SERIOUS ADVERSE EVENT DETAILS

System organ class	Hepatobiliary disorders
Event term	BILIARY COLIC
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA

Version 14.0

VALUES FOR SERIOUS ADVERSE EVENT PER REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	0	249	0	0	0	0
ACT-064992 3 mg	1	250	1	0	0	0
ACT-064992 10 mg	0	242	0	0	0	0

Serious adverse event 211

SERIOUS ADVERSE EVENT DETAILS

System organ class	Hepatobiliary disorders
Event term	CHOLANGITIS
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PER REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	0	249	0	0	0	0
ACT-064992 3 mg	1	250	1	1	0	0
ACT-064992 10 mg	0	242	0	0	0	0

Serious adverse event 212

SERIOUS ADVERSE EVENT DETAILS

System organ class	Hepatobiliary disorders
Event term	ISCHAEMIC HEPATITIS
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PER REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	0	249	0	0	0	0
ACT-064992 3 mg	1	250	1	0	0	0
ACT-064992 10 mg	0	242	0	0	0	0

Serious adverse event 213

SERIOUS ADVERSE EVENT DETAILS

System organ class	Hepatobiliary disorders
Event term	LIVER INJURY
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PER REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	0	249	0	0	0	0
ACT-064992 3 mg	1	250	1	1	0	0
ACT-064992 10 mg	0	242	0	0	0	0

Serious adverse event 214

SERIOUS ADVERSE EVENT DETAILS

System organ class	Hepatobiliary disorders
Event term	HEPATIC CIRRHOSIS

Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PE… REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I… TREATMENT, NU…
Placebo	1	249	1	1	0	0
ACT-064992 3 mg	0	250	0	0	0	0
ACT-064992 10 mg	0	242	0	0	0	0

Serious adverse event 215

SERIOUS ADVERSE EVENT DETAILS

System organ class	Hepatobiliary disorders
Event term	POST CHOLECYSTECTOMY SYNDROME
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PE… REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I… TREATMENT, NU…
Placebo	1	249	0	0	0	0
ACT-064992 3 mg	0	250	0	0	0	0
ACT-064992 10 mg	0	242	0	0	0	0

Serious adverse event 216

SERIOUS ADVERSE EVENT DETAILS

System organ class	Pregnancy, puerperium and perinatal conditions
Event term	PREGNANCY
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PE… REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I… TREATMENT, NU…
Placebo	2	249	2	0	0	0
ACT-064992 3 mg	5	250	5	1	0	0
ACT-064992 10 mg	0	242	0	0	0	0

Serious adverse event 217

SERIOUS ADVERSE EVENT DETAILS

System organ class	Pregnancy, puerperium and perinatal conditions
Event term	COMPLICATION OF PREGNANCY
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PE… REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I… TREATMENT, NU…
Placebo	1	249	1	0	0	0
ACT-064992 3						

mg	0	250	0	0	0	0
ACT-064992 10 mg	0	242	0	0	0	0

Serious adverse event 218

SERIOUS ADVERSE EVENT DETAILS

System organ class	Vascular disorders
Event term	HYPOTENSION
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PER REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	3	249	3	0	0	0
ACT-064992 3 mg	1	250	1	0	0	0
ACT-064992 10 mg	1	242	2	2	0	0

Serious adverse event 219

SERIOUS ADVERSE EVENT DETAILS

System organ class	Vascular disorders
Event term	HYPOVOLAEMIC SHOCK
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PER REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	1	249	1	0	0	0
ACT-064992 3 mg	1	250	1	0	0	0
ACT-064992 10 mg	0	242	0	0	0	0

Serious adverse event 220

SERIOUS ADVERSE EVENT DETAILS

System organ class	Vascular disorders
Event term	ARTERIOVENOUS FISTULA
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PER REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	0	249	0	0	0	0
ACT-064992 3 mg	1	250	1	0	0	0
ACT-064992 10 mg	0	242	0	0	0	0

Serious adverse event 221

SERIOUS ADVERSE EVENT DETAILS

System organ class	Vascular disorders
Event term	ORTHOSTATIC HYPOTENSION
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name	

and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PER REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	0	249	0	0	0	0
ACT-064992 3 mg	0	250	0	0	0	0
ACT-064992 10 mg	1	242	1	0	0	0

Serious adverse event 222

SERIOUS ADVERSE EVENT DETAILS

System organ class	Vascular disorders
Event term	ARTERIAL THROMBOSIS
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PER REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	1	249	1	0	0	0
ACT-064992 3 mg	0	250	0	0	0	0
ACT-064992 10 mg	0	242	0	0	0	0

Serious adverse event 223

SERIOUS ADVERSE EVENT DETAILS

System organ class	Vascular disorders
Event term	CIRCULATORY COLLAPSE
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PER REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	1	249	1	0	0	0
ACT-064992 3 mg	0	250	0	0	0	0
ACT-064992 10 mg	0	242	0	0	0	0

Serious adverse event 224

SERIOUS ADVERSE EVENT DETAILS

System organ class	Vascular disorders
Event term	HYPERTENSIVE CRISIS
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PER REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	1	249	1	0	0	0
ACT-064992 3 mg	0	250	0	0	0	0
ACT-064992 10 mg	0	242	0	0	0	0

Serious adverse event 225

SERIOUS ADVERSE EVENT DETAILS

System organ class	Vascular disorders
Event term	VASCULITIS NECROTISING
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PER REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	1	249	1	0	0	0
ACT-064992 3 mg	0	250	0	0	0	0
ACT-064992 10 mg	0	242	0	0	0	0

Serious adverse event 226

SERIOUS ADVERSE EVENT DETAILS

System organ class	Metabolism and nutrition disorders
Event term	DEHYDRATION
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PER REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	1	249	1	0	0	0
ACT-064992 3 mg	1	250	1	0	0	0
ACT-064992 10 mg	0	242	0	0	0	0

Serious adverse event 227

SERIOUS ADVERSE EVENT DETAILS

System organ class	Metabolism and nutrition disorders
Event term	HYPONATRAEMIA
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PER REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	1	249	2	0	0	0
ACT-064992 3 mg	1	250	1	0	0	0
ACT-064992 10 mg	0	242	0	0	0	0

Serious adverse event 228

SERIOUS ADVERSE EVENT DETAILS

System organ class	Metabolism and nutrition disorders
Event term	ELECTROLYTE IMBALANCE
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PER REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	0	249	0	0	0	0
ACT-064992 3 mg	0	250	0	0	0	0
ACT-064992 10 mg	1	242	1	0	0	0

Serious adverse event 229

SERIOUS ADVERSE EVENT DETAILS

System organ class	Metabolism and nutrition disorders
Event term	FLUID OVERLOAD
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PER REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	0	249	0	0	0	0
ACT-064992 3 mg	1	250	1	0	0	0
ACT-064992 10 mg	0	242	0	0	0	0

Serious adverse event 230

SERIOUS ADVERSE EVENT DETAILS

System organ class	Metabolism and nutrition disorders
Event term	HYPERGLYCAEMIA
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PER REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	0	249	0	0	0	0
ACT-064992 3 mg	1	250	1	0	0	0
ACT-064992 10 mg	0	242	0	0	0	0

Serious adverse event 231

SERIOUS ADVERSE EVENT DETAILS

System organ class	Metabolism and nutrition disorders
Event term	HYPOGLYCAEMIA
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PER REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	0	249	0	0	0	0
ACT-064992 3 mg	1	250	1	0	0	0
ACT-064992 10 mg	0	242	0	0	0	0

Serious adverse event 232

SERIOUS ADVERSE EVENT DETAILS

System organ class	Metabolism and nutrition disorders
Event term	DIABETES MELLITUS
Additional description	
Assessment type	systematic

Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PER REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	1	249	1	0	0	0
ACT-064992 3 mg	0	250	0	0	0	0
ACT-064992 10 mg	0	242	0	0	0	0

Serious adverse event 233

SERIOUS ADVERSE EVENT DETAILS

System organ class	Metabolism and nutrition disorders
Event term	DIABETIC KETOACIDOSIS
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PER REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	1	249	1	0	0	0
ACT-064992 3 mg	0	250	0	0	0	0
ACT-064992 10 mg	0	242	0	0	0	0

Serious adverse event 234

SERIOUS ADVERSE EVENT DETAILS

System organ class	Metabolism and nutrition disorders
Event term	GOUT
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PER REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	1	249	1	0	0	0
ACT-064992 3 mg	0	250	0	0	0	0
ACT-064992 10 mg	0	242	0	0	0	0

Serious adverse event 235

SERIOUS ADVERSE EVENT DETAILS

System organ class	Metabolism and nutrition disorders
Event term	HYPERURICAEMIA
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PER REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	1	249	1	0	0	0
ACT-064992 3 mg	0	250	0	0	0	0
ACT-064992 10 mg	0	242	0	0	0	0

Serious adverse event 236

SERIOUS ADVERSE EVENT DETAILS

System organ class	Metabolism and nutrition disorders
Event term	TYPE 2 DIABETES MELLITUS
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PER REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	1	249	1	0	0	0
ACT-064992 3 mg	0	250	0	0	0	0
ACT-064992 10 mg	0	242	0	0	0	0

Serious adverse event 237

SERIOUS ADVERSE EVENT DETAILS

System organ class	Psychiatric disorders
Event term	CONFUSIONAL STATE
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PER REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	1	249	1	0	0	0
ACT-064992 3 mg	1	250	1	0	0	0
ACT-064992 10 mg	0	242	0	0	0	0

Serious adverse event 238

SERIOUS ADVERSE EVENT DETAILS

System organ class	Psychiatric disorders
Event term	ALCOHOLISM
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PER REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	0	249	0	0	0	0
ACT-064992 3 mg	1	250	1	0	0	0
ACT-064992 10 mg	0	242	0	0	0	0

Serious adverse event 239

SERIOUS ADVERSE EVENT DETAILS

System organ class	Psychiatric disorders
Event term	MENTAL DISORDER
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA

Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PER REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	0	249	0	0	0	0
ACT-064992 3 mg	0	250	0	0	0	0
ACT-064992 10 mg	1	242	1	0	0	0

Serious adverse event 240

SERIOUS ADVERSE EVENT DETAILS

System organ class	Psychiatric disorders
Event term	MENTAL STATUS CHANGES
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PER REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	0	249	0	0	0	0
ACT-064992 3 mg	1	250	1	0	0	0
ACT-064992 10 mg	0	242	0	0	0	0

Serious adverse event 241

SERIOUS ADVERSE EVENT DETAILS

System organ class	Blood and lymphatic system disorders
Event term	DRUG ABUSE
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PER REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	1	249	1	0	0	0
ACT-064992 3 mg	0	250	0	0	0	0
ACT-064992 10 mg	0	242	0	0	0	0

Serious adverse event 242

SERIOUS ADVERSE EVENT DETAILS

System organ class	Skin and subcutaneous tissue disorders
Event term	SKIN ULCER
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PER REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	0	249	0	0	0	0
ACT-064992 3 mg	2	250	2	0	0	0
ACT-064992 10 mg	1	242	1	0	0	0

Serious adverse event 243

SERIOUS ADVERSE EVENT DETAILS

System organ class	Skin and subcutaneous tissue disorders
Event term	ECZEMA

Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PE… REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	0	249	0	0	0	0
ACT-064992 3 mg	1	250	1	0	0	0
ACT-064992 10 mg	0	242	0	0	0	0

Serious adverse event 244

SERIOUS ADVERSE EVENT DETAILS

System organ class	Skin and subcutaneous tissue disorders
Event term	LEUKOCYTOCLASTIC VASCULITIS
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PE… REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	1	249	1	0	0	0
ACT-064992 3 mg	0	250	0	0	0	0
ACT-064992 10 mg	0	242	0	0	0	0

Serious adverse event 245

SERIOUS ADVERSE EVENT DETAILS

System organ class	Skin and subcutaneous tissue disorders
Event term	PURPURA
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PE… REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	1	249	1	0	0	0
ACT-064992 3 mg	0	250	0	0	0	0
ACT-064992 10 mg	0	242	0	0	0	0

Serious adverse event 246

SERIOUS ADVERSE EVENT DETAILS

System organ class	Surgical and medical procedures
Event term	HIP ARTHROPLASTY
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PE… REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	1	249	1	0	0	0
ACT-064992 3						

mg	0	250	0	0	0	0
ACT-064992 10 mg	1	242	1	0	0	0

Serious adverse event 247

SERIOUS ADVERSE EVENT DETAILS

System organ class	Surgical and medical procedures
Event term	CARDIAC PACEMAKER INSERTION
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PER REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	0	249	0	0	0	0
ACT-064992 3 mg	1	250	1	0	0	0
ACT-064992 10 mg	0	242	0	0	0	0

Serious adverse event 248

SERIOUS ADVERSE EVENT DETAILS

System organ class	Surgical and medical procedures
Event term	HEART AND LUNG TRANSPLANT
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PER REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	0	249	0	0	0	0
ACT-064992 3 mg	1	250	1	0	0	0
ACT-064992 10 mg	0	242	0	0	0	0

Serious adverse event 249

SERIOUS ADVERSE EVENT DETAILS

System organ class	Surgical and medical procedures
Event term	TOOTH EXTRACTION
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PER REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	1	249	1	0	0	0
ACT-064992 3 mg	0	250	0	0	0	0
ACT-064992 10 mg	0	242	0	0	0	0

Serious adverse event 250

SERIOUS ADVERSE EVENT DETAILS

System organ class	Congenital, familial and genetic disorders
Event term	GLYCOGEN STORAGE DISEASE TYPE V
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name	

and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PER REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	0	249	0	0	0	0
ACT-064992 3 mg	1	250	1	0	0	0
ACT-064992 10 mg	0	242	0	0	0	0

Serious adverse event 251

SERIOUS ADVERSE EVENT DETAILS

System organ class	Endocrine disorders
Event term	ADRENAL INSUFFICIENCY
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PER REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	0	249	0	0	0	0
ACT-064992 3 mg	0	250	0	0	0	0
ACT-064992 10 mg	1	242	1	0	0	0

Serious adverse event 252

SERIOUS ADVERSE EVENT DETAILS

System organ class	Eye disorders
Event term	GLAUCOMA
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR SERIOUS ADVERSE EVENT PER REPORTING GROUP

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NUMBER	OCCURENCES CAUSALLY RELATED TO TREATMENT, NUMBER	FATALITIES, NUMBER	FATALITIES CAUSALLY I TREATMENT, NU
Placebo	0	249	0	0	0	0
ACT-064992 3 mg	0	250	0	0	0	0
ACT-064992 10 mg	1	242	2	0	0	0

Non-serious adverse events

Non-serious adverse event 1

NON-SERIOUS ADVERSE EVENT DETAILS

System organ class	Infections and infestations
Event term	UPPER RESPIRATORY TRACT INFECTION
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR NON-SERIOUS ADVERSE EVENT PER REPORTING GROUP

Threshold for non-serious adverse event reporting is	5%

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NU
PLACEBO	32	249	67
ACT-064992 3 MG	48	250	83
ACT-064992 10 MG			

	37	242	66

Non-serious adverse event 2

NON-SERIOUS ADVERSE EVENT DETAILS

System organ class	General disorders and administration site conditions
Event term	OEDEMA PERIPHERAL
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR NON-SERIOUS ADVERSE EVENT PER REPORTING GROUP

Threshold for non-serious adverse event reporting is 5%

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NU
PLACEBO	45	249	52
ACT-064992 3 MG	40	250	53
ACT-064992 10 MG	44	242	56

Non-serious adverse event 3

NON-SERIOUS ADVERSE EVENT DETAILS

System organ class	Infections and infestations
Event term	NASOPHARYNGITIS
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR NON-SERIOUS ADVERSE EVENT PER REPORTING GROUP

Threshold for non-serious adverse event reporting is 5%

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NU
PLACEBO	26	249	35
ACT-064992 3 MG	37	250	52
ACT-064992 10 MG	34	242	51

Non-serious adverse event 4

NON-SERIOUS ADVERSE EVENT DETAILS

System organ class	Nervous system disorders
Event term	HEADACHE
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR NON-SERIOUS ADVERSE EVENT PER REPORTING GROUP

Threshold for non-serious adverse event reporting is 5%

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NU
PLACEBO	22	249	25
ACT-064992 3 MG	33	250	42
ACT-064992 10 MG	33	242	40

Non-serious adverse event 5

NON-SERIOUS ADVERSE EVENT DETAILS

System organ class	Respiratory, thoracic and mediastinal disorders
Event term	PULMONARY ARTERIAL HYPERTENSION
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA

Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0
VALUES FOR NON-SERIOUS ADVERSE EVENT PER REPORTING GROUP	
Threshold for non-serious adverse event reporting is	5%

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NU
PLACEBO	33	249	35
ACT-064992 3 MG	29	250	31
ACT-064992 10 MG	27	242	27

Non-serious adverse event 6

NON-SERIOUS ADVERSE EVENT DETAILS	
System organ class	Nervous system disorders
Event term	DIZZINESS
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0
VALUES FOR NON-SERIOUS ADVERSE EVENT PER REPORTING GROUP	
Threshold for non-serious adverse event reporting is	5%

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NU
PLACEBO	27	249	29
ACT-064992 3 MG	24	250	26
ACT-064992 10 MG	26	242	31

Non-serious adverse event 7

NON-SERIOUS ADVERSE EVENT DETAILS	
System organ class	Blood and lymphatic system disorders
Event term	ANAEMIA
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0
VALUES FOR NON-SERIOUS ADVERSE EVENT PER REPORTING GROUP	
Threshold for non-serious adverse event reporting is	5%

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NU
PLACEBO	7	249	9
ACT-064992 3 MG	18	250	19
ACT-064992 10 MG	30	242	36

Non-serious adverse event 8

NON-SERIOUS ADVERSE EVENT DETAILS	
System organ class	Infections and infestations
Event term	BRONCHITIS
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0
VALUES FOR NON-SERIOUS ADVERSE EVENT PER REPORTING GROUP	
Threshold for non-serious adverse event reporting is	5%

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NU
PLACEBO	13	249	16
	19	250	22

ACT-064992 10 MG	27	242	34

Non-serious adverse event 9

NON-SERIOUS ADVERSE EVENT DETAILS

System organ class	Respiratory, thoracic and mediastinal disorders
Event term	COUGH
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR NON-SERIOUS ADVERSE EVENT PER REPORTING GROUP

Threshold for non-serious adverse event reporting is 5%

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NU
PLACEBO	30	249	35
ACT-064992 3 MG	20	250	31
ACT-064992 10 MG	21	242	25

Non-serious adverse event 10

NON-SERIOUS ADVERSE EVENT DETAILS

System organ class	Respiratory, thoracic and mediastinal disorders
Event term	DYSPNOEA
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR NON-SERIOUS ADVERSE EVENT PER REPORTING GROUP

Threshold for non-serious adverse event reporting is 5%

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NU
PLACEBO	21	249	23
ACT-064992 3 MG	24	250	29
ACT-064992 10 MG	16	242	19

Non-serious adverse event 11

NON-SERIOUS ADVERSE EVENT DETAILS

System organ class	General disorders and administration site conditions
Event term	CHEST PAIN
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR NON-SERIOUS ADVERSE EVENT PER REPORTING GROUP

Threshold for non-serious adverse event reporting is 5%

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NU
PLACEBO	19	249	22
ACT-064992 3 MG	18	250	22
ACT-064992 10 MG	17	242	19

Non-serious adverse event 12

NON-SERIOUS ADVERSE EVENT DETAILS

System organ class	Blood and lymphatic system disorders
Event term	DIARRHOEA
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse	MedDRA

events in these results is

Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR NON-SERIOUS ADVERSE EVENT PER REPORTING GROUP

Threshold for non-serious adverse event reporting is 5%

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NU
PLACEBO	16	249	19
ACT-064992 3 MG	14	250	23
ACT-064992 10 MG	21	242	27

Non-serious adverse event 13

NON-SERIOUS ADVERSE EVENT DETAILS

System organ class	Infections and infestations
Event term	URINARY TRACT INFECTION
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR NON-SERIOUS ADVERSE EVENT PER REPORTING GROUP

Threshold for non-serious adverse event reporting is 5%

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NU
PLACEBO	11	249	11
ACT-064992 3 MG	16	250	19
ACT-064992 10 MG	19	242	22

Non-serious adverse event 14

NON-SERIOUS ADVERSE EVENT DETAILS

System organ class	Psychiatric disorders
Event term	INSOMNIA
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR NON-SERIOUS ADVERSE EVENT PER REPORTING GROUP

Threshold for non-serious adverse event reporting is 5%

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NU
PLACEBO	10	249	11
ACT-064992 3 MG	17	250	24
ACT-064992 10 MG	17	242	18

Non-serious adverse event 15

NON-SERIOUS ADVERSE EVENT DETAILS

System organ class	Blood and lymphatic system disorders
Event term	HYPOKALAEMIA
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR NON-SERIOUS ADVERSE EVENT PER REPORTING GROUP

Threshold for non-serious adverse event reporting is 5%

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NU

[illegible]	14	249	14
ACT-064992 3 MG	13	250	16
ACT-064992 10 MG	14	242	17

Non-serious adverse event 16

NON-SERIOUS ADVERSE EVENT DETAILS

System organ class	Vascular disorders
Event term	HYPOTENSION
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR NON-SERIOUS ADVERSE EVENT PER REPORTING GROUP

Threshold for non-serious adverse event reporting is 5%

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NU
PLACEBO	8	249	9
ACT-064992 3 MG	13	250	14
ACT-064992 10 MG	14	242	15

Non-serious adverse event 17

NON-SERIOUS ADVERSE EVENT DETAILS

System organ class	Cardiac disorders
Event term	RIGHT VENTRICULAR FAILURE
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR NON-SERIOUS ADVERSE EVENT PER REPORTING GROUP

Threshold for non-serious adverse event reporting is 5%

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NU
PLACEBO	18	249	20
ACT-064992 3 MG	16	250	18
ACT-064992 10 MG	10	242	12

Non-serious adverse event 18

NON-SERIOUS ADVERSE EVENT DETAILS

System organ class	Blood and lymphatic system disorders
Event term	ARTHRALGIA
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR NON-SERIOUS ADVERSE EVENT PER REPORTING GROUP

Threshold for non-serious adverse event reporting is 5%

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NU
PLACEBO	9	249	9
ACT-064992 3 MG	15	250	23
ACT-064992 10 MG	11	242	12

Non-serious adverse event 19

NON-SERIOUS ADVERSE EVENT DETAILS

System organ class	Infections and infestations
Event term	PHARYNGITIS
Additional description	
Assessment type	systematic

Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0
VALUES FOR NON-SERIOUS ADVERSE EVENT PER REPORTING GROUP	
Threshold for non-serious adverse event reporting is	5%

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NU
PLACEBO	7	249	8
ACT-064992 3 MG	11	250	14
ACT-064992 10 MG	15	242	18

Non-serious adverse event 20

NON-SERIOUS ADVERSE EVENT DETAILS	
System organ class	Cardiac disorders
Event term	PALPITATIONS
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0
VALUES FOR NON-SERIOUS ADVERSE EVENT PER REPORTING GROUP	
Threshold for non-serious adverse event reporting is	5%

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NU
PLACEBO	13	249	16
ACT-064992 3 MG	13	250	13
ACT-064992 10 MG	12	242	13

Non-serious adverse event 21

NON-SERIOUS ADVERSE EVENT DETAILS	
System organ class	Infections and infestations
Event term	INFLUENZA
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0
VALUES FOR NON-SERIOUS ADVERSE EVENT PER REPORTING GROUP	
Threshold for non-serious adverse event reporting is	5%

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NU
PLACEBO	4	249	5
ACT-064992 3 MG	11	250	13
ACT-064992 10 MG	14	242	16

Non-serious adverse event 22

NON-SERIOUS ADVERSE EVENT DETAILS	
System organ class	Musculoskeletal and connective tissue disorders
Event term	BACK PAIN
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0
VALUES FOR NON-SERIOUS ADVERSE EVENT PER REPORTING GROUP	
Threshold for non-serious adverse event reporting is	5%

PLACEBO	21	249	25
ACT-064992 3 MG	15	250	16
ACT-064992 10 MG	9	242	10

Non-serious adverse event 23

NON-SERIOUS ADVERSE EVENT DETAILS

System organ class	Gastrointestinal disorders
Event term	NAUSEA
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR NON-SERIOUS ADVERSE EVENT PER REPORTING GROUP

Threshold for non-serious adverse event reporting is 5%

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NU
PLACEBO	13	249	14
ACT-064992 3 MG	12	250	17
ACT-064992 10 MG	12	242	14

Non-serious adverse event 24

NON-SERIOUS ADVERSE EVENT DETAILS

System organ class	Infections and infestations
Event term	RESPIRATORY TRACT INFECTION VIRAL
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR NON-SERIOUS ADVERSE EVENT PER REPORTING GROUP

Threshold for non-serious adverse event reporting is 5%

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NU
PLACEBO	9	249	11
ACT-064992 3 MG	9	250	10
ACT-064992 10 MG	15	242	18

Non-serious adverse event 25

NON-SERIOUS ADVERSE EVENT DETAILS

System organ class	Nervous system disorders
Event term	SYNCOPE
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0

VALUES FOR NON-SERIOUS ADVERSE EVENT PER REPORTING GROUP

Threshold for non-serious adverse event reporting is 5%

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NU
PLACEBO	17	249	20
ACT-064992 3 MG	15	250	21
ACT-064992 10 MG	8	242	11

Non-serious adverse event 26

NON-SERIOUS ADVERSE EVENT DETAILS

System organ class	General disorders and administration site conditions
Event term	FATIGUE
Additional description	

Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0
VALUES FOR NON-SERIOUS ADVERSE EVENT PER REPORTING GROUP	
Threshold for non-serious adverse event reporting is	5%

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NU
PLACEBO	15	249	16
ACT-064992 3 MG	11	250	11
ACT-064992 10 MG	8	242	10

Non-serious adverse event 27

NON-SERIOUS ADVERSE EVENT DETAILS	
System organ class	Gastrointestinal disorders
Event term	VOMITING
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0
VALUES FOR NON-SERIOUS ADVERSE EVENT PER REPORTING GROUP	
Threshold for non-serious adverse event reporting is	5%

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NU
PLACEBO	17	249	19
ACT-064992 3 MG	7	250	9
ACT-064992 10 MG	10	242	10

Non-serious adverse event 28

NON-SERIOUS ADVERSE EVENT DETAILS	
System organ class	Gastrointestinal disorders
Event term	DYSPEPSIA
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0
VALUES FOR NON-SERIOUS ADVERSE EVENT PER REPORTING GROUP	
Threshold for non-serious adverse event reporting is	5%

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NU
PLACEBO	14	249	17
ACT-064992 3 MG	10	250	10
ACT-064992 10 MG	7	242	7

Non-serious adverse event 29

NON-SERIOUS ADVERSE EVENT DETAILS	
System organ class	Musculoskeletal and connective tissue disorders
Event term	PAIN IN EXTREMITY
Additional description	
Assessment type	systematic
Default dictionary for reporting Adverse events in these results is	MedDRA
Do you want to use a different name and version for reporting this adverse event?	no
Dictionary name	MedDRA
Version	14.0
VALUES FOR NON-SERIOUS ADVERSE EVENT PER REPORTING GROUP	
Threshold for non-serious adverse event reporting is	5%

REPORTING GROUPS	SUBJECTS AFFECTED NUMBER	SUBJECTS EXPOSED NUMBER	OCCURRENCES ALL NU
PLACEBO	14	249	17
ACT-064992 3 MG	10	250	11
ACT-064992 10 MG	7	242	8

MORE INFORMATION

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol: Yes

DATE	DESCRIPTION
2008-07-18	Global Protocol Amendment 1: Exclusion criteria were added and the treatment period was adjusted to include the "+7 days" after EOT. This had an impact definition of the primary endpoint. Pharmacokinetic sampling was extended to all patients and detailed follow up for elevated liver enzymes was added. SAE changed (waived reporting).
2009-05-07	Global Protocol Amendment 2: Inclusion criteria were changed and SAE reporting was changed (back from Amendment 1, no waivers).
2009-09-22	Global Protocol Amendment 3: The sample size was adjusted based on the blinded event rate being lower than expected and safety follow up for elevated liv was made more stringent (more frequent monitoring).
2011-09-23	Global Protocol Amendment 4: The interpretation of the results was clarified.

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

Limitations and caveats applicable to this summary of the results

Online references

http://www.ncbi.nlm.nih.gov/pubmed/23984728