Clinical trial results:
A Phase 2, Randomized, Double-Blind, Placebo-Controlled, Parallel Group, Multi-Center Study to Investigate the Safety and Efficacy of MultiStem (PF-05285401) in Subjects With Moderate to Severe Ulcerative Colitis

Due to the EudraCT – Results system being out of service between 31 July 2015 and 12 January 2016, these results have been published in compliance with revised timelines.

Summary

EudraCT number	2010-022766-27
Trial protocol	SE BE HU SK IT
Global end of trial date	19 November 2014

Results information

Result version number	v1 (current)
This version publication date	27 July 2016
First version publication date	27 July 2016

Trial information

Trial identification

Sponsor protocol code	B3041001

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	-
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Pfizer, Inc.
Sponsor organisation address	235 E 42nd Street, New York, United States, 10017
Public contact	Pfizer, Inc., Pfizer ClinicalTrials.gov Call Center, 001 8007181021, ClinicalTrials.gov_Inquiries@pfizer.com
Scientific contact	Pfizer ClinicalTrials.gov Call Center, Pfizer, Inc., 001 8007181021, ClinicalTrials.gov_Inquiries@pfizer.com

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	08 July 2015
Is this the analysis of the primary completion data?	Yes
Primary completion date	19 November 2014
Global end of trial reached?	Yes
Global end of trial date	19 November 2014
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The main objective of the trial was to evaluate the safety and tolerability of intravenous doses of MultiStem in moderate-to-severe ulcerative colitis.

Protection of trial subjects:

The study used an independent External Data Monitoring Committee (EDMC), who was responsible for ongoing monitoring of the safety of subjects according to the Charter. The recommendations made by the EDMC to alter the conduct of the study was forwarded to Pfizer for final decision.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	28 February 2011
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Canada: 4
Country: Number of subjects enrolled	Germany: 12
Country: Number of subjects enrolled	Hungary: 10
Country: Number of subjects enrolled	Italy: 2
Country: Number of subjects enrolled	Slovakia: 5
Country: Number of subjects enrolled	Sweden: 9
Country: Number of subjects enrolled	United States: 63
Worldwide total number of subjects	105
EEA total number of subjects	38

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0

Adolescents (12-17 years)	0
Adults (18-64 years)	95
From 65 to 84 years	10
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

There were 3 cohorts planned. Cohorts 1 and 2 each included 9 subjects. The size of Cohort 3 was reviewed as the study progressed, based purely upon emerging variability estimates of the primary endpoints.

Period 1

Period 1 title	Overall Study
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Investigator, Subject

Arms

Are arms mutually exclusive?	Yes
Arm title	Cohort 1: Placebo, MultiStem 300

Arm description:

Subjects received a single dose (Day 1) or 3 doses (Day 1, Week 1, Week 2) of placebo infusion, followed by a single dose of MultiStem 300 Million Cells infusion at Week 8.

Arm type	Experimental
Investigational medicinal product name	MultiStem
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

300

Arm title	Cohort 2: Placebo, MultiStem 750

Arm description:

Subjects received a single dose of placebo infusion on Day 1, followed by a single dose of MultiStem 750 Million Cells infusion at Week 8.

Arm type	Experimental
Investigational medicinal product name	MultiStem
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

750

Arm title	Cohort 1: MultiStem 300, Placebo

Arm description:

Subjects received a single dose of MultiStem 300 Million Cells infusion on Day 1, followed by a single dose of placebo infusion at Week 8.

Arm type	Experimental

Investigational medicinal product name	MultiStem
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

300

Arm title	Cohort 1: MultiStem 300 (x3), Placebo

Arm description:

Subjects received up to 3 doses of MultiStem 300 Million Cells infusion (Day 1, Week, Week 2), followed by a single dose of placebo infusion at Week 8.

Arm type	Experimental
Investigational medicinal product name	MultiStem
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

300

Arm title	Cohort 2: MultiStem 750, Placebo

Arm description:

Subjects received a single dose of MultiStem 750 Million Cells infusion on Day 1, followed by a single dose of placebo infusion at Week 8.

Arm type	Experimental
Investigational medicinal product name	MultiStem
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

750

Arm title	Cohort 3: MultiStem 750, MultiStem 750

Arm description:

Subjects received a single dose of MultiStem 750 Million Cells infusion on Day 1, followed by a single dose of MultiStem 750 Million Cells infusion at Week 8.

Arm type	Experimental
Investigational medicinal product name	MultiStem
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

750

Arm title	Cohort 3: MultiStem 750, Placebo

Arm description:

Subjects received a single dose of MultiStem 750 Million Cells infusion on Day 1, followed by a single dose of placebo infusion at Week 8.

Arm type	Experimental

Investigational medicinal product name	MultiStem
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

750

Arm title	Cohort 3: Placebo, MultiStem 750

Arm description:

Subjects received a single dose of placebo infusion on Day 1, followed by a single dose of MultiStem 750 Million Cells infusion at Week 8.

Arm type	Experimental
Investigational medicinal product name	MultiStem
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

750

Arm title	Cohort 3: Placebo, Placebo

Arm description:

Subjects received a single dose of placebo infusion on Day 1, followed by a single dose of placebo infusion at Week 8.

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

placebo

Number of subjects in period 1	Cohort 1: Placebo, MultiStem 300	Cohort 2: Placebo, MultiStem 750	Cohort 1: MultiStem 300, Placebo
Started	2	3	2
Completed	0	2	2
Not completed	2	1	0
Consent withdrawn by subject	2	1	-
Adverse event, non-fatal	-	-	-
Insufficient Clinical Response	-	-	-
Unspecified	-	-	-
Lost to follow-up	-	-	-

Number of subjects in period 1	Cohort 1: MultiStem 300 (x3), Placebo	Cohort 2: MultiStem 750, Placebo	Cohort 3: MultiStem 750, MultiStem 750
Started	4	6	23
Completed	1	2	13
Not completed	3	4	10

Consent withdrawn by subject	2	-	4
Adverse event, non-fatal	1	-	2
Insufficient Clinical Response	-	1	3
Unspecified	-	2	-
Lost to follow-up	-	1	1

Number of subjects in period 1	Cohort 3: MultiStem 750, Placebo	Cohort 3: Placebo, MultiStem 750	Cohort 3: Placebo, Placebo
Started	25	19	21
Completed	17	15	13
Not completed	8	4	8
Consent withdrawn by subject	2	3	3
Adverse event, non-fatal	-	-	1
Insufficient Clinical Response	6	-	3
Unspecified	-	-	-
Lost to follow-up	-	1	1

Period 2	
Period 2 title	Pooled Cohort 3
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator
Arms	
Are arms mutually exclusive?	No
Arm title	Pooled MultiStem
Arm description: -	
Arm type	Experimental
Investigational medicinal product name	MultiStem
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use
Dosage and administration details: 350 M or 750 M	
Arm title	Pooled Placebo
Arm description: -	
Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:
placebo

Number of subjects in period 2	Pooled MultiStem	Pooled Placebo
Started	48	40
Completed	30	28
Not completed	18	12
Consent withdrawn by subject	6	6
Adverse event, non-fatal	2	1
Insufficient Clinical Response	9	3
Lost to follow-up	1	2

Baseline characteristics

Reporting groups	
Reporting group title	Cohort 1: Placebo, MultiStem 300
Reporting group description:	
Subjects received a single dose (Day 1) or 3 doses (Day 1, Week 1, Week 2) of placebo infusion, followed by a single dose of MultiStem 300 Million Cells infusion at Week 8.	
Reporting group title	Cohort 2: Placebo, MultiStem 750
Reporting group description:	
Subjects received a single dose of placebo infusion on Day 1, followed by a single dose of MultiStem 750 Million Cells infusion at Week 8.	
Reporting group title	Cohort 1: MultiStem 300, Placebo
Reporting group description:	
Subjects received a single dose of MultiStem 300 Million Cells infusion on Day 1, followed by a single dose of placebo infusion at Week 8.	
Reporting group title	Cohort 1: MultiStem 300 (x3), Placebo
Reporting group description:	
Subjects received up to 3 doses of MultiStem 300 Million Cells infusion (Day 1, Week, Week 2), followed by a single dose of placebo infusion at Week 8.	
Reporting group title	Cohort 2: MultiStem 750, Placebo
Reporting group description:	
Subjects received a single dose of MultiStem 750 Million Cells infusion on Day 1, followed by a single dose of placebo infusion at Week 8.	
Reporting group title	Cohort 3: MultiStem 750, MultiStem 750
Reporting group description:	
Subjects received a single dose of MultiStem 750 Million Cells infusion on Day 1, followed by a single dose of MultiStem 750 Million Cells infusion at Week 8.	
Reporting group title	Cohort 3: MultiStem 750, Placebo
Reporting group description:	
Subjects received a single dose of MultiStem 750 Million Cells infusion on Day 1, followed by a single dose of placebo infusion at Week 8.	
Reporting group title	Cohort 3: Placebo, MultiStem 750
Reporting group description:	
Subjects received a single dose of placebo infusion on Day 1, followed by a single dose of MultiStem 750 Million Cells infusion at Week 8.	
Reporting group title	Cohort 3: Placebo, Placebo
Reporting group description:	
Subjects received a single dose of placebo infusion on Day 1, followed by a single dose of placebo infusion at Week 8.	

Reporting group values	Cohort 1: Placebo, MultiStem 300	Cohort 2: Placebo, MultiStem 750	Cohort 1: MultiStem 300, Placebo
Number of subjects	2	3	2
Age categorical			
Units: Subjects			
In Utero	0	0	0
Pre-term newborn - gestational age <37 wk	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0

Adults (18-64 years)	1	3	1
Elderly (From 65-84 years)	1	0	1
Elderly 85 years and over	0	0	0
Age Continuous |			
Units: years			
arithmetic mean	61	52	58
standard deviation	± 7.1	± 7	± 19.8
Gender, Male/Female			
Units: participants			
Male	2	2	2
Female	0	1	0

Reporting group values	Cohort 1: MultiStem 300 (x3), Placebo	Cohort 2: MultiStem 750, Placebo	Cohort 3: MultiStem 750, MultiStem 750
Number of subjects	4	6	23
Age categorical			
Units: Subjects			
In Utero	0	0	0
Pre-term newborn - gestational age <37 wk	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	4	6	21
Elderly (From 65-84 years)	0	0	2
Elderly 85 years and over	0	0	0
Age Continuous |			
Units: years			
arithmetic mean	45	40	43.4
standard deviation	± 11.1	± 14	± 12.8
Gender, Male/Female			
Units: participants			
Male	3	1	16
Female	1	5	7

Reporting group values	Cohort 3: MultiStem 750, Placebo	Cohort 3: Placebo, MultiStem 750	Cohort 3: Placebo, Placebo
Number of subjects	25	19	21
Age categorical			
Units: Subjects			
In Utero	0	0	0
Pre-term newborn - gestational age <37 wk	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	23	18	18
Elderly (From 65-84 years)	2	1	3
Elderly 85 years and over	0	0	0

Age Continuous |			
Units: years			
arithmetic mean	38.8	39.8	42.5
standard deviation	± 13.4	± 12.5	± 15.7
Gender, Male/Female			
Units: participants			
Male	13	16	14
Female	12	3	7

Reporting group values	Total		
Number of subjects	105		
Age categorical			
Units: Subjects			
In Utero	0		
Pre-term newborn - gestational age <37 wk	0		
Newborns (0-27 days)	0		
Infants and toddlers (28 days-23 months)	0		
Children (2-11 years)	0		
Adolescents (12-17 years)	0		
Adults (18-64 years)	95		
Elderly (From 65-84 years)	10		
Elderly 85 years and over	0		
Age Continuous |			
Units: years			
arithmetic mean			
standard deviation	-		
Gender, Male/Female			
Units: participants			
Male	69		
Female	36		

End points

End points reporting groups

Reporting group title	Cohort 1: Placebo, MultiStem 300
Reporting group description:	
Subjects received a single dose (Day 1) or 3 doses (Day 1, Week 1, Week 2) of placebo infusion, followed by a single dose of MultiStem 300 Million Cells infusion at Week 8.	
Reporting group title	Cohort 2: Placebo, MultiStem 750
Reporting group description:	
Subjects received a single dose of placebo infusion on Day 1, followed by a single dose of MultiStem 750 Million Cells infusion at Week 8.	
Reporting group title	Cohort 1: MultiStem 300, Placebo
Reporting group description:	
Subjects received a single dose of MultiStem 300 Million Cells infusion on Day 1, followed by a single dose of placebo infusion at Week 8.	
Reporting group title	Cohort 1: MultiStem 300 (x3), Placebo
Reporting group description:	
Subjects received up to 3 doses of MultiStem 300 Million Cells infusion (Day 1, Week, Week 2), followed by a single dose of placebo infusion at Week 8.	
Reporting group title	Cohort 2: MultiStem 750, Placebo
Reporting group description:	
Subjects received a single dose of MultiStem 750 Million Cells infusion on Day 1, followed by a single dose of placebo infusion at Week 8.	
Reporting group title	Cohort 3: MultiStem 750, MultiStem 750
Reporting group description:	
Subjects received a single dose of MultiStem 750 Million Cells infusion on Day 1, followed by a single dose of MultiStem 750 Million Cells infusion at Week 8.	
Reporting group title	Cohort 3: MultiStem 750, Placebo
Reporting group description:	
Subjects received a single dose of MultiStem 750 Million Cells infusion on Day 1, followed by a single dose of placebo infusion at Week 8.	
Reporting group title	Cohort 3: Placebo, MultiStem 750
Reporting group description:	
Subjects received a single dose of placebo infusion on Day 1, followed by a single dose of MultiStem 750 Million Cells infusion at Week 8.	
Reporting group title	Cohort 3: Placebo, Placebo
Reporting group description:	
Subjects received a single dose of placebo infusion on Day 1, followed by a single dose of placebo infusion at Week 8.	
Reporting group title	Pooled MultiStem
Reporting group description: -	
Reporting group title	Pooled Placebo
Reporting group description: -	

Primary: Change From Baseline in Endoscopic Score (as Measured by Modified Baron Score) at Week 8

End point title	Change From Baseline in Endoscopic Score (as Measured by Modified Baron Score) at Week 8
End point description:	
Modified Baron Score is an instrument designed to measure endoscopic activity of ulcerative colitis. It classifies the mucosal inflammation in 4 grades (0=normal, 1=granular mucosa with an abnormal vascular pattern, 2=friable mucosa, 3=microulceration with spontaneous bleeding, 4=gross ulceration with spontaneous bleeding).	

End point type	Primary

End point timeframe:

Baseline and Week 8

End point values	Pooled MultiStem	Pooled Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	48	40		
Units: scores on a scale				
arithmetic mean (standard deviation)				
Baseline	3.13 (± 1.104)	3.1 (± 1.128)		
Change at Week 8	0.1 (± 1.134)	-0.3 (± 1.091)		

Statistical analyses

Statistical analysis title	Change From Baseline in Endoscopic Score (Week 8)

Statistical analysis description:

Pooled MultiStem versus Pooled Placebo

Comparison groups	Pooled MultiStem v Pooled Placebo
Number of subjects included in analysis	88
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.96 [1]
Method	ANCOVA
Parameter estimate	Mean difference (final values)
Point estimate	0.4
Confidence interval	
level	Other: 80 %
sides	2-sided
lower limit	0.12
upper limit	0.69
Variability estimate	Standard error of the mean
Dispersion value	0.223

Notes:

[1] - 1-sided p-value

Primary: Change From Baseline in Rectal Bleeding Mayo Subscore at Week 4

End point title	Change From Baseline in Rectal Bleeding Mayo Subscore at Week 4

End point description:

Mayo Score is an instrument designed to measure disease activity of ulcerative colitis. Mayo subscores for rectal bleeding range from 0 to 3, with higher scores indicating more severe disease.

End point type	Primary

End point timeframe:

Baseline and Week 4

End point values	Pooled MultiStem	Pooled Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	48	40		
Units: scores on a scale				
arithmetic mean (standard deviation)				
Baseline	1.42 (± 0.942)	1.23 (± 0.832)		
Change at Week 4	-0.44 (± 0.943)	-0.38 (± 0.705)		

Statistical analyses

Statistical analysis title	Rectal Bleeding Mayo Subscore (Week 4)
Statistical analysis description:	
Pooled MultiStem versus Pooled Placebo (Week 4)	
Comparison groups	Pooled MultiStem v Pooled Placebo
Number of subjects included in analysis	88
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.54 [2]
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	0.02
Confidence interval	
level	Other: 80 %
sides	2-sided
lower limit	-0.19
upper limit	0.22
Variability estimate	Standard error of the mean
Dispersion value	0.161
Notes:	
[2] - 1-sided p-value	

Primary: Change From Baseline in Rectal Bleeding Mayo Subscore at Week 8

End point title	Change From Baseline in Rectal Bleeding Mayo Subscore at Week 8
End point description:	
Mayo Score is an instrument designed to measure disease activity of ulcerative colitis. Mayo subscores for rectal bleeding range from 0 to 3, with higher scores indicating more severe disease.	
End point type	Primary
End point timeframe:	
Baseline and Week 8	

End point values	Pooled MultiStem	Pooled Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	48	40		
Units: scores on a scale				
arithmetic mean (standard deviation)	-0.46 (± 1.051)	-0.43 (± 0.874)		

Statistical analyses

Statistical analysis title	Rectal Bleeding Mayo Subscore (Week 8)

Statistical analysis description:

Pooled MultiStem versus Pooled Placebo (Week 8)

Comparison groups	Pooled MultiStem v Pooled Placebo
Number of subjects included in analysis	88
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.67 [3]
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	0.08
Confidence interval	
level	Other: 80 %
sides	2-sided
lower limit	-0.15
upper limit	0.3
Variability estimate	Standard error of the mean
Dispersion value	0.174

Notes:

[3] - 1-sided p-value

Primary: Number of Subjects with Treatment-Emergent Adverse Events (AEs) and Serious Adverse Events (SAEs)

End point title	Number of Subjects with Treatment-Emergent Adverse Events (AEs) and Serious Adverse Events (SAEs)[4]

End point description:

An AE was any untoward medical occurrence in a subject who received study drug. An SAE was an AE resulting in any of the following outcomes or deemed significant for any other reason: death; initial or prolonged inpatient hospitalization; life-threatening experience (immediate risk of dying); persistent or significant disability/incapacity; congenital anomaly. Treatment-emergent are events between first dose of study drug and up to 30 days after last dose that were absent before treatment or that worsened relative to pre-treatment state. AEs included both SAEs and non-SAEs.

End point type	Primary

End point timeframe:

Baseline up to Week 52

Notes:

[4] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: No statistical analysis was planned for this primary endpoint. Adverse events were reported in accordance with the sponsor reporting standards.

End point values	Cohort 1: Placebo, MultiStem 300	Cohort 2: Placebo, MultiStem 750	Cohort 1: MultiStem 300, Placebo	Cohort 1: MultiStem 300 (x3), Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2	3	2	4
Units: subjects				
AEs	2	3	0	4
SAEs	1	0	0	3

End point values	Cohort 2: MultiStem 750, Placebo	Cohort 3: MultiStem 750, MultiStem 750	Cohort 3: MultiStem 750, Placebo	Cohort 3: Placebo, MultiStem 750
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	23	25	19
Units: subjects				
AEs	5	20	18	16
SAEs	0	7	4	5

End point values	Cohort 3: Placebo, Placebo			
Subject group type	Reporting group			
Number of subjects analysed	21			
Units: subjects				
AEs	19			
SAEs	4			

Statistical analyses

No statistical analyses for this end point

Primary: Incidence of Treatment-Emergent AEs by System Organ Class (SOC)

End point title	Incidence of Treatment-Emergent AEs by System Organ Class (SOC)[5]

End point description:

End point type	Primary

End point timeframe:

Baseline up to Week 52

Notes:

[5] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: No statistical analysis was planned for this primary endpoint. Adverse events were reported in accordance with the sponsor reporting standards.

End point values	Cohort 1: Placebo, MultiStem 300	Cohort 2: Placebo, MultiStem 750	Cohort 1: MultiStem 300, Placebo	Cohort 1: MultiStem 300 (x3), Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2	3	2	4
Units: subjects				
BLOOD AND LYMPHATIC SYSTEM DISORDERS	0	0	0	0
CARDIAC DISORDERS	0	0	0	0
EAR AND LABYRINTH DISORDERS	0	0	0	0
ENDOCRINE DISORDERS	0	0	0	0
EYE DISORDERS	0	0	0	0
GASTROINTESTINAL DISORDERS	2	1	0	2
GENERAL DISORDERS	2	1	0	3
IMMUNE SYSTEM DISORDERS	0	0	0	1
INFECTIONS AND INFESTATIONS	1	1	0	1
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	0	1	0	1
INVESTIGATIONS	0	1	0	0
METABOLISM AND NUTRITION DISORDERS	0	0	0	1
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	0	2	0	0
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED	0	0	0	0
NERVOUS SYSTEM DISORDERS	0	1	0	1
PSYCHIATRIC DISORDERS	0	0	0	0
RENAL AND URINARY DISORDERS	0	0	0	0
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	1	1	0	0
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	0	0	0	1
SURGICAL AND MEDICAL PROCEDURES	0	0	0	0
VASCULAR DISORDERS	0	0	0	0

End point values	Cohort 2: MultiStem 750, Placebo	Cohort 3: MultiStem 750, MultiStem 750	Cohort 3: MultiStem 750, Placebo	Cohort 3: Placebo, MultiStem 750
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	23	25	19
Units: subjects				
BLOOD AND LYMPHATIC SYSTEM DISORDERS	0	5	0	3
CARDIAC DISORDERS	0	1	0	1
EAR AND LABYRINTH DISORDERS	0	1	0	1
ENDOCRINE DISORDERS	0	0	1	1
EYE DISORDERS	0	1	0	0
GASTROINTESTINAL DISORDERS	4	13	10	11
GENERAL DISORDERS	1	8	5	5
IMMUNE SYSTEM DISORDERS	0	0	2	0
INFECTIONS AND INFESTATIONS	1	10	9	9
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	0	2	2	2

INVESTIGATIONS	1	4	1	5
METABOLISM AND NUTRITION DISORDERS	0	2	0	1
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	2	6	5	2
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED	0	1	0	0
NERVOUS SYSTEM DISORDERS	1	1	3	9
PSYCHIATRIC DISORDERS	0	1	1	3
RENAL AND URINARY DISORDERS	0	1	1	0
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	0	5	5	1
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	1	4	4	3
SURGICAL AND MEDICAL PROCEDURES	0	1	0	1
VASCULAR DISORDERS	2	1	1	2

End point values	Cohort 3: Placebo, Placebo			
Subject group type	Reporting group			
Number of subjects analysed	21			
Units: subjects				
BLOOD AND LYMPHATIC SYSTEM DISORDERS	4			
CARDIAC DISORDERS	1			
EAR AND LABYRINTH DISORDERS	1			
ENDOCRINE DISORDERS	0			
EYE DISORDERS	3			
GASTROINTESTINAL DISORDERS	12			
GENERAL DISORDERS	6			
IMMUNE SYSTEM DISORDERS	0			
INFECTIONS AND INFESTATIONS	7			
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	1			
INVESTIGATIONS	3			
METABOLISM AND NUTRITION DISORDERS	1			
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	1			
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED	0			
NERVOUS SYSTEM DISORDERS	6			
PSYCHIATRIC DISORDERS	2			
RENAL AND URINARY DISORDERS	0			
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	4			
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	2			
SURGICAL AND MEDICAL PROCEDURES	0			
VASCULAR DISORDERS	1			

Statistical analyses

No statistical analyses for this end point

Primary: Number of Treatment-Emergent AEs by Severity

End point title	Number of Treatment-Emergent AEs by Severity[6]

End point description:

The intensity grades were defined as follows: mild=does not interfere with subject's usual function; moderate=interferes to some extent with subject's usual function; severe=interferes significantly with subject's usual function.

End point type	Primary

End point timeframe:

Baseline up to Week 52

Notes:

[6] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: No statistical analysis was planned for this primary endpoint. Adverse events were reported in accordance with the sponsor reporting standards.

End point values	Cohort 1: Placebo, MultiStem 300	Cohort 2: Placebo, MultiStem 750	Cohort 1: MultiStem 300, Placebo	Cohort 1: MultiStem 300 (x3), Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2	3	2	4
Units: adverse events				
Mild AEs	6	16	0	8
Moderate AEs	4	0	0	5
Severe AEs	1	0	0	4

End point values	Cohort 2: MultiStem 750, Placebo	Cohort 3: MultiStem 750, MultiStem 750	Cohort 3: MultiStem 750, Placebo	Cohort 3: Placebo, MultiStem 750
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	23	25	19
Units: adverse events				
Mild AEs	13	61	35	56
Moderate AEs	2	33	31	21
Severe AEs	0	13	8	4

End point values	Cohort 3: Placebo, Placebo			

Subject group type	Reporting group			
Number of subjects analysed	21			
Units: adverse events				
Mild AEs	48			
Moderate AEs	17			
Severe AEs	3			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Rectal Bleeding Mayo Subscore at Week 12 and Week 16

End point title	Change From Baseline in Rectal Bleeding Mayo Subscore at Week 12 and Week 16

End point description:

Mayo Score is an instrument designed to measure disease activity of ulcerative colitis. Mayo subscores for rectal bleeding range from 0 to 3, with higher scores indicating more severe disease.

End point type	Secondary

End point timeframe:

Baseline, Week 12, Week 16

End point values	Cohort 1: Placebo, MultiStem 300	Cohort 2: Placebo, MultiStem 750	Cohort 1: MultiStem 300, Placebo	Cohort 1: MultiStem 300 (x3), Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2	3	2	4
Units: scores on a scale				
arithmetic mean (standard deviation)				
Change at Week 12 (n=0,0,0,0,0,22,25,17,19)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
Change at Week 16 (n=2,3,2,4,5,21,24,17,19)	-1.5 (± 0.707)	-1 (± 1)	0 (± 0)	0 (± 0.816)

End point values	Cohort 2: MultiStem 750, Placebo	Cohort 3: MultiStem 750, MultiStem 750	Cohort 3: MultiStem 750, Placebo	Cohort 3: Placebo, MultiStem 750
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	23	25	19
Units: scores on a scale				
arithmetic mean (standard deviation)				
Change at Week 12 (n=0,0,0,0,0,22,25,17,19)	99999 (± 99999)	-0.77 (± 0.869)	-0.64 (± 1.114)	-0.53 (± 0.874)
Change at Week 16 (n=2,3,2,4,5,21,24,17,19)	-0.6 (± 1.14)	-0.57 (± 0.978)	-0.92 (± 1.1)	-0.47 (± 0.874)

End point values	Cohort 3: Placebo, Placebo			
Subject group type	Reporting group			
Number of subjects analysed	21			
Units: scores on a scale				
arithmetic mean (standard deviation)				
Change at Week 12 (n=0,0,0,0,0,22,25,17,19)	-0.47 (± 0.905)			
Change at Week 16 (n=2,3,2,4,5,21,24,17,19)	-0.58 (± 0.838)			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects With Laboratory Test Abnormalities

End point title	Number of Subjects With Laboratory Test Abnormalities

End point description:

The total number of subjects with laboratory test abnormalities with or without regard to baseline abnormality was assessed. Laboratory parameters included: hematology (hemoglobin, hematocrit, red blood cell [RBC] count, platelet count, white blood cell [WBC] count, total neutrophils, eosinophils, monocytes, basophils, lymphocytes, erythrocyte sedimentation rate); chemistry (blood urea nitrogen and creatinine, glucose, calcium, sodium, potassium, chloride, total bicarbonate, aspartate aminotransferase, alanine aminotransferase, total bilirubin, alkaline phosphatase, uric acid, albumin, total protein; urinalysis (pH, glucose, protein, blood, ketones, nitrites, leukocyte esterase, microscopy (only if urine dipstick was positive for blood, protein, nitrites or leukocyte esterase); other (follicle-stimulating hormone, human chorionic gonadotropin, stool microbiology, creatinine kinase, direct bilirubin, indirect bilirubin, gamma-glutamyl transferase, international normalized ratio.

End point type	Secondary

End point timeframe:

Baseline up to Week 24

End point values	Cohort 1: Placebo, MultiStem 300	Cohort 2: Placebo, MultiStem 750	Cohort 1: MultiStem 300, Placebo	Cohort 1: MultiStem 300 (x3), Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2	3	2	4
Units: subjects				
Normal/Abnormal Baseline(n=2,3,2,4,6,23,25,19,21)	2	2	1	4
Normal Baseline (n=2,3,2,4,6,23,25,19,21)	2	2	1	3
Abnormal Baseline (n=2,3,2,2,3,22,19,15,18)	1	1	1	1

End point values	Cohort 2: MultiStem 750, Placebo	Cohort 3: MultiStem 750, MultiStem 750	Cohort 3: MultiStem 750, Placebo	Cohort 3: Placebo, MultiStem 750
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	23	25	19
Units: subjects				
Normal/Abnormal Baseline(n=2,3,2,4,6,23,25,19,21)	4	14	20	15
Normal Baseline (n=2,3,2,4,6,23,25,19,21)	4	9	16	12
Abnormal Baseline (n=2,3,2,2,3,22,19,15,18)	2	7	4	4

End point values	Cohort 3: Placebo, Placebo			
Subject group type	Reporting group			
Number of subjects analysed	21			
Units: subjects				
Normal/Abnormal Baseline(n=2,3,2,4,6,23,25,19,21)	17			
Normal Baseline (n=2,3,2,4,6,23,25,19,21)	13			
Abnormal Baseline (n=2,3,2,2,3,22,19,15,18)	6			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects With Potentially Clinically Significant Vital Signs Findings

End point title	Number of Subjects With Potentially Clinically Significant Vital Signs Findings

End point description:

Vital signs assessment included pulse rate, systolic blood pressure (SBP) and diastolic blood pressure (DBP). Criteria for vital sign values meeting potential clinical concern included: SBP <90 millimeters of mercury (mm Hg) and >=30 mm Hg increase/decrease from baseline, DBP <50 mm Hg and >=20 mm Hg increase/decrease from baseline, pulse rate <40 or >120 beats per minute (bpm),

End point type	Secondary

End point timeframe:

Baseline up to Week 52

End point values	Cohort 1: Placebo, MultiStem 300	Cohort 2: Placebo, MultiStem 750	Cohort 1: MultiStem 300, Placebo	Cohort 1: MultiStem 300 (x3), Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2	3	2	4
Units: subjects				
Supine SBP <90 mm Hg	0	0	0	0
Supine DBP <50 mm Hg	0	0	0	0
Supine Pulse Rate <40 bpm	0	0	0	0
Supine Pulse Rate >120 bpm	0	0	0	0
Supine SBP >=30 mm Hg Increase From Baseline	0	0	0	1
Supine DBP >=20 mm Hg Increase From Baseline	2	0	0	1
Supine SBP >=30 mm Hg Decrease From Baseline	0	0	0	1
Supine DBP >=20 mm Hg Decrease From Baseline	1	1	0	0

End point values	Cohort 2: MultiStem 750, Placebo	Cohort 3: MultiStem 750, MultiStem 750	Cohort 3: MultiStem 750, Placebo	Cohort 3: Placebo, MultiStem 750
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	23	25	19
Units: subjects				
Supine SBP <90 mm Hg	2	0	0	0
Supine DBP <50 mm Hg	0	0	1	0
Supine Pulse Rate <40 bpm	0	0	0	0
Supine Pulse Rate >120 bpm	0	3	0	1
Supine SBP >=30 mm Hg Increase From Baseline	1	1	3	1
Supine DBP >=20 mm Hg Increase From Baseline	0	3	0	2
Supine SBP >=30 mm Hg Decrease From Baseline	0	1	1	1
Supine DBP >=20 mm Hg Decrease From Baseline	0	6	1	3

End point values	Cohort 3: Placebo, Placebo			
Subject group type	Reporting group			
Number of subjects analysed	21			
Units: subjects				
Supine SBP <90 mm Hg	0			
Supine DBP <50 mm Hg	0			
Supine Pulse Rate <40 bpm	0			
Supine Pulse Rate >120 bpm	0			
Supine SBP >=30 mm Hg Increase From Baseline	2			
Supine DBP >=20 mm Hg Increase From Baseline	4			

Supine SBP >=30 mm Hg Decrease From Baseline	1			
Supine DBP >=20 mm Hg Decrease From Baseline	0			

Statistical analyses

No statistical analyses for this end point

Secondary: Fold Change From Baseline in Fecal Calprotectin at Weeks 4, 8, 12, and 16

End point title	Fold Change From Baseline in Fecal Calprotectin at Weeks 4, 8, 12, and 16

End point description:

Fecal calprotectin, a very stable marker, is a 36kDa calcium and zinc binding protein which is neutrophil-derived. It represents 60% of cytosolic proteins in granulocytes and is a measurement of neutrophil migration to the gastrointestinal tract.

End point type	Secondary

End point timeframe:

Baseline, Weeks 4, 8, 12 and 16

End point values	Cohort 1: Placebo, MultiStem 300	Cohort 2: Placebo, MultiStem 750	Cohort 1: MultiStem 300, Placebo	Cohort 1: MultiStem 300 (x3), Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2	3	2	4
Units: milligrams per kilogram (mg/kg)				
geometric mean (geometric coefficient of variation)				
Baseline (n=2,3,1,4,5,21,23,19,20)	690.7549 (± 17)	1189.8169 (± 22)	739.23 (± 99999)	898.2758 (± 89)
Change at Week 4 (n=2,3,1,3,5,20,21,18,19)	0.6297 (± 50)	1.868 (± 103)	2.0264 (± 99999)	2.0549 (± 112)
Change at Week 8 (n=1,2,1,3,2,18,20,17,20)	2.4504 (± 99999)	2.4559 (± 51)	2.6199 (± 99999)	0.5744 (± 52)
Change at Week 12 (n=0,0,0,0,0,20,21,17,18)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
Change at Week 16 (n=2,3,1,4,4,18,18,16,17)	2.1672 (± 49)	0.7679 (± 32)	1.1956 (± 99999)	0.4459 (± 139)

End point values	Cohort 2: MultiStem 750, Placebo	Cohort 3: MultiStem 750, MultiStem 750	Cohort 3: MultiStem 750, Placebo	Cohort 3: Placebo, MultiStem 750
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	23	25	19
Units: milligrams per kilogram (mg/kg)				
geometric mean (geometric coefficient of variation)				

Baseline (n=2,3,1,4,5,21,23,19,20)	874.1363 (± 1462)	576.5796 (± 237)	476.1504 (± 222)	513.2139 (± 208)
Change at Week 4 (n=2,3,1,3,5,20,21,18,19)	1.094 (± 91)	1.2196 (± 158)	0.8179 (± 314)	1.0541 (± 166)
Change at Week 8 (n=1,2,1,3,2,18,20,17,20)	0.3282 (± 2)	1.0704 (± 220)	0.7462 (± 235)	0.8598 (± 227)
Change at Week 12 (n=0,0,0,0,0,20,21,17,18)	99999 (± 99999)	0.9947 (± 171)	0.8269 (± 310)	0.8788 (± 293)
Change at Week 16 (n=2,3,1,4,4,18,18,16,17)	0.2474 (± 4517)	0.6473 (± 277)	0.8486 (± 149)	0.5473 (± 309)

End point values	Cohort 3: Placebo, Placebo			
Subject group type	Reporting group			
Number of subjects analysed	21			
Units: milligrams per kilogram (mg/kg)				
geometric mean (geometric coefficient of variation)				
Baseline (n=2,3,1,4,5,21,23,19,20)	821.1953 (± 220)			
Change at Week 4 (n=2,3,1,3,5,20,21,18,19)	0.6722 (± 193)			
Change at Week 8 (n=1,2,1,3,2,18,20,17,20)	0.3479 (± 242)			
Change at Week 12 (n=0,0,0,0,0,20,21,17,18)	0.5279 (± 171)			
Change at Week 16 (n=2,3,1,4,4,18,18,16,17)	0.5275 (± 243)			

Statistical analyses

Statistical analysis title	Fecal Calprotectin (Week 4)
Statistical analysis description: Pooled MultiStem versus Pooled Placebo (Week 4)	
Comparison groups	Cohort 3: MultiStem 750, MultiStem 750 v Cohort 3: MultiStem 750, Placebo v Cohort 3: Placebo, MultiStem 750 v Cohort 3: Placebo, Placebo
Number of subjects included in analysis	88
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.53 [7]
Method	Mixed models analysis
Parameter estimate	Geometric Mean Ratio
Point estimate	1.02
Confidence interval	
level	Other: 80 %
sides	2-sided
lower limit	0.73
upper limit	1.42

Notes:
[7] - 1-sided p-value

Statistical analysis title	Fecal Calprotectin (Week 8)
Statistical analysis description:	
Pooled MultiStem versus Pooled Placebo (Week 8)	
Comparison groups	Cohort 3: MultiStem 750, MultiStem 750 v Cohort 3: MultiStem 750, Placebo v Cohort 3: Placebo, MultiStem 750 v Cohort 3: Placebo, Placebo
Number of subjects included in analysis	88
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.91 [8]
Method	Mixed models analysis
Parameter estimate	Geometric Mean Ratio
Point estimate	1.48
Confidence interval	
level	Other: 80 %
sides	2-sided
lower limit	1.02
upper limit	2.14

Notes:
[8] - 1-sided p-value

Statistical analysis title	Fecal Calprotectin (Week 12)
Statistical analysis description:	
Cohort 3 MM versus Cohort 3 PP (Week 12)	
Comparison groups	Cohort 3: MultiStem 750, MultiStem 750 v Cohort 3: Placebo, Placebo
Number of subjects included in analysis	44
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.81 [9]
Method	Mixed models analysis
Parameter estimate	Geometric Mean Ratio
Point estimate	1.38
Confidence interval	
level	Other: 80 %
sides	2-sided
lower limit	0.86
upper limit	2.23

Notes:
[9] - 1-sided p-value

Statistical analysis title	Fecal Calprotectin (Week 12)
Statistical analysis description:	
Cohort 3 MP versus Cohort 3 PP (Week 12)	
Comparison groups	Cohort 3: MultiStem 750, Placebo v Cohort 3: Placebo, Placebo

Number of subjects included in analysis	46
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.44 [10]
Method	Mixed models analysis
Parameter estimate	Geometric Mean Ratio
Point estimate	0.94
Confidence interval	
level	Other: 80 %
sides	2-sided
lower limit	0.59
upper limit	1.51

Notes:

[10] - 1-sided p-value

Statistical analysis title	Fecal Calprotectin (Week 12)
Statistical analysis description:	
Cohort 3 PM versus Cohort 3 PP (Week 12)	
Comparison groups	Cohort 3: Placebo, MultiStem 750 v Cohort 3: Placebo, Placebo
Number of subjects included in analysis	40
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.67 [11]
Method	Mixed models analysis
Parameter estimate	Geometric Mean Ratio
Point estimate	1.18
Confidence interval	
level	Other: 80 %
sides	2-sided
lower limit	0.72
upper limit	1.94

Notes:

[11] - 1-sided p-value

Statistical analysis title	Fecal Calprotectin (Week 16)
Statistical analysis description:	
Cohort 3 MM versus Cohort 3 PP (Week 16)	
Comparison groups	Cohort 3: MultiStem 750, MultiStem 750 v Cohort 3: Placebo, Placebo
Number of subjects included in analysis	44
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.62 [12]
Method	Mixed models analysis
Parameter estimate	Geometric Mean Ratio
Point estimate	1.12
Confidence interval	
level	Other: 80 %
sides	2-sided
lower limit	0.68
upper limit	1.84

Notes:
[12] - 1-sided p-value

Statistical analysis title	Fecal Calprotectin (Week 16)
Statistical analysis description:	
Cohort 3 MP versus Cohort 3 PP (Week 16)	
Comparison groups	Cohort 3: MultiStem 750, Placebo v Cohort 3: Placebo, Placebo
Number of subjects included in analysis	46
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.45 [13]
Method	Mixed models analysis
Parameter estimate	Geometric Mean Ratio
Point estimate	0.95
Confidence interval	
level	Other: 80 %
sides	2-sided
lower limit	0.58
upper limit	1.57

Notes:
[13] - 1-sided p-value

Statistical analysis title	Fecal Calprotectin (Week 16)
Statistical analysis description:	
Cohort 3 PM versus Cohort 3 PP (Week 16)	
Comparison groups	Cohort 3: Placebo, MultiStem 750 v Cohort 3: Placebo, Placebo
Number of subjects included in analysis	40
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.3 [14]
Method	Mixed models analysis
Parameter estimate	Geometric Mean Ratio
Point estimate	0.81
Confidence interval	
level	Other: 80 %
sides	2-sided
lower limit	0.49
upper limit	1.36

Notes:
[14] - 1-sided p-value

Secondary: Fold Change From Baseline in C-Reactive Protein (CRP) at Weeks 4, 8, 12, and 16

End point title	Fold Change From Baseline in C-Reactive Protein (CRP) at Weeks 4, 8, 12, and 16

End point description:

CRP is an acute-phase protein which provides an objective criterion of inflammatory activity. CRP has a short half-life (19 hours) and therefore rises early after the onset of inflammation and rapidly decreases after resolution of the inflammation. It is induced by interleukin-6, TNF-alpha and other pro-inflammatory cytokines that are produced within the intestinal lamina propria.

End point type	Secondary

End point timeframe:
Baseline, Weeks 4, 8, 12 and 16

End point values	Cohort 1: Placebo, MultiStem 300	Cohort 2: Placebo, MultiStem 750	Cohort 1: MultiStem 300, Placebo	Cohort 1: MultiStem 300 (x3), Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2	3	2	4
Units: milligrams per deciliter (mg/dL)				
geometric mean (geometric coefficient of variation)				
Baseline (n=2,3,2,4,6,22,25,19,20)	1.272 (± 45)	1.527 (± 118)	0.229 (± 34)	0.578 (± 37)
Change at Week 4 (n=2,3,2,3,6,21,25,18,20)	0.289 (± 9)	0.555 (± 82)	1.937 (± 42)	1.285 (± 60)
Change at Week 8 (n=1,3,1,3,5,21,25,19,20)	1.39 (± 99999)	0.745 (± 49)	2.331 (± 99999)	1.172 (± 20)
Change at Week 12 (n=0,0,0,0,0,21,24,17,18)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
Change at Week 16 (n=2,3,2,4,5,20,24,17,18)	0.956 (± 164)	0.481 (± 56)	0.606 (± 248)	0.869 (± 14)

End point values	Cohort 2: MultiStem 750, Placebo	Cohort 3: MultiStem 750, MultiStem 750	Cohort 3: MultiStem 750, Placebo	Cohort 3: Placebo, MultiStem 750
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	23	25	19
Units: milligrams per deciliter (mg/dL)				
geometric mean (geometric coefficient of variation)				
Baseline (n=2,3,2,4,6,22,25,19,20)	0.18 (± 74)	0.613 (± 339)	0.542 (± 236)	0.397 (± 157)
Change at Week 4 (n=2,3,2,3,6,21,25,18,20)	1.446 (± 54)	0.891 (± 147)	0.764 (± 140)	0.999 (± 103)
Change at Week 8 (n=1,3,1,3,5,21,25,19,20)	1.555 (± 31)	1.189 (± 146)	0.759 (± 207)	1.2 (± 113)
Change at Week 12 (n=0,0,0,0,0,21,24,17,18)	99999 (± 99999)	0.937 (± 211)	0.71 (± 365)	0.782 (± 149)
Change at Week 16 (n=2,3,2,4,5,20,24,17,18)	1.184 (± 54)	0.776 (± 156)	0.425 (± 178)	0.612 (± 133)

End point values	Cohort 3: Placebo, Placebo			
Subject group type	Reporting group			
Number of subjects analysed	21			
Units: milligrams per deciliter (mg/dL)				
geometric mean (geometric coefficient of variation)				
Baseline (n=2,3,2,4,6,22,25,19,20)	0.453 (± 297)			

Change at Week 4 (n=2,3,2,3,6,21,25,18,20)	0.588 (± 132)			
Change at Week 8 (n=1,3,1,3,5,21,25,19,20)	0.623 (± 150)			
Change at Week 12 (n=0,0,0,0,0,21,24,17,18)	0.373 (± 155)			
Change at Week 16 (n=2,3,2,4,5,20,24,17,18)	0.417 (± 197)			

Statistical analyses

Statistical analysis title	Fold Change From Baseline in CRP (Week 4)
Statistical analysis description: Pooled MultiStem versus Pooled Placebo (Week 4)	
Comparison groups	Cohort 3: MultiStem 750, MultiStem 750 v Cohort 3: MultiStem 750, Placebo v Cohort 3: Placebo, MultiStem 750 v Cohort 3: Placebo, Placebo
Number of subjects included in analysis	88
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.79 [15]
Method	Mixed models analysis
Parameter estimate	Geometric Mean Ratio
Point estimate	1.17
Confidence interval	
level	Other: 80 %
sides	2-sided
lower limit	0.91
upper limit	1.51

Notes:

[15] - 1-sided p-value

Statistical analysis title	Fold Change From Baseline in CRP (Week 8)
Statistical analysis description: Pooled MultiStem versus Pooled Placebo (Week 8)	
Comparison groups	Cohort 3: MultiStem 750, MultiStem 750 v Cohort 3: MultiStem 750, Placebo v Cohort 3: Placebo, MultiStem 750 v Cohort 3: Placebo, Placebo
Number of subjects included in analysis	88
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.8 [16]
Method	Mixed models analysis
Parameter estimate	Geometric Mean Ratio
Point estimate	1.21
Confidence interval	
level	Other: 80 %
sides	2-sided
lower limit	0.9
upper limit	1.63

Notes:
[16] - 1-sided p-value

Statistical analysis title	Fold Change From Baseline in CRP (Week 12)
Statistical analysis description:	
Cohort 3 MM versus Cohort 3 PP (Week 12)	
Comparison groups	Cohort 3: MultiStem 750, MultiStem 750 v Cohort 3: Placebo, Placebo
Number of subjects included in analysis	44
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.99 [17]
Method	Mixed models analysis
Parameter estimate	Geometric Mean Ratio
Point estimate	2.75
Confidence interval	
level	Other: 80 %
sides	2-sided
lower limit	1.63
upper limit	4.64

Notes:
[17] - 1-sided p-value

Statistical analysis title	Fold Change From Baseline in CRP (Week 12)
Statistical analysis description:	
Cohort 3 MP versus Cohort 3 PP (Week 12)	
Comparison groups	Cohort 3: MultiStem 750, Placebo v Cohort 3: Placebo, Placebo
Number of subjects included in analysis	46
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.96 [18]
Method	Mixed models analysis
Parameter estimate	Geometric Mean Ratio
Point estimate	1.96
Confidence interval	
level	Other: 80 %
sides	2-sided
lower limit	1.19
upper limit	3.25

Notes:
[18] - 1-sided p-value

Statistical analysis title	Fold Change From Baseline in CRP (Week 12)
Statistical analysis description:	
Cohort 3 PM versus Cohort 3 PP (Week 12)	
Comparison groups	Cohort 3: Placebo, MultiStem 750 v Cohort 3: Placebo, Placebo

Number of subjects included in analysis	40
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.95 [19]
Method	Mixed models analysis
Parameter estimate	Geometric Mean Ratio
Point estimate	1.98
Confidence interval	
level	Other: 80 %
sides	2-sided
lower limit	1.15
upper limit	3.41

Notes:

[19] - 1-sided p-value

Statistical analysis title	Fold Change From Baseline in CRP (Week 16)
Statistical analysis description:	
Cohort 3 MM versus Cohort 3 PP (Week 16)	
Comparison groups	Cohort 3: MultiStem 750, MultiStem 750 v Cohort 3: Placebo, Placebo
Number of subjects included in analysis	44
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.99 [20]
Method	Mixed models analysis
Parameter estimate	Geometric Mean Ratio
Point estimate	2.3
Confidence interval	
level	Other: 80 %
sides	2-sided
lower limit	1.52
upper limit	3.48

Notes:

[20] - 1-sided p-value

Statistical analysis title	Fold Change From Baseline in CRP (Week 16)
Statistical analysis description:	
Cohort 3 MP versus Cohort 3 PP (Week 16)	
Comparison groups	Cohort 3: MultiStem 750, Placebo v Cohort 3: Placebo, Placebo
Number of subjects included in analysis	46
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.62 [21]
Method	Mixed models analysis
Parameter estimate	Geometric Mean Ratio
Point estimate	1.1
Confidence interval	
level	Other: 80 %
sides	2-sided
lower limit	0.74
upper limit	1.63

Notes:
[21] - 1-sided p-value

Statistical analysis title	Fold Change From Baseline in CRP (Week 16)
Statistical analysis description:	
Cohort 3 PM versus Cohort 3 PP (Week 16)	
Comparison groups	Cohort 3: Placebo, MultiStem 750 v Cohort 3: Placebo, Placebo
Number of subjects included in analysis	40
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.89 [22]
Method	Mixed models analysis
Parameter estimate	Geometric Mean Ratio
Point estimate	1.51
Confidence interval	
level	Other: 80 %
sides	2-sided
lower limit	0.98
upper limit	2.32

Notes:
[22] - 1-sided p-value

Secondary: Percentage of Subjects With Rectal Bleeding Mayo Subscore of Zero at Weeks 4, 8, 12, and 16

End point title	Percentage of Subjects With Rectal Bleeding Mayo Subscore of Zero at Weeks 4, 8, 12, and 16
End point description:	
Mayo subscores for rectal bleeding range from 0 to 3 (0=no blood seen; 1=streaks of blood with stool less than half the time; 2=obvious blood with stool most of the time; 3=blood alone passes).	
End point type	Secondary
End point timeframe:	
Week 4, 8, 12 and 16	

End point values	Cohort 1: Placebo, MultiStem 300	Cohort 2: Placebo, MultiStem 750	Cohort 1: MultiStem 300, Placebo	Cohort 1: MultiStem 300 (x3), Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2	3	2	4
Units: percentage of subjects				
number (not applicable)				
Week 4	50	66.7	50	33.3
Week 8	50	66.7	50	33.3
Week 12	99999	99999	99999	99999
Week 16	50	100	50	50

End point values	Cohort 2: MultiStem 750,	Cohort 3: MultiStem 750,	Cohort 3: MultiStem 750,	Cohort 3: Placebo,

	Placebo	MultiStem 750	Placebo	MultiStem 750
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	23	25	19
Units: percentage of subjects				
number (not applicable)				
Week 4	40	52.2	28	31.6
Week 8	40	47.8	36	31.6
Week 12	99999	63.6	40	52.9
Week 16	40	52.4	50	41.2

End point values	Cohort 3: Placebo, Placebo			
Subject group type	Reporting group			
Number of subjects analysed	21			
Units: percentage of subjects				
number (not applicable)				
Week 4	42.9			
Week 8	47.6			
Week 12	47.4			
Week 16	57.9			

Statistical analyses

Statistical analysis title	Rectal Bleeding Mayo Subscore of Zero (Week 4)
Statistical analysis description:	
Pooled MultiStem versus Pooled Placebo (Week 4)	
Comparison groups	Cohort 3: MultiStem 750, MultiStem 750 v Cohort 3: MultiStem 750, Placebo v Cohort 3: Placebo, MultiStem 750 v Cohort 3: Placebo, Placebo
Number of subjects included in analysis	88
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.34 [23]
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	1.21
Confidence interval	
level	Other: 80 %
sides	2-sided
lower limit	0.66
upper limit	2.19

Notes:

[23] - 1-sided p-value

Statistical analysis title	Rectal Bleeding Mayo Subscore of Zero (Week 8)

Statistical analysis description:	
Pooled MultiStem versus Pooled Placebo (Week 8)	
Comparison groups	Cohort 3: MultiStem 750, MultiStem 750 v Cohort 3: MultiStem 750, Placebo v Cohort 3: Placebo, MultiStem 750 v Cohort 3: Placebo, Placebo
Number of subjects included in analysis	88
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.33 [24]
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	1.23
Confidence interval	
level	Other: 80 %
sides	2-sided
lower limit	0.68
upper limit	2.23

Notes:

[24] - 1-sided p-value

Statistical analysis title	Rectal Bleeding Mayo Subscore of Zero (Week 12)
Statistical analysis description:	
Cohort 3 MM versus Cohort 3 PP (Week 12)	
Comparison groups	Cohort 3: MultiStem 750, MultiStem 750 v Cohort 3: Placebo, Placebo
Number of subjects included in analysis	44
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.1 [25]
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	2.37
Confidence interval	
level	Other: 80 %
sides	2-sided
lower limit	0.99
upper limit	5.67

Notes:

[25] - 1-sided p-value

Statistical analysis title	Rectal Bleeding Mayo Subscore of Zero (Week 12)
Statistical analysis description:	
Cohort 3 MP versus Cohort 3 PP (Week 12)	
Comparison groups	Cohort 3: MultiStem 750, Placebo v Cohort 3: Placebo, Placebo
Number of subjects included in analysis	46
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.74 [26]
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	0.66

Confidence interval	
level	Other: 80 %
sides	2-sided
lower limit	0.28
upper limit	1.55

Notes:

[26] - 1-sided p-value

Statistical analysis title	Rectal Bleeding Mayo Subscore of Zero (Week 12)

Statistical analysis description:

Cohort 3 PM versus Cohort 3 PP (Week 12)

Comparison groups	Cohort 3: Placebo, MultiStem 750 v Cohort 3: Placebo, Placebo
Number of subjects included in analysis	40
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.48 [27]
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	1.04
Confidence interval	
level	Other: 80 %
sides	2-sided
lower limit	0.41
upper limit	2.64

Notes:

[27] - 1-sided p-value

Statistical analysis title	Rectal Bleeding Mayo Subscore of Zero (Week 16)

Statistical analysis description:

Cohort 3 MM versus Cohort 3 PP (Week 16)

Comparison groups	Cohort 3: MultiStem 750, MultiStem 750 v Cohort 3: Placebo, Placebo
Number of subjects included in analysis	44
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.58 [28]
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	0.88
Confidence interval	
level	Other: 80 %
sides	2-sided
lower limit	0.38
upper limit	2.03

Notes:

[28] - 1-sided p-value

Statistical analysis title	Rectal Bleeding Mayo Subscore of Zero (Week 16)

Statistical analysis description:

Cohort 3 MP versus Cohort 3 PP (Week 16)

Comparison groups	Cohort 3: MultiStem 750, Placebo v Cohort 3: Placebo, Placebo
Number of subjects included in analysis	46
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.68 [29]
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	0.74
Confidence interval	
level	Other: 80 %
sides	2-sided
lower limit	0.33
upper limit	1.66

Notes:
[29] - 1-sided p-value

Statistical analysis title	Rectal Bleeding Mayo Subscore of Zero (Week 16)

Statistical analysis description:
Cohort 3 PM versus Cohort 3 PP (Week 16)

Comparison groups	Cohort 3: Placebo, MultiStem 750 v Cohort 3: Placebo, Placebo
Number of subjects included in analysis	40
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.84 [30]
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	0.51
Confidence interval	
level	Other: 80 %
sides	2-sided
lower limit	0.21
upper limit	1.23

Notes:
[30] - 1-sided p-value

Secondary: Percentage of Subjects in Endoscopic Remission at Week 8

End point title	Percentage of Subjects in Endoscopic Remission at Week 8

End point description:
Endoscopic remission is defined as modified Baron Endoscopic Score equal to 0.

End point type	Secondary

End point timeframe:
Week 8

End point values	Cohort 1: Placebo, MultiStem 300	Cohort 2: Placebo, MultiStem 750	Cohort 1: MultiStem 300, Placebo	Cohort 1: MultiStem 300 (x3), Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2	3	2	4
Units: percentage of subjects				
number (not applicable)	0	0	0	0

End point values	Cohort 2: MultiStem 750, Placebo	Cohort 3: MultiStem 750, MultiStem 750	Cohort 3: MultiStem 750, Placebo	Cohort 3: Placebo, MultiStem 750
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	23	25	19
Units: percentage of subjects				
number (not applicable)	16.7	4.3	4	0

End point values	Cohort 3: Placebo, Placebo			
Subject group type	Reporting group			
Number of subjects analysed	21			
Units: percentage of subjects				
number (not applicable)	9.5			

Statistical analyses

Statistical analysis title	Endoscopic Remission (Week 8)
Statistical analysis description: Pooled MultiStem versus Pooled Placebo	
Comparison groups	Cohort 3: MultiStem 750, MultiStem 750 v Cohort 3: MultiStem 750, Placebo v Cohort 3: Placebo, MultiStem 750 v Cohort 3: Placebo, Placebo
Number of subjects included in analysis	88
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.57 [31]
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	0.83
Confidence interval	
level	Other: 80 %
sides	2-sided
lower limit	0.22
upper limit	3.07

Notes:
[31] - 1-sided p-value

Secondary: Percentage of Subjects in Clinical Remission at Week 8

End point title	Percentage of Subjects in Clinical Remission at Week 8

End point description:

Clinical remission is defined as a total Mayo score of 2 points or lower, with no individual subscores exceeding 1 point.

End point type	Secondary

End point timeframe:

Week 8

End point values	Cohort 1: Placebo, MultiStem 300	Cohort 2: Placebo, MultiStem 750	Cohort 1: MultiStem 300, Placebo	Cohort 1: MultiStem 300 (x3), Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2	3	2	4
Units: percentage of subjects				
number (not applicable)	0	0	0	0

End point values	Cohort 2: MultiStem 750, Placebo	Cohort 3: MultiStem 750, MultiStem 750	Cohort 3: MultiStem 750, Placebo	Cohort 3: Placebo, MultiStem 750
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	23	25	19
Units: percentage of subjects				
number (not applicable)	0	0	8	0

End point values	Cohort 3: Placebo, Placebo			
Subject group type	Reporting group			
Number of subjects analysed	21			
Units: percentage of subjects				
number (not applicable)	19			

Statistical analyses

Statistical analysis title	Clinical Remission (Week 8)

Statistical analysis description:

Pooled MultiStem versus Pooled Placebo

Comparison groups	Cohort 3: MultiStem 750, MultiStem 750 v Cohort 3: MultiStem 750, Placebo v Cohort 3: Placebo, MultiStem 750 v Cohort 3:

	Placebo, Placebo
Number of subjects included in analysis	88
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.85 [32]
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	0.39
Confidence interval	
level	Other: 80 %
sides	2-sided
lower limit	0.12
upper limit	1.23

Notes:

[32] - 1-sided p-value

Secondary: Percentage of Subjects With Decrease From Baseline of at Least 1 Point in Rectal Bleeding Mayo Subscore at Weeks 4, 8, 12, and 16

End point title	Percentage of Subjects With Decrease From Baseline of at Least 1 Point in Rectal Bleeding Mayo Subscore at Weeks 4, 8, 12, and 16

End point description:

Mayo subscores for rectal bleeding range from 0 to 3 (0=no blood seen; 1=streaks of blood with stool less than half the time; 2=obvious blood with stool most of the time; 3=blood alone passes). A decrease from baseline score indicates improvement.

End point type	Secondary

End point timeframe:

Baseline, Weeks 4, 8, 12 and 16

End point values	Cohort 1: Placebo, MultiStem 300	Cohort 2: Placebo, MultiStem 750	Cohort 1: MultiStem 300, Placebo	Cohort 1: MultiStem 300 (x3), Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2	3	2	4
Units: percentage of subjects				
number (not applicable)				
Week 4	100	66.7	0	0
Week 8	100	33.3	0	0
Week 12	99999	99999	99999	99999
Week 16	100	66.7	0	25

End point values	Cohort 2: MultiStem 750, Placebo	Cohort 3: MultiStem 750, MultiStem 750	Cohort 3: MultiStem 750, Placebo	Cohort 3: Placebo, MultiStem 750
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	23	25	19
Units: percentage of subjects				
number (not applicable)				

Week 4	40	43.5	48	21.1
Week 8	40	34.8	48	31.6
Week 12	99999	54.5	60	41.2
Week 16	60	47.6	58.3	35.3

End point values	Cohort 3: Placebo, Placebo			
Subject group type	Reporting group			
Number of subjects analysed	21			
Units: percentage of subjects				
number (not applicable)				
Week 4	38.1			
Week 8	47.6			
Week 12	52.6			
Week 16	47.4			

Statistical analyses

Statistical analysis title	Rectal Bleeding Mayo Subscore (Week 4)
Statistical analysis description:	
Pooled MultiStem versus Pooled Placebo (Week 4)	
Comparison groups	Cohort 3: MultiStem 750, MultiStem 750 v Cohort 3: MultiStem 750, Placebo v Cohort 3: Placebo, MultiStem 750 v Cohort 3: Placebo, Placebo
Number of subjects included in analysis	88
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.05 [33]
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	2.27
Confidence interval	
level	Other: 80 %
sides	2-sided
lower limit	1.21
upper limit	4.24

Notes:

[33] - 1-sided p-value

Statistical analysis title	Rectal Bleeding Mayo Subscore (Week 8)
Statistical analysis description:	
Pooled MultiStem versus Pooled Placebo (Week 8)	
Comparison groups	Cohort 3: MultiStem 750, MultiStem 750 v Cohort 3: MultiStem 750, Placebo v Cohort 3: Placebo, MultiStem 750 v Cohort 3: Placebo, Placebo

Number of subjects included in analysis	88
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.43 [34]
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	1.09
Confidence interval	
level	Other: 80 %
sides	2-sided
lower limit	0.61
upper limit	1.95

Notes:

[34] - 1-sided p-value

Statistical analysis title	Rectal Bleeding Mayo Subscore (Week 12)
Statistical analysis description:	
Cohort 3 MM versus Cohort 3 PP (Week 12)	
Comparison groups	Cohort 3: MultiStem 750, MultiStem 750 v Cohort 3: Placebo, Placebo
Number of subjects included in analysis	44
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.44 [35]
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	1.11
Confidence interval	
level	Other: 80 %
sides	2-sided
lower limit	0.45
upper limit	2.76

Notes:

[35] - 1-sided p-value

Statistical analysis title	Rectal Bleeding Mayo Subscore (Week 12)
Statistical analysis description:	
Cohort 3 MP versus Cohort 3 PP (Week 12)	
Comparison groups	Cohort 3: MultiStem 750, Placebo v Cohort 3: Placebo, Placebo
Number of subjects included in analysis	46
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.38 [36]
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	1.23
Confidence interval	
level	Other: 80 %
sides	2-sided
lower limit	0.5
upper limit	3.04

Notes:
[36] - 1-sided p-value

Statistical analysis title	Rectal Bleeding Mayo Subscore (Week 12)
Statistical analysis description:	
Cohort 3 PM versus Cohort 3 PP (Week 12)	
Comparison groups	Cohort 3: Placebo, MultiStem 750 v Cohort 3: Placebo, Placebo
Number of subjects included in analysis	40
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.89 [37]
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	0.38
Confidence interval	
level	Other: 80 %
sides	2-sided
lower limit	0.14
upper limit	1.04

Notes:
[37] - 1-sided p-value

Statistical analysis title	Rectal Bleeding Mayo Subscore (Week 16)
Statistical analysis description:	
Cohort 3 MM versus Cohort 3 PP (Week 16)	
Comparison groups	Cohort 3: MultiStem 750, MultiStem 750 v Cohort 3: Placebo, Placebo
Number of subjects included in analysis	44
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.47 [38]
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	1.05
Confidence interval	
level	Other: 80 %
sides	2-sided
lower limit	0.45
upper limit	2.42

Notes:
[38] - 1-sided p-value

Statistical analysis title	Rectal Bleeding Mayo Subscore (Week 16)
Statistical analysis description:	
Cohort 3 MP versus Cohort 3 PP (Week 16)	
Comparison groups	Cohort 3: MultiStem 750, Placebo v Cohort 3: Placebo, Placebo

Number of subjects included in analysis	46
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.24 [39]
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	1.58
Confidence interval	
level	Other: 80 %
sides	2-sided
lower limit	0.7
upper limit	3.57

Notes:

[39] - 1-sided p-value

Statistical analysis title	Rectal Bleeding Mayo Subscore (Week 16)

Statistical analysis description:

Cohort 3 PM versus Cohort 3 PP (Week 16)

Comparison groups	Cohort 3: Placebo, MultiStem 750 v Cohort 3: Placebo, Placebo
Number of subjects included in analysis	40
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.81 [40]
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	0.53
Confidence interval	
level	Other: 80 %
sides	2-sided
lower limit	0.22
upper limit	1.32

Notes:

[40] - 1-sided p-value

Secondary: Percentage of Subjects With Endoscopic Response at Week 8

End point title	Percentage of Subjects With Endoscopic Response at Week 8

End point description:

Endoscopic response is defined as a decrease in modified Baron endoscopic score from baseline of at least 2 points.

End point type	Secondary

End point timeframe:

Week 8

End point values	Cohort 1: Placebo, MultiStem 300	Cohort 2: Placebo, MultiStem 750	Cohort 1: MultiStem 300, Placebo	Cohort 1: MultiStem 300 (x3), Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2	3	2	4
Units: percentage of subjects				
number (not applicable)	0	0	0	0

End point values	Cohort 2: MultiStem 750, Placebo	Cohort 3: MultiStem 750, MultiStem 750	Cohort 3: MultiStem 750, Placebo	Cohort 3: Placebo, MultiStem 750
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	23	25	19
Units: percentage of subjects				
number (not applicable)	0	8.7	8	10.5

End point values	Cohort 3: Placebo, Placebo			
Subject group type	Reporting group			
Number of subjects analysed	21			
Units: percentage of subjects				
number (not applicable)	19			

Statistical analyses

Statistical analysis title	Endoscopic Response (Week 8)
Statistical analysis description: Pooled MultiStem versus Pooled Placebo	
Comparison groups	Cohort 3: MultiStem 750, MultiStem 750 v Cohort 3: MultiStem 750, Placebo v Cohort 3: Placebo, MultiStem 750 v Cohort 3: Placebo, Placebo
Number of subjects included in analysis	88
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.84 [41]
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	0.49
Confidence interval	
level	Other: 80 %
sides	2-sided
lower limit	0.2
upper limit	1.24

Notes:
[41] - 1-sided p-value

Secondary: Percentage of Subjects in Clinical Response at Week 8

End point title	Percentage of Subjects in Clinical Response at Week 8

End point description:

Clinical response is defined as a decrease in total Mayo score from baseline of at least 3 points and at least 30 percent (%), with an accompanying decrease in the subscore for rectal bleeding of at least 1 point or an absolute subscore for rectal bleeding of 0 or 1.

End point type	Secondary

End point timeframe:

Week 8

End point values	Cohort 1: Placebo, MultiStem 300	Cohort 2: Placebo, MultiStem 750	Cohort 1: MultiStem 300, Placebo	Cohort 1: MultiStem 300 (x3), Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2	3	2	4
Units: percentage of subjects				
number (not applicable)	50	33.3	0	0

End point values	Cohort 2: MultiStem 750, Placebo	Cohort 3: MultiStem 750, MultiStem 750	Cohort 3: MultiStem 750, Placebo	Cohort 3: Placebo, MultiStem 750
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	23	25	19
Units: percentage of subjects				
number (not applicable)	0	4.3	24	15.8

End point values	Cohort 3: Placebo, Placebo			
Subject group type	Reporting group			
Number of subjects analysed	21			
Units: percentage of subjects				
number (not applicable)	42.9			

Statistical analyses

Statistical analysis title	Clinical Response (Week 8)

Statistical analysis description:

Pooled MultiStem versus Pooled Placebo

Comparison groups	Cohort 3: MultiStem 750, MultiStem 750 v Cohort 3: MultiStem

	750, Placebo v Cohort 3: Placebo, MultiStem 750 v Cohort 3: Placebo, Placebo
Number of subjects included in analysis	88
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.96 [42]
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	0.3
Confidence interval	
level	Other: 80 %
sides	2-sided
lower limit	0.12
upper limit	0.73

Notes:

[42] - 1-sided p-value

Secondary: Change From Baseline in Total Mayo Scores at Week 8

End point title	Change From Baseline in Total Mayo Scores at Week 8

End point description:

Mayo Score is an instrument designed to measure disease activity of ulcerative colitis, with total score ranging from 0 to 12. It consists of 4 subscores (stool frequency, rectal bleeding, findings of flexible proctosigmoidoscopy, and physician global assessment [PGA]), each graded from 0 to 3, with higher scores indicating more severe disease.

End point type	Secondary

End point timeframe:

Baseline, Week 8

End point values	Cohort 1: Placebo, MultiStem 300	Cohort 2: Placebo, MultiStem 750	Cohort 1: MultiStem 300, Placebo	Cohort 1: MultiStem 300 (x3), Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2	3	2	4
Units: scores on a scale				
arithmetic mean (standard deviation)				
Baseline (n=2,3,2,4,6,23,25,19,21)	10 (± 2.828)	7.33 (± 1.155)	8.5 (± 0.707)	7.75 (± 0.957)
Change at Week 8 (n=2,3,2,3,5,23,25,19,21)	-2 (± 1.414)	0 (± 2.646)	1 (± 1.414)	0.33 (± 0.577)

End point values	Cohort 2: MultiStem 750, Placebo	Cohort 3: MultiStem 750, MultiStem 750	Cohort 3: MultiStem 750, Placebo	Cohort 3: Placebo, MultiStem 750
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	23	25	19
Units: scores on a scale				
arithmetic mean (standard deviation)				
Baseline (n=2,3,2,4,6,23,25,19,21)	7.5 (± 2.258)	8.74 (± 1.839)	8.48 (± 2.143)	8.47 (± 1.806)
Change at Week 8 (n=2,3,2,3,5,23,25,19,21)	-0.6 (± 0.894)	-0.78 (± 2.066)	-1.2 (± 2.872)	-0.89 (± 2.132)

End point values	Cohort 3: Placebo, Placebo			
Subject group type	Reporting group			
Number of subjects analysed	21			
Units: scores on a scale				
arithmetic mean (standard deviation)				
Baseline (n=2,3,2,4,6,23,25,19,21) Change at Week 8 (n=2,3,2,3,5,23,25,19,21)	8.14 (± 2.2) -2 (± 2.683)			

Statistical analyses

Statistical analysis title	Total Mayo Scores (Week 8)
Statistical analysis description: Pooled MultiStem versus Pooled Placebo	
Comparison groups	Cohort 3: MultiStem 750, MultiStem 750 v Cohort 3: MultiStem 750, Placebo v Cohort 3: Placebo, MultiStem 750 v Cohort 3: Placebo, Placebo
Number of subjects included in analysis	88
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.87 [43]
Method	ANCOVA
Parameter estimate	Mean difference (final values)
Point estimate	0.58
Confidence interval	
level	Other: 80 %
sides	2-sided
lower limit	-0.08
upper limit	1.24
Variability estimate	Standard error of the mean
Dispersion value	0.513

Notes:

[43] - 1-sided p-value

Secondary: Change From Baseline in Partial Mayo Scores at Weeks 4, 8, 12, and 16

End point title	Change From Baseline in Partial Mayo Scores at Weeks 4, 8, 12, and 16

End point description:

A Partial Mayo Score (Mayo score without endoscopy) ranges from 0 (normal or inactive disease) to 9 (severe disease) and calculated as the sum of 3 subscores (stool frequency, rectal bleeding and PGA) with each ranging from 0 to 3 (0=normal, 1=mild, 2=moderate, 3=severe). Higher scores indicate more severe disease.

End point type	Secondary

End point timeframe:

Baseline, Weeks 4, 8, 12 and 16

End point values	Cohort 1: Placebo, MultiStem 300	Cohort 2: Placebo, MultiStem 750	Cohort 1: MultiStem 300, Placebo	Cohort 1: MultiStem 300 (x3), Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2	3	2	4
Units: scores on a scale				
arithmetic mean (standard deviation)				
Baseline (n=2,3,2,4,6,23,25,19,21)	7.5 (± 2.121)	5.33 (± 0.577)	6 (± 1.414)	5.75 (± 0.5)
Change at Week 4 (n=2,3,2,3,5,23,25,19,21)	-3 (± 0)	-2 (± 1.732)	-0.5 (± 0.707)	0.67 (± 1.528)
Change at Week 8 (n=2,3,2,3,5,23,25,19,21)	-2 (± 1.414)	-1 (± 1.732)	0.5 (± 0.707)	0.33 (± 0.577)
Change at Week 12 (n=0,0,0,0,0,22,25,17,19)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
Change at Week 16 (2,3,2,4,5,21,24,17,19)	-1.5 (± 0.707)	-3 (± 3)	-1 (± 2.828)	-1.25 (± 3.403)

End point values	Cohort 2: MultiStem 750, Placebo	Cohort 3: MultiStem 750, MultiStem 750	Cohort 3: MultiStem 750, Placebo	Cohort 3: Placebo, MultiStem 750
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	23	25	19
Units: scores on a scale				
arithmetic mean (standard deviation)				
Baseline (n=2,3,2,4,6,23,25,19,21)	5.5 (± 1.378)	6.22 (± 1.347)	6.08 (± 1.605)	6 (± 1.202)
Change at Week 4 (n=2,3,2,3,5,23,25,19,21)	-0.4 (± 1.14)	-1 (± 1.414)	-0.96 (± 1.791)	-1.16 (± 1.675)
Change at Week 8 (n=2,3,2,3,5,23,25,19,21)	-0.8 (± 1.095)	-0.91 (± 1.756)	-1.12 (± 2.472)	-0.79 (± 1.653)
Change at Week 12 (n=0,0,0,0,0,22,25,17,19)	99999 (± 99999)	-1.91 (± 1.974)	-1.52 (± 2.312)	-2.06 (± 2.135)
Change at Week 16 (2,3,2,4,5,21,24,17,19)	-2.2 (± 1.924)	-1.86 (± 2.061)	-2.54 (± 2.621)	-2.41 (± 2.181)

End point values	Cohort 3: Placebo, Placebo			
Subject group type	Reporting group			
Number of subjects analysed	21			
Units: scores on a scale				
arithmetic mean (standard deviation)				
Baseline (n=2,3,2,4,6,23,25,19,21)	5.71 (± 1.736)			
Change at Week 4 (n=2,3,2,3,5,23,25,19,21)	-1.24 (± 1.895)			
Change at Week 8 (n=2,3,2,3,5,23,25,19,21)	-1.62 (± 2.037)			
Change at Week 12 (n=0,0,0,0,0,22,25,17,19)	-2.11 (± 2.622)			

Change at Week 16 (2,3,2,4,5,21,24,17,19)	-2.63 (± 2.033)			

Statistical analyses

Statistical analysis title	Partial Mayo Scores (Week 4)
Statistical analysis description:	
Pooled MultiStem versus Pooled Placebo (Week 4)	
Comparison groups	Cohort 3: MultiStem 750, MultiStem 750 v Cohort 3: MultiStem 750, Placebo v Cohort 3: Placebo, MultiStem 750 v Cohort 3: Placebo, Placebo
Number of subjects included in analysis	88
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.8 [44]
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	0.29
Confidence interval	
level	Other: 80 %
sides	2-sided
lower limit	-0.15
upper limit	0.74
Variability estimate	Standard error of the mean
Dispersion value	0.345

Notes:

[44] - 1-sided p-value

Statistical analysis title	Partial Mayo Scores (Week 8)
Statistical analysis description:	
Pooled MultiStem versus Pooled Placebo (Week 8)	
Comparison groups	Cohort 3: MultiStem 750, MultiStem 750 v Cohort 3: MultiStem 750, Placebo v Cohort 3: Placebo, MultiStem 750 v Cohort 3: Placebo, Placebo
Number of subjects included in analysis	88
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.77 [45]
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	0.3
Confidence interval	
level	Other: 80 %
sides	2-sided
lower limit	-0.23
upper limit	0.84
Variability estimate	Standard error of the mean
Dispersion value	0.418

Notes:
[45] - 1-sided p-value

Statistical analysis title	Partial Mayo Scores (Week 12)
Statistical analysis description:	
Cohort 3 MM versus Cohort 3 PP (Week 12)	
Comparison groups	Cohort 3: MultiStem 750, MultiStem 750 v Cohort 3: Placebo, Placebo
Number of subjects included in analysis	44
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.74 [46]
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	0.44
Confidence interval	
level	Other: 80 %
sides	2-sided
lower limit	-0.42
upper limit	1.3
Variability estimate	Standard error of the mean
Dispersion value	0.666

Notes:
[46] - 1-sided p-value

Statistical analysis title	Partial Mayo Scores (Week 12)
Statistical analysis description:	
Cohort 3 MP versus Cohort 3 PP (Week 12)	
Comparison groups	Cohort 3: MultiStem 750, Placebo v Cohort 3: Placebo, Placebo
Number of subjects included in analysis	46
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.88 [47]
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	0.76
Confidence interval	
level	Other: 80 %
sides	2-sided
lower limit	-0.08
upper limit	1.59
Variability estimate	Standard error of the mean
Dispersion value	0.645

Notes:
[47] - 1-sided p-value

Statistical analysis title	Partial Mayo Scores (Week 12)
Statistical analysis description:	
Cohort 3 PM versus Cohort 3 PP (Week 12)	
Comparison groups	Cohort 3: Placebo, MultiStem 750 v Cohort 3: Placebo, Placebo

Number of subjects included in analysis	40
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.72 [48]
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	0.42
Confidence interval	
level	Other: 80 %
sides	2-sided
lower limit	-0.5
upper limit	1.33
Variability estimate	Standard error of the mean
Dispersion value	0.705

Notes:

[48] - 1-sided p-value

Statistical analysis title	Partial Mayo Scores (Week 16)
Statistical analysis description:	
Cohort 3 MM versus Cohort 3 PP (Week 16)	
Comparison groups	Cohort 3: MultiStem 750, MultiStem 750 v Cohort 3: Placebo, Placebo
Number of subjects included in analysis	44
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.97 [49]
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	1.21
Confidence interval	
level	Other: 80 %
sides	2-sided
lower limit	0.37
upper limit	2.06
Variability estimate	Standard error of the mean
Dispersion value	0.656

Notes:

[49] - 1-sided p-value

Statistical analysis title	Partial Mayo Scores (Week 16)
Statistical analysis description:	
Cohort 3 MP versus Cohort 3 PP (Week 16)	
Comparison groups	Cohort 3: MultiStem 750, Placebo v Cohort 3: Placebo, Placebo
Number of subjects included in analysis	46
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.75 [50]
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	0.43

Confidence interval	
level	Other: 80 %
sides	2-sided
lower limit	-0.39
upper limit	1.25
Variability estimate	Standard error of the mean
Dispersion value	0.635

Notes:

[50] - 1-sided p-value

Statistical analysis title	Partial Mayo Scores (Week 16)

Statistical analysis description:

Cohort 3 PM versus Cohort 3 PP (Week 16)

Comparison groups	Cohort 3: Placebo, MultiStem 750 v Cohort 3: Placebo, Placebo
Number of subjects included in analysis	40
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.85 [51]
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	0.73
Confidence interval	
level	Other: 80 %
sides	2-sided
lower limit	-0.16
upper limit	1.63
Variability estimate	Standard error of the mean
Dispersion value	0.692

Notes:

[51] - 1-sided p-value

Secondary: Change From Baseline in Biopsy Histology Scores at Week 8

End point title	Change From Baseline in Biopsy Histology Scores at Week 8

End point description:

A 15 to 25 centimeter (cm) biopsy sample of inflamed mucosal tissue was taken from the worst affected area and scored using the Riley Index. The Riley Index is a histologic scoring system for the assessment of the activity and severity of ulcerative colitis; it consists of 6 histologic features (acute inflammatory cell infiltrate, crypt abscesses, mucin depletion, surface epithelial integrity, chronic inflammatory cell infiltrate, and crypt architectural irregularities), all scored on a 4-point scale (higher scores indicate more severe disease).

End point type	Secondary

End point timeframe:

Baseline and Week 8

End point values	Cohort 1: Placebo, MultiStem 300	Cohort 2: Placebo, MultiStem 750	Cohort 1: MultiStem 300, Placebo	Cohort 1: MultiStem 300 (x3), Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2	3	2	4
Units: scores on a scale				
arithmetic mean (standard deviation)				
Baseline(n=2,3,2,4,5,22,24,18,21)	9 (± 1.41)	9.7 (± 3.79)	11 (± 2.83)	7 (± 3.92)
Change at Week 4 (n=2,3,1,3,5,21,24,15,20)	-3.5 (± 4.95)	1.3 (± 1.15)	-3 (± 99999)	-1 (± 1.73)

End point values	Cohort 2: MultiStem 750, Placebo	Cohort 3: MultiStem 750, MultiStem 750	Cohort 3: MultiStem 750, Placebo	Cohort 3: Placebo, MultiStem 750
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	23	25	19
Units: scores on a scale				
arithmetic mean (standard deviation)				
Baseline(n=2,3,2,4,5,22,24,18,21)	10.8 (± 3.77)	9.4 (± 4.37)	10.4 (± 4.24)	9.9 (± 4.17)
Change at Week 4 (n=2,3,1,3,5,21,24,15,20)	-0.4 (± 2.07)	1.4 (± 4.63)	-1 (± 3.76)	0.9 (± 4.09)

End point values	Cohort 3: Placebo, Placebo			
Subject group type	Reporting group			
Number of subjects analysed	21			
Units: scores on a scale				
arithmetic mean (standard deviation)				
Baseline(n=2,3,2,4,5,22,24,18,21)	9.7 (± 5.14)			
Change at Week 4 (n=2,3,1,3,5,21,24,15,20)	-1.5 (± 4.8)			

Statistical analyses

Statistical analysis title	Biopsy Histology Scores (Week 8)
Statistical analysis description: Pooled MultiStem versus Pooled Placebo	
Comparison groups	Cohort 3: MultiStem 750, MultiStem 750 v Cohort 3: MultiStem 750, Placebo v Cohort 3: Placebo, MultiStem 750 v Cohort 3: Placebo, Placebo
Number of subjects included in analysis	88
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.75 [52]
Method	ANCOVA
Parameter estimate	Mean difference (final values)
Point estimate	0.52

Confidence interval	
level	Other: 80 %
sides	2-sided
lower limit	-0.46
upper limit	1.49
Variability estimate	Standard error of the mean
Dispersion value	0.753

Notes:

[52] - 1-sided p-value

Secondary: Change From Baseline in Patient-Reported Rectal Bleeding up to Week 16

End point title	Change From Baseline in Patient-Reported Rectal Bleeding up to Week 16

End point description:

Patient-reported diary data assessed the number of bowel movements (BM) per day when not having a flare and the presence of blood in the stools (rectal bleeding [RB]), if any.

End point type	Secondary

End point timeframe:

Baseline and Week 16

End point values	Cohort 1: Placebo, MultiStem 300	Cohort 2: Placebo, MultiStem 750	Cohort 1: MultiStem 300, Placebo	Cohort 1: MultiStem 300 (x3), Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2	3	2	4
Units: scores on a scale				
arithmetic mean (standard deviation)				
BM: Baseline(n=2,3,2,4,6,23,25,19,21)	12.5 (± 4.95)	8 (± 2.784)	6.75 (± 2.475)	11.75 (± 10.506)
BM: Change at Week 1 (n=2,3,2,4,5,23,25,19,21)	-1.6 (± 2.263)	-1.89 (± 1.786)	4.15 (± 2.845)	-0.6 (± 2.177)
BM: Change at Week 4 (n=2,2,2,3,5,23,23,16,19	-1.43 (± 3.435)	-1.89 (± 5.101)	2.36 (± 0.505)	0.17 (± 2.038)
BM: Change at Week 8 (n=2,3,2,3,6,23,23,16,19)	-1.67 (± 3.771)	-0.86 (± 3.517)	3.18 (± 0.758)	0.17 (± 2.754)
BM: Change at Week 12 (n=1,1,1,2,2,21,25,16,18)	0.14 (± 99999)	1.43 (± 99999)	1.57 (± 99999)	-1.68 (± 2.374)
BM: Change at Week 16 (n=1,3,2,3,4,22,24,16,18)	0 (± 99999)	-2.51 (± 3.716)	1.72 (± 0.596)	-0.12 (± 2.324)
RB: Baseline (n=2,3,2,4,6,23,25,19,21)	1.25 (± 1.061)	1.17 (± 1.258)	1 (± 1.414)	1 (± 0.816)
RB: Change at Week 1 (n=2,3,2,4,5,23,25,19,21)	-0.32 (± 0.253)	-1 (± 1.167)	-0.33 (± 0.471)	-0.12 (± 0.158)
RB: Change at Week 4 (n=2,2,2,3,5,23,23,16,19)	-0.75 (± 0.354)	-0.29 (± 1.01)	-0.25 (± 0.354)	0.14 (± 0.378)
RB: Change at Week 8 (n=2,3,2,3,6,22,23,13,20)	-0.75 (± 0.354)	-0.5 (± 0.5)	0 (± 0)	0.33 (± 0.577)
RB: Change at Week 12 (n=1,1,1,2,2,21,25,16,18)	-0.57 (± 99999)	0 (± 99999)	0 (± 99999)	0 (± 0)
RB: Change at Week 16 (n=1,3,2,3,4,22,24,16,18)	-1 (± 99999)	-1.17 (± 1.258)	-0.1 (± 0.141)	0.33 (± 0.577)

End point values	Cohort 2: MultiStem 750, Placebo	Cohort 3: MultiStem 750, MultiStem 750	Cohort 3: MultiStem 750, Placebo	Cohort 3: Placebo, MultiStem 750
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	23	25	19
Units: scores on a scale				
arithmetic mean (standard deviation)				
BM: Baseline(n=2,3,2,4,6,23,25,19,21)	8.42 (± 3.089)	7.5 (± 3.49)	7.78 (± 3.781)	7.5 (± 3.571)
BM: Change at Week 1 (n=2,3,2,4,5,23,25,19,21)	0.4 (± 1.3)	-0.42 (± 1.509)	-0.59 (± 1.657)	-0.56 (± 1.215)
BM: Change at Week 4 (n=2,2,2,3,5,23,23,16,19	1.31 (± 1.432)	-0.81 (± 2.088)	0.28 (± 3.956)	-0.63 (± 1.856)
BM: Change at Week 8 (n=2,3,2,3,6,23,23,16,19)	0.41 (± 2.131)	-0.89 (± 2.864)	-1.15 (± 2.833)	0.18 (± 2.531)
BM: Change at Week 12 (n=1,1,1,2,2,21,25,16,18)	0 (± 0)	-0.67 (± 3.152)	-0.59 (± 4.428)	-1.77 (± 2.301)
BM: Change at Week 16 (n=1,3,2,3,4,22,24,16,18)	-2.45 (± 2.208)	-1.81 (± 3.278)	-2.17 (± 3.523)	-1.68 (± 2.899)
RB: Baseline (n=2,3,2,4,6,23,25,19,21)	1.33 (± 0.816)	1.2 (± 0.974)	1.46 (± 0.978)	0.97 (± 0.95)
RB: Change at Week 1 (n=2,3,2,4,5,23,25,19,21)	-0.3 (± 0.415)	-0.36 (± 0.697)	-0.24 (± 0.805)	-0.05 (± 0.574)
RB: Change at Week 4 (n=2,2,2,3,5,23,23,16,19)	-0.71 (± 0.99)	-0.34 (± 0.863)	-0.47 (± 0.84)	-0.27 (± 0.738)
RB: Change at Week 8 (n=2,3,2,3,6,22,23,13,20)	-0.47 (± 1.035)	-0.4 (± 0.709)	-0.51 (± 0.805)	-0.19 (± 0.997)
RB: Change at Week 12 (n=1,1,1,2,2,21,25,16,18)	0 (± 0)	-0.6 (± 0.792)	-0.49 (± 1.084)	-0.48 (± 0.829)
RB: Change at Week 16 (n=1,3,2,3,4,22,24,16,18)	-1.14 (± 0.865)	-0.41 (± 0.936)	-0.86 (± 1.106)	-0.41 (± 0.838)

End point values	Cohort 3: Placebo, Placebo			
Subject group type	Reporting group			
Number of subjects analysed	21			
Units: scores on a scale				
arithmetic mean (standard deviation)				
BM: Baseline(n=2,3,2,4,6,23,25,19,21)	6.88 (± 4.886)			
BM: Change at Week 1 (n=2,3,2,4,5,23,25,19,21)	-0.81 (± 3.421)			
BM: Change at Week 4 (n=2,2,2,3,5,23,23,16,19	-1.08 (± 2.575)			
BM: Change at Week 8 (n=2,3,2,3,6,23,23,16,19)	-1.41 (± 3.208)			
BM: Change at Week 12 (n=1,1,1,2,2,21,25,16,18)	-2.02 (± 3.502)			
BM: Change at Week 16 (n=1,3,2,3,4,22,24,16,18)	-1.86 (± 3.616)			
RB: Baseline (n=2,3,2,4,6,23,25,19,21)	1.05 (± 0.82)			
RB: Change at Week 1 (n=2,3,2,4,5,23,25,19,21)	-0.1 (± 0.408)			

RB: Change at Week 4 (n=2,2,2,3,5,23,23,16,19)	-0.26 (± 0.604)			
RB: Change at Week 8 (n=2,3,2,3,6,22,23,13,20)	-0.51 (± 0.967)			
RB: Change at Week 12 (n=1,1,1,2,2,21,25,16,18)	-0.39 (± 0.783)			
RB: Change at Week 16 (n=1,3,2,3,4,22,24,16,18)	-0.39 (± 0.874)			

Statistical analyses

Statistical analysis title	Patient-Reported Rectal Bleeding up to Week 16
Statistical analysis description: Pooled MultiStem versus Pooled Placebo (Week 4)	
Comparison groups	Cohort 3: MultiStem 750, MultiStem 750 v Cohort 3: MultiStem 750, Placebo v Cohort 3: Placebo, MultiStem 750 v Cohort 3: Placebo, Placebo
Number of subjects included in analysis	88
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.51 [53]
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	0
Confidence interval	
level	Other: 80 %
sides	2-sided
lower limit	-0.18
upper limit	0.19
Variability estimate	Standard error of the mean
Dispersion value	0.144

Notes:

[53] - 1-sided p-value

Statistical analysis title	Patient-Reported Rectal Bleeding up to Week 16
Statistical analysis description: Pooled MultiStem versus Pooled Placebo (Week 8)	
Comparison groups	Cohort 3: MultiStem 750, MultiStem 750 v Cohort 3: MultiStem 750, Placebo v Cohort 3: Placebo, MultiStem 750 v Cohort 3: Placebo, Placebo
Number of subjects included in analysis	88
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.62 [54]
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	0.05

Confidence interval	
level	Other: 80 %
sides	2-sided
lower limit	-0.16
upper limit	0.25
Variability estimate	Standard error of the mean
Dispersion value	0.158

Notes:

[54] - 1-sided p-value

Statistical analysis title	Patient-Reported Rectal Bleeding up to Week 16
Statistical analysis description:	
Cohort 3 MM versus Cohort 3 PP (Week 12)	
Comparison groups	Cohort 3: MultiStem 750, MultiStem 750 v Cohort 3: Placebo, Placebo
Number of subjects included in analysis	44
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.29 [55]
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-0.12
Confidence interval	
level	Other: 80 %
sides	2-sided
lower limit	-0.39
upper limit	0.16
Variability estimate	Standard error of the mean
Dispersion value	0.213

Notes:

[55] - 1-sided p-value

Statistical analysis title	Patient-Reported Rectal Bleeding up to Week 16
Statistical analysis description:	
Cohort 3 MP versus Cohort 3 PP (Week 12)	
Comparison groups	Cohort 3: MultiStem 750, Placebo v Cohort 3: Placebo, Placebo
Number of subjects included in analysis	46
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.74 [56]
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	0.13
Confidence interval	
level	Other: 80 %
sides	2-sided
lower limit	-0.14
upper limit	0.4
Variability estimate	Standard error of the mean
Dispersion value	0.209

Notes:
[56] - 1-sided p-value

Statistical analysis title	Patient-Reported Rectal Bleeding up to Week 16
Statistical analysis description:	
Cohort 3 PM versus Cohort 3 PP (Week 12)	
Comparison groups	Cohort 3: Placebo, MultiStem 750 v Cohort 3: Placebo, Placebo
Number of subjects included in analysis	40
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.36 [57]
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-0.08
Confidence interval	
level	Other: 80 %
sides	2-sided
lower limit	-0.37
upper limit	0.21
Variability estimate	Standard error of the mean
Dispersion value	0.226

Notes:
[57] - 1-sided p-value

Statistical analysis title	Patient-Reported Rectal Bleeding up to Week 16
Statistical analysis description:	
Cohort 3 MM versus Cohort 3 PP (Week 16)	
Comparison groups	Cohort 3: MultiStem 750, MultiStem 750 v Cohort 3: Placebo, Placebo
Number of subjects included in analysis	44
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.56 [58]
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	0.04
Confidence interval	
level	Other: 80 %
sides	2-sided
lower limit	-0.26
upper limit	0.34
Variability estimate	Standard error of the mean
Dispersion value	0.234

Notes:
[58] - 1-sided p-value

Statistical analysis title	Patient-Reported Rectal Bleeding up to Week 16
Statistical analysis description:	
Cohort 3 MP versus Cohort 3 PP (Week 16)	
Comparison groups	Cohort 3: MultiStem 750, Placebo v Cohort 3: Placebo, Placebo

Number of subjects included in analysis	46
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.18 [59]
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-0.21
Confidence interval	
level	Other: 80 %
sides	2-sided
lower limit	-0.51
upper limit	0.09
Variability estimate	Standard error of the mean
Dispersion value	0.231

Notes:

[59] - 1-sided p-value

Statistical analysis title	Patient-Reported Rectal Bleeding up to Week 16

Statistical analysis description:

Cohort 3 PM versus Cohort 3 PP (Week 16)

Comparison groups	Cohort 3: Placebo, MultiStem 750 v Cohort 3: Placebo, Placebo
Number of subjects included in analysis	40
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.31 [60]
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-0.12
Confidence interval	
level	Other: 80 %
sides	2-sided
lower limit	-0.45
upper limit	0.2
Variability estimate	Standard error of the mean
Dispersion value	0.25

Notes:

[60] - 1-sided p-value

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Baseline up to 28 days after last study drug administration.

Adverse event reporting additional description:

The same event may appear as both an AE and a SAE. However, what is presented are distinct events. An event may be categorized as serious in 1 subject and as non-serious in another, or 1 subject may have experienced both an AE and SAE during the study. All treated subjects were included in the analysis.

Assessment type	Non-systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	17.1

Reporting groups

Reporting group title	Cohort 1: Placebo, MultiStem 300

Reporting group description:

Subjects received a single dose (Day 1) or 3 doses (Day 1, Week 1, Week 2) of placebo infusion, followed by a single dose of MultiStem 300 Million Cells infusion at Week 8.

Reporting group title	Cohort 1: MultiStem 300, Placebo

Reporting group description:

Subjects received a single dose of MultiStem 300 Million Cells infusion on Day 1, followed by a single dose of placebo infusion at Week 8.

Reporting group title	Cohort 2: Placebo, MultiStem 750

Reporting group description:

Subjects received a single dose of placebo infusion on Day 1, followed by a single dose of MultiStem 750 Million Cells infusion at Week 8.

Reporting group title	Cohort 1: MultiStem 300 (x3), Placebo

Reporting group description:

Subjects received up to 3 doses of MultiStem 300 Million Cells infusion (Day 1, Week, Week 2), followed by a single dose of placebo infusion at Week 8.

Reporting group title	Cohort 3: MultiStem 750, MultiStem 750

Reporting group description:

Subjects received a single dose of MultiStem 750 Million Cells infusion on Day 1, followed by a single dose of MultiStem 750 Million Cells infusion at Week 8.

Reporting group title	Cohort 2: MultiStem 750, Placebo

Reporting group description:

Subjects received a single dose of MultiStem 750 Million Cells infusion on Day 1, followed by a single dose of placebo infusion at Week 8.

Reporting group title	Cohort 3: MultiStem 750, Placebo

Reporting group description:

Subjects received a single dose of MultiStem 750 Million Cells infusion on Day 1, followed by a single dose of placebo infusion at Week 8.

Reporting group title	Cohort 3: Placebo, MultiStem 750

Reporting group description:

Subjects received a single dose of placebo infusion on Day 1, followed by a single dose of MultiStem 750 Million Cells infusion at Week 8.

Reporting group title	Cohort 3: Placebo, Placebo

Reporting group description:

Subjects received a single dose of placebo infusion on Day 1, followed by a single dose of placebo infusion at Week 8.

Serious adverse events	Cohort 1: Placebo, MultiStem 300	Cohort 1: MultiStem 300, Placebo	Cohort 2: Placebo, MultiStem 750
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 2 (50.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Adenocarcinoma of colon			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Diastolic hypertension			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Ventricular tachycardia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Epilepsy			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Superior sagittal sinus thrombosis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			

subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancytopenia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Hypersensitivity			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis ulcerative			
subjects affected / exposed	1 / 2 (50.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			

Abdominal abscess			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium difficile colitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium difficile infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pelvic sepsis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Perirectal abscess			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Cohort 1: MultiStem 300 (x3), Placebo	Cohort 3: MultiStem 750, MultiStem 750	Cohort 2: MultiStem 750, Placebo
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 4 (75.00%)	7 / 23 (30.43%)	0 / 6 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0

Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Adenocarcinoma of colon			
subjects affected / exposed	0 / 4 (0.00%)	1 / 23 (4.35%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Diastolic hypertension			
subjects affected / exposed	0 / 4 (0.00%)	0 / 23 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Ventricular tachycardia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 23 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Epilepsy			
subjects affected / exposed	0 / 4 (0.00%)	0 / 23 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Superior sagittal sinus thrombosis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 23 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 4 (0.00%)	1 / 23 (4.35%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancytopenia			
subjects affected / exposed	0 / 4 (0.00%)	1 / 23 (4.35%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Hypersensitivity			

subjects affected / exposed	1 / 4 (25.00%)	0 / 23 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 4 (0.00%)	1 / 23 (4.35%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis			
subjects affected / exposed	1 / 4 (25.00%)	0 / 23 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis ulcerative			
subjects affected / exposed	1 / 4 (25.00%)	5 / 23 (21.74%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 7	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			
subjects affected / exposed	0 / 4 (0.00%)	1 / 23 (4.35%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	0 / 4 (0.00%)	1 / 23 (4.35%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Abdominal abscess			
subjects affected / exposed	0 / 4 (0.00%)	1 / 23 (4.35%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium difficile colitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 23 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium difficile infection			

subjects affected / exposed	0 / 4 (0.00%)	0 / 23 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 23 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pelvic sepsis			
subjects affected / exposed	0 / 4 (0.00%)	1 / 23 (4.35%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Perirectal abscess			
subjects affected / exposed	0 / 4 (0.00%)	1 / 23 (4.35%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 23 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Cohort 3: MultiStem 750, Placebo	Cohort 3: Placebo, MultiStem 750	Cohort 3: Placebo, Placebo
Total subjects affected by serious adverse events			
subjects affected / exposed	4 / 25 (16.00%)	5 / 19 (26.32%)	4 / 21 (19.05%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Adenocarcinoma of colon			
subjects affected / exposed	0 / 25 (0.00%)	0 / 19 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Diastolic hypertension			

subjects affected / exposed	0 / 25 (0.00%)	1 / 19 (5.26%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Ventricular tachycardia			
subjects affected / exposed	0 / 25 (0.00%)	0 / 19 (0.00%)	1 / 21 (4.76%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Epilepsy			
subjects affected / exposed	0 / 25 (0.00%)	1 / 19 (5.26%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Superior sagittal sinus thrombosis			
subjects affected / exposed	0 / 25 (0.00%)	0 / 19 (0.00%)	1 / 21 (4.76%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 25 (0.00%)	0 / 19 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancytopenia			
subjects affected / exposed	0 / 25 (0.00%)	0 / 19 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Hypersensitivity			
subjects affected / exposed	0 / 25 (0.00%)	0 / 19 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal pain			

subjects affected / exposed	0 / 25 (0.00%)	0 / 19 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis			
subjects affected / exposed	1 / 25 (4.00%)	0 / 19 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis ulcerative			
subjects affected / exposed	1 / 25 (4.00%)	2 / 19 (10.53%)	3 / 21 (14.29%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			
subjects affected / exposed	0 / 25 (0.00%)	0 / 19 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	0 / 25 (0.00%)	0 / 19 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Abdominal abscess			
subjects affected / exposed	0 / 25 (0.00%)	0 / 19 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium difficile colitis			
subjects affected / exposed	0 / 25 (0.00%)	0 / 19 (0.00%)	1 / 21 (4.76%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium difficile infection			
subjects affected / exposed	1 / 25 (4.00%)	1 / 19 (5.26%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			

subjects affected / exposed	1 / 25 (4.00%)	0 / 19 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pelvic sepsis			
subjects affected / exposed	0 / 25 (0.00%)	0 / 19 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Perirectal abscess			
subjects affected / exposed	0 / 25 (0.00%)	0 / 19 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 25 (0.00%)	1 / 19 (5.26%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Frequency threshold for reporting non-serious adverse events: 5 %

Non-serious adverse events	Cohort 1: Placebo, MultiStem 300	Cohort 1: MultiStem 300, Placebo	Cohort 2: Placebo, MultiStem 750
Total subjects affected by non-serious adverse events			
subjects affected / exposed	2 / 2 (100.00%)	0 / 2 (0.00%)	3 / 3 (100.00%)
Vascular disorders			
Flushing			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hot flush			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypertension			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Surgical and medical procedures			
Ileostomy			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Chest discomfort			
subjects affected / exposed	1 / 2 (50.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Chest pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Chills			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Fatigue			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Influenza like illness			
subjects affected / exposed	1 / 2 (50.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Oedema peripheral			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Pyrexia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	1 / 2 (50.00%)	0 / 2 (0.00%)	1 / 3 (33.33%)
occurrences (all)	1	0	1
Dyspnoea			
subjects affected / exposed	1 / 2 (50.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Epistaxis			

subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Nasal congestion			
subjects affected / exposed	1 / 2 (50.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Oropharyngeal pain			
subjects affected / exposed	1 / 2 (50.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Psychiatric disorders			
Anxiety			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Confusional state			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Depression			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Investigations			
Antibody test			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Bacterial test			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood albumin decreased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood bilirubin increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood glucose increased			

subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood urine present			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
C-reactive protein increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Cold agglutinins			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Heart rate increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Prostatic specific antigen increased			
subjects affected / exposed[1]	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Weight decreased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Contusion			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Fall			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Incision site pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Laceration			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Skeletal injury			

subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Cardiac disorders			
Tachycardia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Amnesia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dizziness			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Epilepsy			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Lethargy			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Paraesthesia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Lymphadenopathy			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Vertigo			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			

Abdominal pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Abdominal pain upper			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Abdominal tenderness			
subjects affected / exposed	1 / 2 (50.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Colitis ulcerative			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Defaecation urgency			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Diarrhoea			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dyspepsia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Gastritis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	1 / 2 (50.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Haematochezia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Nausea			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Painful defaecation			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Perianal erythema			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Rectal haemorrhage			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Tongue disorder			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Vomiting			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Dermatitis contact			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Erythema			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Night sweats			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Rash macular			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Skin lesion			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Urticaria			

subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Cushingoid			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Back pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Costochondritis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Muscle spasms			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Muscle tightness			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Myalgia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Osteoarthritis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Pain in jaw			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			

Bacteriuria			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Bronchitis			
subjects affected / exposed	1 / 2 (50.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Cellulitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Influenza			
subjects affected / exposed	1 / 2 (50.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Nasopharyngitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pharyngitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Upper respiratory tract infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	2
Urinary tract infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hyperglycaemia			

subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypokalaemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Cohort 1: MultiStem 300 (x3), Placebo	Cohort 3: MultiStem 750, MultiStem 750	Cohort 2: MultiStem 750, Placebo
Total subjects affected by non-serious adverse events			
subjects affected / exposed	3 / 4 (75.00%)	18 / 23 (78.26%)	5 / 6 (83.33%)
Vascular disorders			
Flushing			
subjects affected / exposed	0 / 4 (0.00%)	0 / 23 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Hot flush			
subjects affected / exposed	0 / 4 (0.00%)	0 / 23 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Hypertension			
subjects affected / exposed	0 / 4 (0.00%)	0 / 23 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Surgical and medical procedures			
Ileostomy			
subjects affected / exposed	0 / 4 (0.00%)	0 / 23 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	1 / 4 (25.00%)	3 / 23 (13.04%)	0 / 6 (0.00%)
occurrences (all)	1	4	0
Chest discomfort			
subjects affected / exposed	0 / 4 (0.00%)	0 / 23 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Chest pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 23 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Chills			
subjects affected / exposed	2 / 4 (50.00%)	1 / 23 (4.35%)	0 / 6 (0.00%)
occurrences (all)	3	1	0

Fatigue			
subjects affected / exposed	0 / 4 (0.00%)	2 / 23 (8.70%)	0 / 6 (0.00%)
occurrences (all)	0	3	0
Influenza like illness			
subjects affected / exposed	0 / 4 (0.00%)	1 / 23 (4.35%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Oedema peripheral			
subjects affected / exposed	0 / 4 (0.00%)	0 / 23 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pain			
subjects affected / exposed	0 / 4 (0.00%)	1 / 23 (4.35%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Pyrexia			
subjects affected / exposed	3 / 4 (75.00%)	2 / 23 (8.70%)	0 / 6 (0.00%)
occurrences (all)	7	2	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	0 / 4 (0.00%)	3 / 23 (13.04%)	0 / 6 (0.00%)
occurrences (all)	0	3	0
Dyspnoea			
subjects affected / exposed	0 / 4 (0.00%)	1 / 23 (4.35%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Epistaxis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 23 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Nasal congestion			
subjects affected / exposed	0 / 4 (0.00%)	0 / 23 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	0 / 4 (0.00%)	1 / 23 (4.35%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Psychiatric disorders			
Anxiety			
subjects affected / exposed	0 / 4 (0.00%)	0 / 23 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Confusional state			

subjects affected / exposed	0 / 4 (0.00%)	0 / 23 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Depression			
subjects affected / exposed	0 / 4 (0.00%)	0 / 23 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 23 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Investigations			
Antibody test			
subjects affected / exposed	0 / 4 (0.00%)	0 / 23 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Bacterial test			
subjects affected / exposed	0 / 4 (0.00%)	0 / 23 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Blood albumin decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 23 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Blood bilirubin increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 23 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Blood glucose increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 23 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Blood urine present			
subjects affected / exposed	0 / 4 (0.00%)	0 / 23 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
C-reactive protein increased			
subjects affected / exposed	0 / 4 (0.00%)	1 / 23 (4.35%)	0 / 6 (0.00%)
occurrences (all)	0	5	0
Cold agglutinins			
subjects affected / exposed	0 / 4 (0.00%)	0 / 23 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Heart rate increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 23 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1

Prostatic specific antigen increased			
subjects affected / exposed[1]	0 / 3 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Weight decreased			
subjects affected / exposed	0 / 4 (0.00%)	2 / 23 (8.70%)	0 / 6 (0.00%)
occurrences (all)	0	2	0
Injury, poisoning and procedural complications			
Contusion			
subjects affected / exposed	0 / 4 (0.00%)	0 / 23 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Fall			
subjects affected / exposed	0 / 4 (0.00%)	1 / 23 (4.35%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Incision site pain			
subjects affected / exposed	1 / 4 (25.00%)	0 / 23 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Laceration			
subjects affected / exposed	0 / 4 (0.00%)	0 / 23 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Skeletal injury			
subjects affected / exposed	0 / 4 (0.00%)	0 / 23 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Tachycardia			
subjects affected / exposed	0 / 4 (0.00%)	1 / 23 (4.35%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Nervous system disorders			
Amnesia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 23 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Dizziness			
subjects affected / exposed	0 / 4 (0.00%)	0 / 23 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Epilepsy			
subjects affected / exposed	0 / 4 (0.00%)	0 / 23 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0

Headache			
subjects affected / exposed	0 / 4 (0.00%)	1 / 23 (4.35%)	0 / 6 (0.00%)
occurrences (all)	0	2	0
Lethargy			
subjects affected / exposed	1 / 4 (25.00%)	0 / 23 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Paraesthesia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 23 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 4 (0.00%)	4 / 23 (17.39%)	0 / 6 (0.00%)
occurrences (all)	0	6	0
Lymphadenopathy			
subjects affected / exposed	0 / 4 (0.00%)	0 / 23 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Vertigo			
subjects affected / exposed	0 / 4 (0.00%)	1 / 23 (4.35%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 4 (0.00%)	3 / 23 (13.04%)	0 / 6 (0.00%)
occurrences (all)	0	4	0
Abdominal pain upper			
subjects affected / exposed	0 / 4 (0.00%)	0 / 23 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Abdominal tenderness			
subjects affected / exposed	0 / 4 (0.00%)	0 / 23 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Colitis ulcerative			
subjects affected / exposed	0 / 4 (0.00%)	5 / 23 (21.74%)	0 / 6 (0.00%)
occurrences (all)	0	8	0
Defaecation urgency			
subjects affected / exposed	0 / 4 (0.00%)	0 / 23 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Diarrhoea			

subjects affected / exposed	0 / 4 (0.00%)	3 / 23 (13.04%)	0 / 6 (0.00%)
occurrences (all)	0	3	0
Dyspepsia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 23 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Gastritis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 23 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 4 (0.00%)	0 / 23 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Haematochezia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 23 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	0 / 4 (0.00%)	3 / 23 (13.04%)	2 / 6 (33.33%)
occurrences (all)	0	4	2
Painful defaecation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 23 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Perianal erythema			
subjects affected / exposed	1 / 4 (25.00%)	0 / 23 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Rectal haemorrhage			
subjects affected / exposed	0 / 4 (0.00%)	0 / 23 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Tongue disorder			
subjects affected / exposed	0 / 4 (0.00%)	0 / 23 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	0 / 4 (0.00%)	0 / 23 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Dermatitis contact			
subjects affected / exposed	1 / 4 (25.00%)	0 / 23 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0

Erythema			
subjects affected / exposed	0 / 4 (0.00%)	0 / 23 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Night sweats			
subjects affected / exposed	0 / 4 (0.00%)	0 / 23 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Pruritus			
subjects affected / exposed	0 / 4 (0.00%)	0 / 23 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	0 / 4 (0.00%)	1 / 23 (4.35%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Rash macular			
subjects affected / exposed	1 / 4 (25.00%)	0 / 23 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Skin lesion			
subjects affected / exposed	0 / 4 (0.00%)	0 / 23 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Urticaria			
subjects affected / exposed	0 / 4 (0.00%)	0 / 23 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Cushingoid			
subjects affected / exposed	0 / 4 (0.00%)	0 / 23 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 4 (0.00%)	1 / 23 (4.35%)	0 / 6 (0.00%)
occurrences (all)	0	2	0
Back pain			
subjects affected / exposed	0 / 4 (0.00%)	3 / 23 (13.04%)	0 / 6 (0.00%)
occurrences (all)	0	4	0
Costochondritis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 23 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Muscle spasms			

subjects affected / exposed	0 / 4 (0.00%)	0 / 23 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Muscle tightness			
subjects affected / exposed	0 / 4 (0.00%)	0 / 23 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Myalgia			
subjects affected / exposed	0 / 4 (0.00%)	3 / 23 (13.04%)	0 / 6 (0.00%)
occurrences (all)	0	3	0
Osteoarthritis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 23 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	0 / 4 (0.00%)	0 / 23 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pain in jaw			
subjects affected / exposed	0 / 4 (0.00%)	0 / 23 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Infections and infestations			
Bacteriuria			
subjects affected / exposed	0 / 4 (0.00%)	0 / 23 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Bronchitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 23 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Cellulitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 23 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 23 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Influenza			
subjects affected / exposed	0 / 4 (0.00%)	1 / 23 (4.35%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Nasopharyngitis			
subjects affected / exposed	0 / 4 (0.00%)	2 / 23 (8.70%)	0 / 6 (0.00%)
occurrences (all)	0	2	0

Pharyngitis			
subjects affected / exposed	0 / 4 (0.00%)	1 / 23 (4.35%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Sinusitis			
subjects affected / exposed	0 / 4 (0.00%)	3 / 23 (13.04%)	0 / 6 (0.00%)
occurrences (all)	0	3	0
Upper respiratory tract infection			
subjects affected / exposed	1 / 4 (25.00%)	2 / 23 (8.70%)	1 / 6 (16.67%)
occurrences (all)	1	3	1
Urinary tract infection			
subjects affected / exposed	1 / 4 (25.00%)	2 / 23 (8.70%)	0 / 6 (0.00%)
occurrences (all)	1	2	0
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	1 / 4 (25.00%)	1 / 23 (4.35%)	0 / 6 (0.00%)
occurrences (all)	1	1	0
Hyperglycaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 23 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hypokalaemia			
subjects affected / exposed	0 / 4 (0.00%)	2 / 23 (8.70%)	0 / 6 (0.00%)
occurrences (all)	0	2	0

Non-serious adverse events	Cohort 3: MultiStem 750, Placebo	Cohort 3: Placebo, MultiStem 750	Cohort 3: Placebo, Placebo
Total subjects affected by non-serious adverse events			
subjects affected / exposed	16 / 25 (64.00%)	15 / 19 (78.95%)	18 / 21 (85.71%)
Vascular disorders			
Flushing			
subjects affected / exposed	0 / 25 (0.00%)	1 / 19 (5.26%)	1 / 21 (4.76%)
occurrences (all)	0	2	1
Hot flush			
subjects affected / exposed	0 / 25 (0.00%)	0 / 19 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Hypertension			
subjects affected / exposed	0 / 25 (0.00%)	1 / 19 (5.26%)	0 / 21 (0.00%)
occurrences (all)	0	1	0
Surgical and medical procedures			

Ileostomy			
subjects affected / exposed	0 / 25 (0.00%)	1 / 19 (5.26%)	0 / 21 (0.00%)
occurrences (all)	0	1	0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 25 (0.00%)	0 / 19 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Chest discomfort			
subjects affected / exposed	0 / 25 (0.00%)	2 / 19 (10.53%)	1 / 21 (4.76%)
occurrences (all)	0	2	1
Chest pain			
subjects affected / exposed	1 / 25 (4.00%)	0 / 19 (0.00%)	1 / 21 (4.76%)
occurrences (all)	1	0	2
Chills			
subjects affected / exposed	0 / 25 (0.00%)	0 / 19 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	3 / 25 (12.00%)	1 / 19 (5.26%)	2 / 21 (9.52%)
occurrences (all)	3	1	2
Influenza like illness			
subjects affected / exposed	1 / 25 (4.00%)	0 / 19 (0.00%)	0 / 21 (0.00%)
occurrences (all)	3	0	0
Oedema peripheral			
subjects affected / exposed	0 / 25 (0.00%)	1 / 19 (5.26%)	2 / 21 (9.52%)
occurrences (all)	0	1	3
Pain			
subjects affected / exposed	0 / 25 (0.00%)	1 / 19 (5.26%)	0 / 21 (0.00%)
occurrences (all)	0	1	0
Pyrexia			
subjects affected / exposed	2 / 25 (8.00%)	1 / 19 (5.26%)	2 / 21 (9.52%)
occurrences (all)	2	1	2
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	3 / 25 (12.00%)	0 / 19 (0.00%)	0 / 21 (0.00%)
occurrences (all)	3	0	0
Dyspnoea			

subjects affected / exposed	0 / 25 (0.00%)	0 / 19 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	1
Epistaxis			
subjects affected / exposed	0 / 25 (0.00%)	1 / 19 (5.26%)	1 / 21 (4.76%)
occurrences (all)	0	1	2
Nasal congestion			
subjects affected / exposed	1 / 25 (4.00%)	0 / 19 (0.00%)	1 / 21 (4.76%)
occurrences (all)	1	0	1
Oropharyngeal pain			
subjects affected / exposed	3 / 25 (12.00%)	0 / 19 (0.00%)	1 / 21 (4.76%)
occurrences (all)	4	0	1
Psychiatric disorders			
Anxiety			
subjects affected / exposed	1 / 25 (4.00%)	3 / 19 (15.79%)	0 / 21 (0.00%)
occurrences (all)	2	3	0
Confusional state			
subjects affected / exposed	0 / 25 (0.00%)	1 / 19 (5.26%)	0 / 21 (0.00%)
occurrences (all)	0	1	0
Depression			
subjects affected / exposed	0 / 25 (0.00%)	0 / 19 (0.00%)	2 / 21 (9.52%)
occurrences (all)	0	0	2
Insomnia			
subjects affected / exposed	1 / 25 (4.00%)	1 / 19 (5.26%)	1 / 21 (4.76%)
occurrences (all)	1	1	1
Investigations			
Antibody test			
subjects affected / exposed	0 / 25 (0.00%)	1 / 19 (5.26%)	0 / 21 (0.00%)
occurrences (all)	0	1	0
Bacterial test			
subjects affected / exposed	0 / 25 (0.00%)	0 / 19 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Blood albumin decreased			
subjects affected / exposed	0 / 25 (0.00%)	1 / 19 (5.26%)	0 / 21 (0.00%)
occurrences (all)	0	1	0
Blood bilirubin increased			

subjects affected / exposed	0 / 25 (0.00%)	1 / 19 (5.26%)	0 / 21 (0.00%)
occurrences (all)	0	1	0
Blood glucose increased			
subjects affected / exposed	0 / 25 (0.00%)	1 / 19 (5.26%)	0 / 21 (0.00%)
occurrences (all)	0	1	0
Blood urine present			
subjects affected / exposed	0 / 25 (0.00%)	0 / 19 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
C-reactive protein increased			
subjects affected / exposed	0 / 25 (0.00%)	1 / 19 (5.26%)	0 / 21 (0.00%)
occurrences (all)	0	2	0
Cold agglutinins			
subjects affected / exposed	0 / 25 (0.00%)	1 / 19 (5.26%)	0 / 21 (0.00%)
occurrences (all)	0	1	0
Heart rate increased			
subjects affected / exposed	0 / 25 (0.00%)	0 / 19 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Prostatic specific antigen increased			
subjects affected / exposed[1]	0 / 13 (0.00%)	0 / 16 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Weight decreased			
subjects affected / exposed	0 / 25 (0.00%)	1 / 19 (5.26%)	1 / 21 (4.76%)
occurrences (all)	0	2	1
Injury, poisoning and procedural complications			
Contusion			
subjects affected / exposed	0 / 25 (0.00%)	1 / 19 (5.26%)	0 / 21 (0.00%)
occurrences (all)	0	1	0
Fall			
subjects affected / exposed	0 / 25 (0.00%)	0 / 19 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Incision site pain			
subjects affected / exposed	0 / 25 (0.00%)	0 / 19 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Laceration			

subjects affected / exposed	1 / 25 (4.00%)	1 / 19 (5.26%)	0 / 21 (0.00%)
occurrences (all)	1	1	0
Skeletal injury			
subjects affected / exposed	0 / 25 (0.00%)	0 / 19 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Tachycardia			
subjects affected / exposed	0 / 25 (0.00%)	1 / 19 (5.26%)	0 / 21 (0.00%)
occurrences (all)	0	1	0
Nervous system disorders			
Amnesia			
subjects affected / exposed	0 / 25 (0.00%)	1 / 19 (5.26%)	0 / 21 (0.00%)
occurrences (all)	0	1	0
Dizziness			
subjects affected / exposed	1 / 25 (4.00%)	2 / 19 (10.53%)	0 / 21 (0.00%)
occurrences (all)	1	2	0
Epilepsy			
subjects affected / exposed	0 / 25 (0.00%)	1 / 19 (5.26%)	0 / 21 (0.00%)
occurrences (all)	0	2	0
Headache			
subjects affected / exposed	3 / 25 (12.00%)	7 / 19 (36.84%)	6 / 21 (28.57%)
occurrences (all)	3	7	7
Lethargy			
subjects affected / exposed	0 / 25 (0.00%)	0 / 19 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Paraesthesia			
subjects affected / exposed	0 / 25 (0.00%)	2 / 19 (10.53%)	0 / 21 (0.00%)
occurrences (all)	0	3	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 25 (0.00%)	2 / 19 (10.53%)	3 / 21 (14.29%)
occurrences (all)	0	2	4
Lymphadenopathy			
subjects affected / exposed	0 / 25 (0.00%)	1 / 19 (5.26%)	0 / 21 (0.00%)
occurrences (all)	0	1	0
Ear and labyrinth disorders			

Vertigo			
subjects affected / exposed	0 / 25 (0.00%)	1 / 19 (5.26%)	1 / 21 (4.76%)
occurrences (all)	0	1	1
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	2 / 25 (8.00%)	1 / 19 (5.26%)	2 / 21 (9.52%)
occurrences (all)	3	2	2
Abdominal pain upper			
subjects affected / exposed	1 / 25 (4.00%)	1 / 19 (5.26%)	0 / 21 (0.00%)
occurrences (all)	1	1	0
Abdominal tenderness			
subjects affected / exposed	0 / 25 (0.00%)	0 / 19 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Colitis ulcerative			
subjects affected / exposed	2 / 25 (8.00%)	3 / 19 (15.79%)	5 / 21 (23.81%)
occurrences (all)	3	4	5
Defaecation urgency			
subjects affected / exposed	0 / 25 (0.00%)	0 / 19 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Diarrhoea			
subjects affected / exposed	0 / 25 (0.00%)	0 / 19 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Dyspepsia			
subjects affected / exposed	0 / 25 (0.00%)	1 / 19 (5.26%)	1 / 21 (4.76%)
occurrences (all)	0	1	1
Gastritis			
subjects affected / exposed	0 / 25 (0.00%)	1 / 19 (5.26%)	0 / 21 (0.00%)
occurrences (all)	0	1	0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 25 (0.00%)	0 / 19 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Haematochezia			
subjects affected / exposed	1 / 25 (4.00%)	1 / 19 (5.26%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Nausea			

subjects affected / exposed	1 / 25 (4.00%)	1 / 19 (5.26%)	2 / 21 (9.52%)
occurrences (all)	3	1	2
Painful defaecation			
subjects affected / exposed	0 / 25 (0.00%)	1 / 19 (5.26%)	0 / 21 (0.00%)
occurrences (all)	0	1	0
Perianal erythema			
subjects affected / exposed	0 / 25 (0.00%)	0 / 19 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Rectal haemorrhage			
subjects affected / exposed	0 / 25 (0.00%)	1 / 19 (5.26%)	0 / 21 (0.00%)
occurrences (all)	0	1	0
Tongue disorder			
subjects affected / exposed	0 / 25 (0.00%)	0 / 19 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	1 / 25 (4.00%)	2 / 19 (10.53%)	0 / 21 (0.00%)
occurrences (all)	1	3	0
Skin and subcutaneous tissue disorders			
Dermatitis contact			
subjects affected / exposed	0 / 25 (0.00%)	0 / 19 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Erythema			
subjects affected / exposed	0 / 25 (0.00%)	1 / 19 (5.26%)	0 / 21 (0.00%)
occurrences (all)	0	1	0
Night sweats			
subjects affected / exposed	0 / 25 (0.00%)	0 / 19 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	0 / 25 (0.00%)	1 / 19 (5.26%)	0 / 21 (0.00%)
occurrences (all)	0	2	0
Rash			
subjects affected / exposed	2 / 25 (8.00%)	1 / 19 (5.26%)	1 / 21 (4.76%)
occurrences (all)	2	1	1
Rash macular			
subjects affected / exposed	0 / 25 (0.00%)	0 / 19 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0

Skin lesion			
subjects affected / exposed	0 / 25 (0.00%)	1 / 19 (5.26%)	0 / 21 (0.00%)
occurrences (all)	0	1	0
Urticaria			
subjects affected / exposed	0 / 25 (0.00%)	1 / 19 (5.26%)	0 / 21 (0.00%)
occurrences (all)	0	2	0
Endocrine disorders			
Cushingoid			
subjects affected / exposed	1 / 25 (4.00%)	1 / 19 (5.26%)	0 / 21 (0.00%)
occurrences (all)	1	1	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	2 / 25 (8.00%)	1 / 19 (5.26%)	0 / 21 (0.00%)
occurrences (all)	3	1	0
Back pain			
subjects affected / exposed	0 / 25 (0.00%)	0 / 19 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	1
Costochondritis			
subjects affected / exposed	0 / 25 (0.00%)	0 / 19 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Muscle spasms			
subjects affected / exposed	1 / 25 (4.00%)	0 / 19 (0.00%)	0 / 21 (0.00%)
occurrences (all)	1	0	0
Muscle tightness			
subjects affected / exposed	0 / 25 (0.00%)	0 / 19 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Myalgia			
subjects affected / exposed	1 / 25 (4.00%)	0 / 19 (0.00%)	0 / 21 (0.00%)
occurrences (all)	1	0	0
Osteoarthritis			
subjects affected / exposed	0 / 25 (0.00%)	1 / 19 (5.26%)	0 / 21 (0.00%)
occurrences (all)	0	1	0
Pain in extremity			
subjects affected / exposed	1 / 25 (4.00%)	1 / 19 (5.26%)	0 / 21 (0.00%)
occurrences (all)	1	1	0
Pain in jaw			

subjects affected / exposed	0 / 25 (0.00%)	0 / 19 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Bacteriuria			
subjects affected / exposed	0 / 25 (0.00%)	1 / 19 (5.26%)	0 / 21 (0.00%)
occurrences (all)	0	1	0
Bronchitis			
subjects affected / exposed	0 / 25 (0.00%)	0 / 19 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Cellulitis			
subjects affected / exposed	0 / 25 (0.00%)	1 / 19 (5.26%)	0 / 21 (0.00%)
occurrences (all)	0	1	0
Gastroenteritis			
subjects affected / exposed	0 / 25 (0.00%)	1 / 19 (5.26%)	0 / 21 (0.00%)
occurrences (all)	0	1	0
Influenza			
subjects affected / exposed	0 / 25 (0.00%)	1 / 19 (5.26%)	0 / 21 (0.00%)
occurrences (all)	0	2	0
Nasopharyngitis			
subjects affected / exposed	1 / 25 (4.00%)	5 / 19 (26.32%)	4 / 21 (19.05%)
occurrences (all)	1	7	4
Pharyngitis			
subjects affected / exposed	0 / 25 (0.00%)	1 / 19 (5.26%)	0 / 21 (0.00%)
occurrences (all)	0	1	0
Sinusitis			
subjects affected / exposed	2 / 25 (8.00%)	0 / 19 (0.00%)	0 / 21 (0.00%)
occurrences (all)	3	0	0
Upper respiratory tract infection			
subjects affected / exposed	2 / 25 (8.00%)	1 / 19 (5.26%)	1 / 21 (4.76%)
occurrences (all)	3	1	1
Urinary tract infection			
subjects affected / exposed	2 / 25 (8.00%)	0 / 19 (0.00%)	0 / 21 (0.00%)
occurrences (all)	2	0	0
Metabolism and nutrition disorders			
Dehydration			

subjects affected / exposed	0 / 25 (0.00%)	0 / 19 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Hyperglycaemia			
subjects affected / exposed	0 / 25 (0.00%)	1 / 19 (5.26%)	0 / 21 (0.00%)
occurrences (all)	0	1	0
Hypokalaemia			
subjects affected / exposed	0 / 25 (0.00%)	0 / 19 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0

Notes:

[1] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: This AE is gender specific event. The percentages of gender specific events are calculated using the corresponding gender count as denominator.

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
05 October 2012	Interim analysis for futility was added.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported