Tabl of contents

Table 1 Study summary	
Number of patients enrolled, n	55
Number of patients enrolled in EEA, n	0
Number of patients enrolled in United Kingdom, n	55
Number of enrolled patients who received treatment, n	55
Number of patients enrolled patients who received treatment in EEA, n	0
Number of patients enrolled patients who received treatment in United Kingdom, n	55
Dates of enrolment for patients who received treatment, range	01/03/2012 – 25/10/2016
Number of sites, n	3
Number of sites in EEA, n	0
Number of sites in United Kingdom, n	3

EEA = European economic area.

Table 2 Patient demographics and disease characteristics at baseline (Safety Set population)	
	All patients (N=55)
Age (years), median (range)	72 (49 – 89)
Age category (years), n (%)	
18 to 64	8 (14.6)
65 to 84	44 (80)
85 and above	3 (5.4)
Ethnicity, n (%)	
Asian (Bangladeshi)	0
Asian (Pakistani)	1 (1.8)
Asian (Other)	1 (1.8)
Black (African)	4 (7.3)
Black (Caribbean)	8 (14.6)
Black (Other)	1 (1.8)
Chinese	0
Other	3 (5.4)
White	37 (67.3)
White Mixed	0
Gender, n (%)	
Male	55 (100)
Female	0
T category 1997 (based on rectal palpation), n (%)	
T0	0
T1	3 (5.4)
T2	7 (12.7)
T3	20 (36.4)
T4	10 (18.2)
T5	0
Missing	15 (27.3)
Metastatic status, n (%)	
M0	11 (20)
M1	43 (78.2)
Missing	1 (1.8)
ECOG, n (%)	
0 - Fully Active	26 (47.3)
1 - Ambulatory, capable of light work	23 (41.8)
2 - Up and about >50% of time (capable of self-care but not of work activities)	2 (3.6)
3 - Up and about <50% of time (capable of limited self-care)	4 (7.3)
LDH, median (range)	383 (10.1 – 1648)
ALP, median (range)	119 (36 – 719)
Gleason score (n=52), median (range)	8 (6 – 10)

ALP = Alkaline phosphatase. ECOG = Eastern cooperative oncology group. LDH = Lactate dehydrogenase.
N = Number of patients in the Safety Set population.

Table 2 Patient demographics and disease characteristics at baseline (Safety Set population)	
	All patients (N=55)
Safety Set population is defined as all patients enrolled into the trial who received at least one dose of study medication.	

Table 3 Treatment compliance and exposure (Safety Set population)	
	All patients (N=55)
Triamcinolone	
Received their allocated dose over all cycles, n (%)	36 (65.4)
Total treatment duration (weeks), median (range)	26.1 (0.14 – 251.4)
Total treatment duration (weeks) = (last dose date - first dose date +1) / 7. N = Number of patients in the Safety Set population. Safety Set population is defined as all patients enrolled into the trial who received at least one dose of study medication.	

Table 4.1 Adverse events (AEs) summary (Safety Set population)	
	All patients (N=55)
AEs reported, n	1,041
Patients with at least one AE, n	55
AEs per patient [a], median (range)	11 (3 – 81)
≥ Grade 3 AEs reported, n	82
Patients with at least one ≥ Grade 3 AE, n	40
≥ Grade 3 AEs per patient [a], median (range)	2 (1 – 6)
≥ Grade 3 AEs related to Triamcinolone, n	33
Patients with at least one ≥ Grade 3 AE related to Triamcinolone, n	26
≥ Grade 3 AEs related to Triamcinolone per patient [a], median (range)	1 (1 – 4)
SAEs reported, n	50
Patients with at least one SAE, n	27
SAEs per patient [a], median (range)	2 (1 – 4)
Non-serious AEs reported, n	183
Patients with at least one non-serious AE, n	39
Non-serious AEs per patient [a], median (range)	2 (1 – 34)

AE = Adverse event. SAE = Serious adverse event.
[a] This counts each instance once e.g. if a patient has the same term three times this is counted as 3 instances.
Related is defined as very likely, probable or possible.
N = Number of patients in the Safety Set population.
Safety Set population is defined as all patients enrolled into the trial who received at least one dose of study medication.

Table 4.2 Adverse events (AEs) by preferred term (PT)
(Safety Set population)

CTCAE v4.03 PT, n (%)	Grade 1	Grade 2	Grade 3	Grade 4	Grade 5	Total (N=55)
Asthenia	22 (4.6)	25 (5.2)	2 (0.4)	0 (0)	0 (0)	49 (10.1)
Hypertension	7 (1.4)	14 (2.9)	23 (4.8)	0 (0)	0 (0)	44 (9.1)
Muscular weakness	14 (2.9)	24 (5)	1 (0.2)	0 (0)	0 (0)	39 (8.1)
Insomnia	19 (3.9)	11 (2.3)	1 (0.2)	0 (0)	0 (0)	31 (6.4)
Skin atrophy	19 (3.9)	6 (1.2)	1 (0.2)	0 (0)	0 (0)	26 (5.4)
Appetite disorder	16 (3.3)	6 (1.2)	0 (0)	0 (0)	0 (0)	22 (4.6)
Infection	5 (1)	9 (1.9)	2 (0.4)	1 (0.2)	0 (0)	17 (3.5)
Oedema	9 (1.9)	4 (0.8)	2 (0.4)	0 (0)	0 (0)	15 (3.1)
Hyperglycaemia	5 (1)	6 (1.2)	3 (0.6)	0 (0)	0 (0)	14 (2.9)
Constipation	10 (2.1)	2 (0.4)	1 (0.2)	0 (0)	0 (0)	13 (2.7)
Gastritis	8 (1.7)	4 (0.8)	0 (0)	0 (0)	0 (0)	12 (2.5)
Hyperhidrosis	9 (1.9)	2 (0.4)	0 (0)	0 (0)	0 (0)	11 (2.3)
Weight increased	7 (1.4)	4 (0.8)	0 (0)	0 (0)	0 (0)	11 (2.3)
Muscle spasms	10 (2.1)	0 (0)	0 (0)	0 (0)	0 (0)	10 (2.1)
Pain	5 (1)	3 (0.6)	2 (0.4)	0 (0)	0 (0)	10 (2.1)
Stomatitis	8 (1.7)	1 (0.2)	1 (0.2)	0 (0)	0 (0)	10 (2.1)
Musculoskeletal pain	4 (0.8)	3 (0.6)	2 (0.4)	0 (0)	0 (0)	9 (1.9)
Skin injury	5 (1)	2 (0.4)	1 (0.2)	0 (0)	0 (0)	8 (1.7)
Cough	6 (1.2)	0 (0)	0 (0)	0 (0)	0 (0)	6 (1.2)
Dyspnoea	5 (1)	0 (0)	1 (0.2)	0 (0)	0 (0)	6 (1.2)
Joint pain	1 (0.2)	5 (1)	0 (0)	0 (0)	0 (0)	6 (1.2)
Nausea	5 (1)	1 (0.2)	0 (0)	0 (0)	0 (0)	6 (1.2)
Nocturia	3 (0.6)	2 (0.4)	0 (0)	0 (0)	0 (0)	5 (1)
Pulmonary embolism	0 (0)	0 (0)	2 (0.4)	3 (0.6)	0 (0)	5 (1)
Dyspepsia	4 (0.8)	0 (0)	0 (0)	0 (0)	0 (0)	4 (0.8)
Flushing	2 (0.4)	2 (0.4)	0 (0)	0 (0)	0 (0)	4 (0.8)

Pollakiuria	4 (0.8)	0 (0)	0 (0)	0 (0)	0 (0)	4 (0.8)
Depression	1 (0.2)	2 (0.4)	0 (0)	0 (0)	0 (0)	3 (0.6)
Dysgeusia	3 (0.6)	0 (0)	0 (0)	0 (0)	0 (0)	3 (0.6)
Haematuria	2 (0.4)	1 (0.2)	0 (0)	0 (0)	0 (0)	3 (0.6)
Neuropathy	2 (0.4)	1 (0.2)	0 (0)	0 (0)	0 (0)	3 (0.6)
Rash	3 (0.6)	0 (0)	0 (0)	0 (0)	0 (0)	3 (0.6)
Anxiety	2 (0.4)	0 (0)	0 (0)	0 (0)	0 (0)	2 (0.4)
Diarrhoea	2 (0.4)	0 (0)	0 (0)	0 (0)	0 (0)	2 (0.4)
Dizziness	2 (0.4)	0 (0)	0 (0)	0 (0)	0 (0)	2 (0.4)
Dysphonia	2 (0.4)	0 (0)	0 (0)	0 (0)	0 (0)	2 (0.4)
Gastrointestinal haemorrhage	1 (0.2)	0 (0)	1 (0.2)	0 (0)	0 (0)	2 (0.4)
Gastrointestinal toxicity	2 (0.4)	0 (0)	0 (0)	0 (0)	0 (0)	2 (0.4)
Headache	2 (0.4)	0 (0)	0 (0)	0 (0)	0 (0)	2 (0.4)
Myopathy	1 (0.2)	1 (0.2)	0 (0)	0 (0)	0 (0)	2 (0.4)
Sepsis	0 (0)	0 (0)	0 (0)	0 (0)	2 (0.4)	2 (0.4)
Urinary retention	0 (0)	1 (0.2)	1 (0.2)	0 (0)	0 (0)	2 (0.4)
Vomiting	2 (0.4)	0 (0)	0 (0)	0 (0)	0 (0)	2 (0.4)
Abdominal pain	1 (0.2)	0 (0)	0 (0)	0 (0)	0 (0)	1 (0.2)
Aortic stenosis	1 (0.2)	0 (0)	0 (0)	0 (0)	0 (0)	1 (0.2)
Aphasia	0 (0)	1 (0.2)	0 (0)	0 (0)	0 (0)	1 (0.2)
Asthma	0 (0)	1 (0.2)	0 (0)	0 (0)	0 (0)	1 (0.2)
Atrial fibrillation	0 (0)	0 (0)	1 (0.2)	0 (0)	0 (0)	1 (0.2)
Bone pain	0 (0)	1 (0.2)	0 (0)	0 (0)	0 (0)	1 (0.2)
Bursitis	0 (0)	1 (0.2)	0 (0)	0 (0)	0 (0)	1 (0.2)
Cardiac arrest	0 (0)	0 (0)	0 (0)	0 (0)	1 (0.2)	1 (0.2)
Cardiac valve disease	1 (0.2)	0 (0)	0 (0)	0 (0)	0 (0)	1 (0.2)
Cerebrovascular accident	0 (0)	0 (0)	1 (0.2)	0 (0)	0 (0)	1 (0.2)
Chronic obstructive pulmonary disease	0 (0)	1 (0.2)	0 (0)	0 (0)	0 (0)	1 (0.2)
Deep vein thrombosis	0 (0)	1 (0.2)	0 (0)	0 (0)	0 (0)	1 (0.2)
Dehydration	0 (0)	0 (0)	1 (0.2)	0 (0)	0 (0)	1 (0.2)
Disorientation	1 (0.2)	0 (0)	0 (0)	0 (0)	0 (0)	1 (0.2)

Dry skin	1 (0.2)	0 (0)	0 (0)	0 (0)	0 (0)	1 (0.2)
Eczema	1 (0.2)	0 (0)	0 (0)	0 (0)	0 (0)	1 (0.2)
Embolism	0 (0)	0 (0)	1 (0.2)	0 (0)	0 (0)	1 (0.2)
Epistaxis	1 (0.2)	0 (0)	0 (0)	0 (0)	0 (0)	1 (0.2)
External ear disorder	1 (0.2)	0 (0)	0 (0)	0 (0)	0 (0)	1 (0.2)
Fall	0 (0)	1 (0.2)	0 (0)	0 (0)	0 (0)	1 (0.2)
Fatigue	0 (0)	0 (0)	1 (0.2)	0 (0)	0 (0)	1 (0.2)
Flatulence	1 (0.2)	0 (0)	0 (0)	0 (0)	0 (0)	1 (0.2)
Fluid retention	0 (0)	0 (0)	1 (0.2)	0 (0)	0 (0)	1 (0.2)
Fracture	0 (0)	1 (0.2)	0 (0)	0 (0)	0 (0)	1 (0.2)
Gait disturbance	0 (0)	1 (0.2)	0 (0)	0 (0)	0 (0)	1 (0.2)
Gastrointestinal necrosis	0 (0)	0 (0)	0 (0)	1 (0.2)	0 (0)	1 (0.2)
Hyperadrenocorticalism	1 (0.2)	0 (0)	0 (0)	0 (0)	0 (0)	1 (0.2)
Hyperkalaemia	1 (0.2)	0 (0)	0 (0)	0 (0)	0 (0)	1 (0.2)
Hyperthyroidism	1 (0.2)	0 (0)	0 (0)	0 (0)	0 (0)	1 (0.2)
Hypoaesthesia	1 (0.2)	0 (0)	0 (0)	0 (0)	0 (0)	1 (0.2)
Incontinence	1 (0.2)	0 (0)	0 (0)	0 (0)	0 (0)	1 (0.2)
Injury	0 (0)	1 (0.2)	0 (0)	0 (0)	0 (0)	1 (0.2)
Intestinal obstruction	0 (0)	0 (0)	1 (0.2)	0 (0)	0 (0)	1 (0.2)
Malaise	1 (0.2)	0 (0)	0 (0)	0 (0)	0 (0)	1 (0.2)
Migraine	1 (0.2)	0 (0)	0 (0)	0 (0)	0 (0)	1 (0.2)
Onychoclasis	1 (0.2)	0 (0)	0 (0)	0 (0)	0 (0)	1 (0.2)
Orthostatic hypotension	0 (0)	0 (0)	1 (0.2)	0 (0)	0 (0)	1 (0.2)
Palmar-plantar erythrodysaesthesia syndrome	1 (0.2)	0 (0)	0 (0)	0 (0)	0 (0)	1 (0.2)
Paralysis	1 (0.2)	0 (0)	0 (0)	0 (0)	0 (0)	1 (0.2)
Periorbital swelling	1 (0.2)	0 (0)	0 (0)	0 (0)	0 (0)	1 (0.2)
Pneumonitis	0 (0)	1 (0.2)	0 (0)	0 (0)	0 (0)	1 (0.2)
Pruritus	0 (0)	1 (0.2)	0 (0)	0 (0)	0 (0)	1 (0.2)
Second primary malignancy	0 (0)	0 (0)	0 (0)	0 (0)	1 (0.2)	1 (0.2)
Skin hypopigmentation	1 (0.2)	0 (0)	0 (0)	0 (0)	0 (0)	1 (0.2)
Tachycardia	0 (0)	0 (0)	1 (0.2)	0 (0)	0 (0)	1 (0.2)

Throat irritation	1 (0.2)	0 (0)	0 (0)	0 (0)	0 (0)	1 (0.2)
Tinnitus	1 (0.2)	0 (0)	0 (0)	0 (0)	0 (0)	1 (0.2)
Transient ischaemic attack	0 (0)	0 (0)	0 (0)	1 (0.2)	0 (0)	1 (0.2)
Urinary incontinence	0 (0)	1 (0.2)	0 (0)	0 (0)	0 (0)	1 (0.2)
TOTAL	**262 (54.2)**	**155 (32.1)**	**56 (11.6)**	**6 (1.2)**	**4 (0.8)**	**483 (100)**

AE = Adverse event. CTCAE = Common terminology criteria for adverse events. PT = Preferred term.

The worst toxicity for each patient of each AE PT has been reported.

Table has been sorted in descending order by Total then by Grade 5, Grade 4, Grade 3, Grade 2, Grade 1 then alphabetically by PT.

AEs have been grouped by PT.

N = Number of patients in the Safety Set population.

Safety Set population is defined as all patients enrolled into the trial who received at least one dose of study medication.

Table 4.3 Grade 3 and above adverse events (AEs) by preferred term (PT)
(Safety Set population)

CTCAE v4.03 PT, n (%)	Grade 3	Grade 4	Grade 5	Total (N=55)
Hypertension	23 (34.8)	0 (0)	0 (0)	23 (34.8)
Pulmonary embolism	2 (3)	3 (4.5)	0 (0)	5 (7.6)
Hyperglycaemia	3 (4.5)	0 (0)	0 (0)	3 (4.5)
Infection	2 (3)	1 (1.5)	0 (0)	3 (4.5)
Asthenia	2 (3)	0 (0)	0 (0)	2 (3)
Musculoskeletal pain	2 (3)	0 (0)	0 (0)	2 (3)
Oedema	2 (3)	0 (0)	0 (0)	2 (3)
Pain	2 (3)	0 (0)	0 (0)	2 (3)
Sepsis	0 (0)	0 (0)	2 (3)	2 (3)
Atrial fibrillation	1 (1.5)	0 (0)	0 (0)	1 (1.5)
Cardiac arrest	0 (0)	0 (0)	1 (1.5)	1 (1.5)
Cerebrovascular accident	1 (1.5)	0 (0)	0 (0)	1 (1.5)
Constipation	1 (1.5)	0 (0)	0 (0)	1 (1.5)
Dehydration	1 (1.5)	0 (0)	0 (0)	1 (1.5)
Dyspnoea	1 (1.5)	0 (0)	0 (0)	1 (1.5)
Embolism	1 (1.5)	0 (0)	0 (0)	1 (1.5)
Fatigue	1 (1.5)	0 (0)	0 (0)	1 (1.5)
Fluid retention	1 (1.5)	0 (0)	0 (0)	1 (1.5)
Gastrointestinal haemorrhage	1 (1.5)	0 (0)	0 (0)	1 (1.5)
Gastrointestinal necrosis	0 (0)	1 (1.5)	0 (0)	1 (1.5)
Insomnia	1 (1.5)	0 (0)	0 (0)	1 (1.5)
Intestinal obstruction	1 (1.5)	0 (0)	0 (0)	1 (1.5)
Muscular weakness	1 (1.5)	0 (0)	0 (0)	1 (1.5)
Orthostatic hypotension	1 (1.5)	0 (0)	0 (0)	1 (1.5)
Second primary malignancy	0 (0)	0 (0)	1 (1.5)	1 (1.5)
Skin atrophy	1 (1.5)	0 (0)	0 (0)	1 (1.5)
Skin injury	1 (1.5)	0 (0)	0 (0)	1 (1.5)

Stomatitis	1 (1.5)	0 (0)	0 (0)	1 (1.5)
Tachycardia	1 (1.5)	0 (0)	0 (0)	1 (1.5)
Transient ischaemic attack	0 (0)	1 (1.5)	0 (0)	1 (1.5)
Urinary retention	1 (1.5)	0 (0)	0 (0)	1 (1.5)
TOTAL	**56 (84.8)**	**6 (9.1)**	**4 (6.1)**	**66 (100)**

AE = Adverse event. CTCAE = Common terminology criteria for adverse events. PT = Preferred term.

The worst toxicity for each patient of each grade 3 and above AE PT has been reported.

Table has been sorted in descending order by Total then by Grade 5, Grade 4, Grade 3 then alphabetically by PT.

AEs have been grouped by PT.

N = Number of patients in the Safety Set population.

Safety Set population is defined as all patients enrolled into the trial who received at least one dose of study medication.

Table 4.4 Grade 3 and above adverse events (AEs) related to Triamcinolone by preferred term (PT) (Safety Set population)

CTCAE v4.03 PT, n (%)	Grade 3	Grade 4	Grade 5	Total (N=55)
Hypertension	18 (66.7)	0 (0)	0 (0)	18 (66.7)
Embolism	1 (3.7)	0 (0)	0 (0)	1 (3.7)
Gastrointestinal haemorrhage	1 (3.7)	0 (0)	0 (0)	1 (3.7)
Hyperglycaemia	1 (3.7)	0 (0)	0 (0)	1 (3.7)
Infection	1 (3.7)	0 (0)	0 (0)	1 (3.7)
Muscular weakness	1 (3.7)	0 (0)	0 (0)	1 (3.7)
Sepsis	0 (0)	0 (0)	1 (3.7)	1 (3.7)
Skin atrophy	1 (3.7)	0 (0)	0 (0)	1 (3.7)
Stomatitis	1 (3.7)	0 (0)	0 (0)	1 (3.7)
Tachycardia	1 (3.7)	0 (0)	0 (0)	1 (3.7)
Total	**26 (96.3)**	**0 (0)**	**1 (3.7)**	**27 (100)**

AE = Adverse event. CTCAE = Common terminology criteria for adverse events. PT = Preferred term.

The worst toxicity for each patient of each grade 3 and above AE related to Triamcinolone PT has been reported.

Table has been sorted in descending order by Total then by Grade 5, Grade 4, Grade 3 then alphabetically by PT.

Related is defined as very likely, probable or possible.

AEs have been grouped by PT.

N = Number of patients in the Safety Set population.

Safety Set population is defined as all patients enrolled into the trial who received at least one dose of study medication.

Table 4.9 Non-serious adverse events (AEs) by preferred term (PT)
(Safety Set population)

CTCAE v4.03 PT, n (%)	Grade 1	Grade 2	Grade 3	Total (N=55)
Hypertension	2 (1.4)	2 (1.4)	20 (14.3)	24 (17.1)
Asthenia	7 (5)	6 (4.3)	1 (0.7)	14 (10)
Insomnia	6 (4.3)	3 (2.1)	1 (0.7)	10 (7.1)
Muscular weakness	5 (3.6)	3 (2.1)	1 (0.7)	9 (6.4)
Skin atrophy	4 (2.9)	1 (0.7)	1 (0.7)	6 (4.3)
Constipation	3 (2.1)	2 (1.4)	0 (0)	5 (3.6)
Appetite disorder	2 (1.4)	2 (1.4)	0 (0)	4 (2.9)
Muscle spasms	4 (2.9)	0 (0)	0 (0)	4 (2.9)
Hyperglycaemia	1 (0.7)	1 (0.7)	1 (0.7)	3 (2.1)
Infection	0 (0)	3 (2.1)	0 (0)	3 (2.1)
Pollakiuria	3 (2.1)	0 (0)	0 (0)	3 (2.1)
Anxiety	2 (1.4)	0 (0)	0 (0)	2 (1.4)
Cough	2 (1.4)	0 (0)	0 (0)	2 (1.4)
Depression	1 (0.7)	1 (0.7)	0 (0)	2 (1.4)
Dysphonia	2 (1.4)	0 (0)	0 (0)	2 (1.4)
Flushing	0 (0)	2 (1.4)	0 (0)	2 (1.4)
Gastrointestinal haemorrhage	1 (0.7)	0 (0)	1 (0.7)	2 (1.4)
Haematuria	1 (0.7)	1 (0.7)	0 (0)	2 (1.4)
Hyperhidrosis	2 (1.4)	0 (0)	0 (0)	2 (1.4)
Neuropathy	2 (1.4)	0 (0)	0 (0)	2 (1.4)
Oedema	2 (1.4)	0 (0)	0 (0)	2 (1.4)
Pain	0 (0)	2 (1.4)	0 (0)	2 (1.4)
Skin injury	2 (1.4)	0 (0)	0 (0)	2 (1.4)
Aortic stenosis	1 (0.7)	0 (0)	0 (0)	1 (0.7)
Asthma	0 (0)	1 (0.7)	0 (0)	1 (0.7)
Cardiac valve disease	1 (0.7)	0 (0)	0 (0)	1 (0.7)

Deep vein thrombosis	0 (0)	1 (0.7)	0 (0)	1 (0.7)
Dizziness	1 (0.7)	0 (0)	0 (0)	1 (0.7)
Dry skin	1 (0.7)	0 (0)	0 (0)	1 (0.7)
Dysgeusia	1 (0.7)	0 (0)	0 (0)	1 (0.7)
Dyspepsia	1 (0.7)	0 (0)	0 (0)	1 (0.7)
Dyspnoea	1 (0.7)	0 (0)	0 (0)	1 (0.7)
Epistaxis	1 (0.7)	0 (0)	0 (0)	1 (0.7)
External ear disorder	1 (0.7)	0 (0)	0 (0)	1 (0.7)
Flatulence	1 (0.7)	0 (0)	0 (0)	1 (0.7)
Gastritis	1 (0.7)	0 (0)	0 (0)	1 (0.7)
Gastrointestinal toxicity	1 (0.7)	0 (0)	0 (0)	1 (0.7)
Headache	1 (0.7)	0 (0)	0 (0)	1 (0.7)
Hypoaesthesia	1 (0.7)	0 (0)	0 (0)	1 (0.7)
Joint pain	0 (0)	1 (0.7)	0 (0)	1 (0.7)
Malaise	1 (0.7)	0 (0)	0 (0)	1 (0.7)
Migraine	1 (0.7)	0 (0)	0 (0)	1 (0.7)
Musculoskeletal pain	0 (0)	1 (0.7)	0 (0)	1 (0.7)
Myopathy	1 (0.7)	0 (0)	0 (0)	1 (0.7)
Nocturia	0 (0)	1 (0.7)	0 (0)	1 (0.7)
Onychoclasis	1 (0.7)	0 (0)	0 (0)	1 (0.7)
Palmar-plantar erythrodysaesthesia syndrome	1 (0.7)	0 (0)	0 (0)	1 (0.7)
Periorbital swelling	1 (0.7)	0 (0)	0 (0)	1 (0.7)
Pruritus	0 (0)	1 (0.7)	0 (0)	1 (0.7)
Rash	1 (0.7)	0 (0)	0 (0)	1 (0.7)
Stomatitis	0 (0)	0 (0)	1 (0.7)	1 (0.7)
Throat irritation	1 (0.7)	0 (0)	0 (0)	1 (0.7)
Urinary incontinence	0 (0)	1 (0.7)	0 (0)	1 (0.7)
Weight increased	0 (0)	1 (0.7)	0 (0)	1 (0.7)
Total	**76 (54.3)**	**37 (26.4)**	**27 (19.3)**	**140 (100)**

AE = Adverse event. CTCAE = Common terminology criteria for adverse events. PT = Preferred term.

The worst toxicity for each patient of each non-serious AE PT has been reported.

Table has been sorted in descending order by Total then by Grade 5, Grade 4, Grade 3, Grade 2, Grade 1 then alphabetically by PT.

AEs have been grouped by PT.

N = Number of patients in the Safety Set population.

Safety Set population is defined as all patients enrolled into the trial who received at least one dose of study medication.

Table 8 Progression-free survival (PFS)		
	Evaluable population (N=40)	**FAS population (N=55)**
Total events, n (%)	37 (92.5)	52 (94.6)
Progression [a], n (%)	31 (77.5)	41 (74.6)
Death in the absence of progression, n (%)	6 (15.0)	11 (20.0)
Censored patients, n (%)	37 (92.5)	52 (94.6)
Censored at day 1 patients, n (%)	0	0
PFS (months) [b], median (95% CI)	9.0(7.6 – 19.6)	8.6 (6.4 – 17.6)
PFS rate at 6 months, %	75.0	65.4
90% CI	(61.6 – 84.3)	(53.8 – 74.8)
95% CI	(58.5 – 85.7)	(51.3 – 76.4)
CI = Confidence interval. FAS = Full analysis set. PFS = Progression-free survival. [a] Based on local investigator assessments. [b] Calculated using the Kaplan-Meier technique. N = Number of patients in the specified population. Evaluable population is defined as all patients enrolled into the trial who completed at least 2 cycles of study medication and 12 weeks of follow-up. FAS population is defined as all patients enrolled into the trial who received at least one dose of study medication.		

Table 9 Time to prostate specific antigen (PSA) progression (TPP)		
	Evaluable population (N=40)	**FAS population (N=55)**
PSA progression [a], n (%)	31 (77.5)	34 (61.8)
Decline from baseline, n (%)	25 (62.5)	25 (45.4)
No decline from baseline, n (%)	6 (15.0)	9 (16.4)
No evidence of PSA progression, n (%)	9 (22.5)	21 (38.2)
TPP (months) [b], median (95% CI)	10.9 (4.6 – 15.6)	6.5 (4.0 – 14.6)
CI = Confidence interval. FAS = Full analysis set. PSA = Prostate specific antigen. TPP = Time to prostate specific antigen progression. [a] PSA progression is defined according to PCWG3. [b] Calculated using the Kaplan-Meier technique. N = Number of patients in the specified population. Evaluable population is defined as all patients enrolled into the trial who completed at least 2 cycles of study medication and 12 weeks of follow-up. FAS population is defined as all patients enrolled into the trial who received at least one dose of study medication.		

Table 10 Circulating tumour cells (CTC) at baseline compared to cycle 1 day 28										
	Evaluable population					FAS population				
	Baseline		Cycle 1 Day 28			Baseline		Cycle 1 Day 28		
	N1	Mean (SD)	N1	Mean (SD)	*P*	N1	Mean (SD)	N1	Mean (SD)	*P*
CTC count	24	7.3 (11.5)	12	8.0 (13.0)	0.714	35	23.9 (68.9)	17	69.4 (227.6)	0.338

CTC = Circulating tumour cells. FAS = Full analysis set. SD = Standard deviation.
P-values presented are 2-sided p-values from the paired t-test between baseline and the specified post-baseline visit. Highlighted text indicates significant p-values at the 5% level.
N1 = Number of patients in the specified population with a non-missing CTC count at the specified visit and at baseline.
Evaluable population is defined as all patients enrolled into the trial who completed at least 2 cycles of study medication and 12 weeks of follow-up.
FAS population is defined as all patients enrolled into the trial who received at least one dose of study medication.