

<b>Table 1 Adverse events (AEs) summary (Safety Set population)</b>					
	<b>F + A (Continuous) (N=95)</b>	<b>F + A (Intermittent) (N=91)</b>	<b>F + E (N=64)</b>	<b>F (N=60)</b>	<b>All patients (N=310)</b>
AEs reported, n	1,449	1,424	1,374	429	4,676
Patients with at least one AE, n	95	91	64	60	310
AEs per patient [a], median (range)	11.0 (1 – 77)	12 (1 – 78)	19 (1 – 159)	6 (1 – 25)	11 (1 – 159)
≥ Grade 3 AEs reported, n	142	84	73	26	325
Patients with at least one ≥ Grade 3 AE, n	62	48	42	16	168
≥ Grade 3 AEs per patient [a], median (range)	2 (1 – 11)	2 (1 – 6)	1 (1 – 6)	1 (1 – 4)	1 (1 – 11)
Grade 3-4 AEs reported, n	139	82	72	26	319
Patients with at least one Grade 3-4 AE, n	62	48	41	16	167
Grade 3-4 AEs per patient [a], median (range)	2 (1 – 11)	2 (1 – 5)	1 (1 – 6)	1 (1 – 4)	1 (1 – 11)
AEs related to treatment, n	875	927	859	107	2,768
Patients with at least one AE related to treatment, n	88	85	62	38	273
AEs related to treatment per patient [a], median (range)	7 (1 – 50)	9 (1 – 67)	9 (1 – 143)	2 (1 – 10)	7 (1 – 143)
SAEs reported, n	59	42	35	11	147
Patients with at least one SAE, n	34	24	22	8	88
SAEs per patient [a], median (range)	1 (1 – 5)	1 (1 – 5)	1 (1 – 5)	1 (1 – 4)	1 (1 – 5)
Non-serious AEs reported, n	1,390	1,382	1,339	418	4,529
Patients with at least one non-serious AE, n	93	89	63	60	305
Non-serious AEs per patient [a], median (range)	11 (1 – 77)	12 (1 – 75)	18 (1 – 159)	5 (1 – 24)	11 (1 – 159)

A = AZD2014. AE = Adverse event. E = Everolimus. F = Fulvestrant. SAE = Serious adverse event.  
[a] This counts each instance once e.g. if one patient has the same term three times this is counted as 3 instances.  
Related is defined as very likely, probable or possibly related.  
Related to treatment is defined as related to any received treatment i.e. F, A, or E (as applicable).  
N = Number of patients in the specified arm in the Safety Set population.  
Safety Set population includes all patients randomised into the trial who received at least one dose of study treatment, with patients grouped based on received treatment.

<b>Table 2 Serious adverse events (SAEs) by preferred term (PT) (Safety Set population – All patients)</b>						
<b>CTCAE v4.03 PT</b>	<b>Grade 1</b>	<b>Grade 2</b>	<b>Grade 3</b>	<b>Grade 4</b>	<b>Grade 5</b>	<b>Total (N=141)</b>
Infection	1	3	18	2	1	25
Diarrhoea	2	1	5	1	0	9
Rash	1	1	3	1	0	6
Vomiting	0	1	5	0	0	6
Pyrexia	3	2	1	0	0	6
Abdominal pain	0	0	5	0	0	5
Pneumonitis	0	1	4	0	0	5
Dyspnoea	0	1	2	0	1	4
Pulmonary embolism	0	0	2	0	1	3
Cerebrovascular accident	0	0	1	2	0	3
Acute kidney injury	0	0	3	0	0	3
Musculoskeletal pain	0	0	3	0	0	3
Skeletal injury	0	0	3	0	0	3
Bone pain	0	1	2	0	0	3
Nausea	1	1	1	0	0	3
Arrhythmia	0	1	0	0	1	2
Skeletal fracture	0	1	0	1	0	2
Anaemia	0	0	2	0	0	2
Deep vein thrombosis	0	0	2	0	0	2
Renal impairment	0	1	1	0	0	2
Venous thrombosis	0	1	1	0	0	2
Haemorrhage	0	0	0	0	1	1
Coagulopathy	0	0	0	1	0	1
Large intestine perforation	0	0	0	1	0	1
Postictal paralysis	0	0	0	1	0	1
Thrombocytopenia	0	0	0	1	0	1
Acute generalised exanthematous pustulosis	0	0	1	0	0	1
Ascites	0	0	1	0	0	1
Cholecystitis	0	0	1	0	0	1
Cholelithiasis	0	0	1	0	0	1
Device occlusion	0	0	1	0	0	1
Drug-induced liver injury	0	0	1	0	0	1
Fall	0	0	1	0	0	1
Hepatocellular injury	0	0	1	0	0	1
Hepatotoxicity	0	0	1	0	0	1
Hyperglycaemia	0	0	1	0	0	1
Hypersensitivity	0	0	1	0	0	1
Hypertension	0	0	1	0	0	1
Ileus	0	0	1	0	0	1
Muscular weakness	0	0	1	0	0	1
Pain	0	0	1	0	0	1
Pneumonitis chemical	0	0	1	0	0	1
Psoriasis	0	0	1	0	0	1
Retinal detachment	0	0	1	0	0	1
Retinopathy	0	0	1	0	0	1
Syncope	0	0	1	0	0	1
Tremor	0	0	1	0	0	1
Abdominal hernia	0	1	0	0	0	1

Aphasia	0	1	0	0	0	1
Cardiac failure	0	1	0	0	0	1
Clonic convulsion	0	1	0	0	0	1
Colitis	0	1	0	0	0	1
Gastrointestinal haemorrhage	0	1	0	0	0	1
General physical health deterioration	0	1	0	0	0	1
Haematuria	0	1	0	0	0	1
Malaise	0	1	0	0	0	1
Overdose	0	1	0	0	0	1
Periodontal disease	0	1	0	0	0	1
Pleural effusion	0	1	0	0	0	1
Decreased appetite	1	0	0	0	0	1
Thrombosis	1	0	0	0	0	1
Transient ischaemic attack	1	0	0	0	0	1
Urinary retention	1	0	0	0	0	1

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

The worst toxicity for each patient of each SAE 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 includes all patients randomised into the trial who received at least one dose of study treatment, with patients grouped based on received treatment.