Table. Onset and Duration of Adverse Events

	Relugolix (N = 622)			Leuprolide (N = 308)		
	AE n (%)	**Onset (Days)[a]** Median (min, max)	**Duration (Days)[b]** Median (min, max)	**AE** n (%)	**Onset (Days)[a]** Median (min, max)	**Duration (Days)[b]** Median (min, max)
MACE[c]	18 (2.9)	176.5 (38, 343)	N/A	19 (6.2)	132.0 (8, 352)	N/A
AEs occurring in ≥ 10% of patients						
Hot flash	338 (54.3)	19.0 (1, 343)	342.0 (15, 477)	159 (51.6)	33.0 (1, 200)	331.0 (1, 428)
Fatigue	134 (21.5)	45.5 (1, 342)	289.0 (2, 429)	57 (18.5)	41.0 (1, 326)	274.0 (3, 426)
Constipation	76 (12.2)	128.0 (1, 359)	66.5 (2, 409)	30 (9.7)	61.0 (1, 273)	92.5 (3, 410)
Diarrhea[d]	76 (12.2)	75.5 (1, 338)	9.0 (1, 370)	21 (6.8)	133.0 (2, 313)	3.0 (1, 224)
Arthralgia	75 (12.1)	142.0 (1, 355)	160.0 (1, 495)	28 (9.1)	188.5 (1, 370)	129.5 (2, 589)
Grade ≥ 3 AEs in ≥ 1% patients						
Hypertension[e]	10 (1.6)	206.0 (15, 334)	14.5 (1, 328)	2 (0.6)	55.0 (21, 89)	26.5 (2, 51)
Diabetes	6 (1.0)	202.5 (85, 338)	117.5 (1, 204)	2 (0.6)	31.5 (29, 34)	191.5 (53, 330)
Syncope	6 (1.0)	163.0 (79, 315)	N/A	3 (1.0)	83.0 (45, 214)	N/A

Abbreviations: AE, adverse event; MACE, major adverse cardiovascular event; N/A, not applicable.

[a]Time to event is defined as the time from the date of first dose to the initial event (median days).

[b]Duration of AE defined as end date of the event – start date of the event + 1 (median days). Duration is not applicable to point in time events (ie, MACE and syncope).

[c]Search criteria included Myocardial Infarction SMQ (broad), Central Nervous System Hemorrhages and Cerebrovascular Conditions SMQ (broad), and deaths due to all causes.

[d]All diarrhea events were mild or moderate (grade 1 or grade 2) and no patient was withdrawn due to diarrhea.

[e] Grade ≥ 3 hypertension were reported in a higher proportion of patients in the relugolix group (1.6%) than the leuprolide group (0.6%); however, no meaningful differences were observed between groups in the mean changes from baseline over time in systolic or diastolic blood pressure

Adverse event grades are evaluated based on National Cancer Institute Common Terminology Criteria for Adverse Events Version 4.03. MedDRA Version 22.0.