ESM Table 2. Summary of Overall Safety and Selected Adverse Events During 26-Week Double-Blind Extension Period (Weeks 26-52; Period II)[a]

Participants, n (%)	PBO/SITA (n = 153)	SITA 100 mg (n = 313)	CANA 100 mg (n = 316)	CANA 300 mg (n = 321)
Any AE	63 (41.2)	134 (42.8)	138 (43.7)	119 (37.1)
AEs leading to discontinuation	1 (0.7)	8 (2.6)	0	1 (0.3)
AEs related to study drug[b]	7 (4.6)	28 (8.9)	29 (9.2)	16 (5.0)
Serious AEs	3 (2.0)	10 (3.2)	3 (0.9)	4 (1.2)
Deaths	0	1 (0.3)	0	0
Selected AEs				
UTI	10 (6.5)	12 (3.8)	12 (3.8)	6 (1.9)
Genital mycotic infection				
Male[c,d]	0	0	3 (2.0)	1 (0.7)
Female[e,f]	1 (1.4)	2 (1.2)	8 (4.8)	1 (0.6)
Osmotic diuresis-related AEs				
Pollakiuria[g]	0	0	0	2 (0.6)

Polyuria[h]	0	0	0	0
Volume-related AEs				
Postural dizziness	0	0	1 (0.3)	2 (0.6)
Orthostatic hypotension	0	0	0	0

PBO, placebo; SITA, sitagliptin; CANA, canagliflozin; AE, adverse event; UTI, urinary tract infection.

[a]All AEs are reported for regardless of rescue medication.

[b]Possibly, probably, or very likely related to study drug, as assessed by investigators.

[c]PBO/SITA, n = 81; SITA 100 mg, n = 148; CANA 100 mg, n = 148; CANA 300 mg, n = 142.

[d]Including balanitis and balanoposthitis.

[e]PBO/SITA, n = 72; SITA 100 mg, n = 165; CANA 100 mg, n = 168; CANA 300 mg, n = 179.

[f]Including vulvitis, vulvovaginal candidiasis, vulvovaginal mycotic infection, and vulvovaginitis.

[g]Increased urine frequency.

[h]Increased urine volume.