

Table SVII. Treatment-emergent fungal infection adverse events by high-level group terms and preferred term in the constant^a treatment groups from baseline to end of treatment (safety analysis set)

	Placebo			Ustekinumab			Brodalumab 140 mg Q2W			Brodalumab 210 mg Q2W		
	n (%)	E	E/100 PY	n (%)	E	E/100 PY	n (%)	E	E/100 PY	n (%)	E	E/100 PY
<i>Period 1</i>												
Fungal infectious disorders	n=881; 200.2 PYE			n=612; 139.5 PYE			n=1,490; 342.3 PYE			n=1,495; 344.4 PYE		
Tinea pedis	9 (1.0)	9	4.5	6 (1.0)	7	5.0	17 (1.1)	17	5.0	37 (2.5)	41	11.9
Vulvovaginal mycotic infection	3 (0.3)	3	1.5	1 (0.2)	1	0.7	2 (0.1)	2	0.6	10 (0.7)	11	3.2
Oral candidiasis	0			0			3 (0.2)	3	0.9	3 (0.2)	3	0.9
Skin <i>Candida</i>	2 (0.2)	2	1.0	0			1 (0.1)	1	0.3	3 (0.2)	3	0.9
Tinea versicolour	2 (0.2)	2	1.0	1 (0.2)	1	0.7	1 (0.1)	1	0.3	1 (0.1)	1	0.3
Candida infection	0			0			0			4 (0.3)	4	1.2
Vulvovaginal candidiasis	0			0			3 (0.2)	3	0.9	1 (0.1)	1	0.3
Fungal infection	1 (0.1)	1	0.5	1 (0.2)	1	0.7	0			1 (0.1)	1	0.3
Fungal skin infection	0			2 (0.3)	3	2.2	0			1 (0.1)	1	0.3
Oesophageal candidiasis	0			0			2 (0.1)	2	0.6	1 (0.1)	1	0.3
Oral fungal infection	0			0			2 (0.1)	2	0.6	1 (0.1)	1	0.3
Genital candidiasis	0			0			0			2 (0.1)	2	0.6
Onychomycosis	0			0			0			2 (0.1)	2	0.6
Tinea cruris	0			0			1 (0.1)	1	0.3	1 (0.1)	1	0.3
Tinea infection	1 (0.1)	1	0.5	0			0			1 (0.1)	1	0.3
Body tinea	0			0			0			1 (0.1)	1	0.3
Dermatophytosis	0			0			0			1 (0.1)	1	0.3
Fungal oesophagitis	0			0			0			1 (0.1)	1	0.3
Gastritis fungal	0			0			0			0		
Meningitis cryptococcal	0			0			0			1 (0.1)	1	0.3
Upper respiratory fungal infection	0			0			0			1 (0.1)	1	0.3
<i>Period 2</i>												
Fungal infectious disorders	n=612; 432.9 PYE			n=467; 293.3 PYE			n=537; 415.8 PYE					
Tinea pedis	14 (2.3)	17	3.9	15 (3.2)	15	5.1	33 (6.1)	41	9.9			
Oral candidiasis	3 (0.5)	3	0.7	3 (0.6)	3	1.0	8 (1.5)	9	2.2			
Vulvovaginal candidiasis	1 (0.2)	2	0.5	4 (0.9)	4	1.4	8 (1.5)	8	1.9			
Vulvovaginal mycotic infection	1 (0.2)	1	0.2	3 (0.6)	3	1.0	3 (0.6)	4	1.0			
Fungal skin infection	2 (0.3)	4	0.9	0			2 (0.4)	2	0.5			
Oral fungal infection	0			1 (0.2)	1	0.3	2 (0.4)	3	0.7			
Tinea versicolour	2 (0.3)	2	0.5	0			2 (0.4)	2	0.5			
Fungal infection	2 (0.3)	2	0.5	0			0			1 (0.2)	1	0.2
Oesophageal candidiasis	0			1 (0.2)	1	0.3	1 (0.2)	1	0.2			
Onychomycosis	0			0			2 (0.4)	2	0.5			
Skin candida	0			1 (0.2)	1	0.3	1 (0.2)	2	0.5			
Tinea cruris	0			0			2 (0.4)	2	0.5			
Body tinea	0			1 (0.2)	1	0.3	0					
Candida infection	0			0			1 (0.2)	2	0.5			
Coccidioidomycosis	0			0			1 (0.2)	1	0.2			
Meningitis cryptococcal	0			0			1 (0.2)	1	0.2			
Tinea manuum	0			1 (0.2)	1	0.5	0			1 (0.2)	1	0.2
Upper respiratory fungal infection	0			0			1 (0.2)	1	0.2			
<i>Period 3</i>												
Fungal infectious disorders	n=467; 529.5 PYE			n=537; 869.7 PYE								
Oral candidiasis	20 (4.3)	23	4.3	52 (9.7)	82	9.4						
Tinea pedis	4 (0.9)	5	0.9	16 (3.0)	20	2.3						
Vulvovaginal candidiasis	4 (0.9)	4	0.8	11 (2.0)	16	1.8						
Onychomycosis	3 (0.6)	3	0.6	4 (0.7)	6	0.7						
Fungal skin infection	2 (0.4)	2	0.4	4 (0.7)	4	0.5						
Oropharyngeal candidiasis	0			4 (0.7)	5	0.6						
Vulvovaginal mycotic infection	1 (0.2)	1	0.2	3 (0.6)	3	0.3						
Candida infection	0			4 (0.7)	4	0.5						
Oral fungal infection	1 (0.2)	1	0.2	3 (0.6)	5	0.6						
Skin candida	0			1 (0.2)	2	0.2						
Tinea cruris	1 (0.2)	1	0.2	2 (0.4)	2	0.2						
Tinea infection	0			3 (0.6)	3	0.3						
Body tinea	1 (0.2)	1	0.2	1 (0.2)	1	0.1						
Oesophageal candidiasis	1 (0.2)	1	0.2	1 (0.2)	1	0.1						
Balanitis candida	0			1 (0.2)	1	0.1						
Coccidioidomycosis	0			1 (0.2)	1	0.1						
Dermatophytosis	0			1 (0.2)	1	0.1						
Meningitis cryptococcal	0			1 (0.2)	1	0.1						
Oropharyngitis fungal	0			1 (0.2)	1	0.1						
Tinea manuum	1 (0.2)	1	0.2	0								
Tinea versicolour	0			1 (0.2)	1	0.1						
Upper respiratory fungal infection	0			1 (0.2)	1	0.1						

^aConstant treatment groups included all patients exposed to the same planned treatment during the full length of a treatment period. Four time periods were identified: period 1, the initial double-blind, placebo- and ustekinumab-controlled 12-week induction phase; period 2, the ustekinumab-controlled 52-week period; and periods 3 and 4, which covered the open-label extension trials up to the end of treatment or last follow-up.

E: number of events; E/100 PY: event rate per 100 patient-years; PYE: patient-years of exposure; Q2W: every 2 weeks.