

Table SI. Efficacy results and evolution of the main criterion (itch intensity from verbal rating scale) from day 0 to day 42 in the per-protocol population

Itch/VRS	Therapy	Per protocol (PP) population				
		Visit 1 Day 0	Visit 2 Day 14	Visit 3 Day 28	Visit 4 Day 42	
Grades, n (%)						
1	Active	0 (0)	0 (0)	1 (4)	0 (0)	
	Vehicle	0 (0)	0 (0)	1 (3)	0 (0)	
2	Active	0 (0)	4 (17)	6 (25)	7 (29)	
	Vehicle	0 (0)	6 (21)	9 (31)	6 (21)	
3	Active	3 (13)	7 (29)	7 (29)	10 (42)	
	Vehicle	8 (28)	6 (21)	8 (14)	8 (28)	
4	Active	19 (79)	7 (29)	7 (29)	4 (17)	
	Vehicle	19 (66)	10 (34)	9 (38)	9 (31)	
5	Active	2 (8)	3 (13)	3 (13)	3 (13)	
	Vehicle	2 (7)	7 (24)	6 (14)	6 (21)	
<i>Primary criterion itch intensity^a</i>						
VRS ≥ 2, n (%) (p)	Active		5 (21)	5 (21)	7 (29)	
	Vehicle		3 (10)	7 (24)	4 (14)	p=0.3014
VRS ≥ 1, n (%) (p)	Active		11 (46)	13 (54)	17 (71)	
	Vehicle		12 (41)	14 (48)	13 (45)	p=0.1046
VRS <1, n (%) (p)	Active		13 (54)	11 (46)	7 (29)	
	Vehicle		17 (59)	15 (52)	16 (55)	p=0.1046
<i>Secondary criteria</i>						
Pruritus VAS, cm, mean (SD)	Active	7.8 (0.7)	6.1 (2.6)	5.4 (5.0)	4.5 (2.5)	
	Vehicle	7.7 (0.6)	6.3 (2.4)	5.5 (2.8)	5.6 (2.8)	
Insomnia VAS, cm, mean (SD)	Active	7.8 (0.7)		3.2 (2.1)	3.1 (2.2)	
	Vehicle	5.7 (2.6)		3.7 (2.7)	3.8 (3.0)	
SCORAD, mean (SD)	Active	34.9 (5.3)		36.0 (14.8)	28.6 (12.5)	
	Vehicle	35.7 (4.6)		34.4 (13.1)	33.6 (12.7)	
DLQI, mean (SD)	Active	9.3 (4.2)		6.8 (4.2)	6.2 (4.9)	
	Vehicle	11.4 (6.3)		7.8 (6.0)	7.2 (5.6)	
DLQI no + small effect, %	Active	13		46	59	
	Vehicle	6		48	41	
TEWL lesion, mean (SD)	Active	32.3 (12.9)	39.7 (15.2)	35.8 (16.3)	33.1 (14.6)	
	Vehicle	33.6 (11.8)	30.7 (13.9)	32.8 (15.2)	37.6 (14.1)	
TEWL lesion free, mean (SD)	Active	12.6 (4.9)	18.7 (15.4)	16.6 (10.1)	16.0 (8.7)	
	Vehicle	12.2 (6.2)	16.8 (10.1)	14.6 (12.0)	16.5 (12.0)	
<i>Verbal rating scale items</i>						
Roughness, mean (SD)	Active	5.2 (2.4)	3.1 (0.9)	3.0 (0.9)	2.7 (0.9)	
	Vehicle	3.3 (0.8)	3.4 (0.9)	3.0 (1.0)	3.2 (1.1)	
Desquamation, mean (SD)	Active	3.3 (0.9)	2.9 (0.9)	2.6 (0.9)	2.8 (0.8)	
	Vehicle	2.8 (1.1)	3.0 (1.1)	2.9 (1.2)	2.8 (1.3)	
Tension, mean (SD)	Active	2.9 (0.9)	2.8 (1.2)	2.8 (1.0)	2.7 (1.0)	
	Vehicle	3.4 (0.9)	3.2 (1.1)	3.2 (1.0)	3.1 (1.1)	
Burning, mean (SD)	Active	3.0 (0.9)	2.5 (1.1)	2.5 (1.2)	2.5 (1.3)	
	Vehicle	2.9 (1.0)	2.6 (1.2)	2.5 (1.2)	2.7 (1.4)	

^aVerbal rating scale (VRS) ≥2: primary criterion i.e. number of subjects presenting at least 2 grades reduction from baseline to week 4 on the item itch intensity of the 5-point VRS; VRS ≥1 or <1: revised primary criteria to determine potential significant differences.

VAS: visual analogue scale; SD: standard deviation; SCORAD: SCORing of Atopic Dermatitis; DLQI: Dermatological Life Quality Index; TEWL: transepidermal water loss.