B. Tablas suplementarias

Tabla S2. Resumen eficacia de apremilast en psoriasis en localizaciones especiales: uñas, cuero cabelludo y palmoplantar

Localización	Semana	ESTEEM-1[4,5]						ESTEEM-2[4,5]						PSOR-005[4,5]				LIBERATE[6,7]						LAPIS-PSO[8]
Uñas		% Cambio NAPSI desde basal			% Pacientes con NAPSI-50			% Cambio NAPSI desde basal			% Pacientes con NAPSI-50			% Cambio NAPSI desde basal		% Pacientes con NAPSI-50		% Cambio NAPSI (desde NAPSI basal ≥ 1)			% Pacientes con NAPSI-50 (NAPSI basal ≥ 1)			% Pacientes NAPSI-50
		APR	PBO	PBO/APR	APR	PBO	PBO/APR	APR	PBO	PBO/APR	APR	PBO	PBO/APR	APR (30 mg)	PBO	APR (30 mg)	PBO	APR	PBO	PBO/APR	APR	PBO	PBO/APR	APR
Semana	4	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	21,7%
	16	− 22,5%	6,50%	-	33,30%	14,90%	-	− 29,0%	− 7,1%	-	44,60%	18,70%	-	− 42,9%	− 0%	45,50%	18,20%	− 18,7%	− 10,1%	-	-	-	-	62,4%
	32	− 43,6%	-	-25%	45%	-	35%	− 60,0%	-	− 47,6%	55%	-	52%	-	-	-	-	− 42,8%	-	− 40%	46,2%	-	41,3%	-
	52	− 60,2%	-	-	63,00%	-	-	− 59,7%	-	− 62,0%	68,60%	-	64,30%	-	-	-	-	− 48,2%	-	− 48,1%	-	-	-	-
Cuero cabelludo		% Pacientes con Sc-PGA de 0 o 1						% Pacientes con Sc-PGA de 0 o 1										% Pacientes con Sc-PGA de 0 o 1						% Pacientes Sc-PGA 0 o 1
		APR		PBO		PBO/APR		APR		PBO		PBO/APR						APR	PBO	PBO/APR				APR
Semana	4	-		-		-		-		-		-						-	-	-				39,2%
	16	46,5%		17,5%		-		40,9%		17,2%		-						44,4%	25,9%	-				58,4%
	32	37,4%		-		43,6%		32,4%		-		50,7%						50,0%	-	46,6%				-
	52	73,0%		-		-		62,5%		-		53,5%						59,2%	-	50,0%				-
Psoriasis palmoplantar		% Pacientes con PPPGA de 0 o 1 (PPGA basal ≥ 3)		% Pacientes con PPPGA de 0 o 1 (≥ 1 punto de mejora; PPGA basal ≥ 3)				% Pacientes con PPPGA de 0 o 1 (PPGA basal ≥ 3)		% Pacientes con PPPGA de 0 o 1 (≥ 1 punto de mejora; PPGA basal ≥ 3)				% Pacientes con PPPGA de 0 o 1 (PPGA basal ≥ 3)		% Pacientes con PPPGA de 0 o 1 (≥ 1 punto de mejora; PPGA basal ≥ 3)								% Pacientes PPPGA 0 o 1
		APR	PBO	APR	PBO			APR	PBO	APR	PBO			APR	PBO	APR	PBO							APR
Semana	4	-	-	-	-			-	-	-	-			-	-	-	-							48,8%
	16	38,6%	30,8%	63,3%	44,7%			65,4%	31,3%	70,5%	37,0%			66,7%	20,0%	70,4%	31,8%							69,0%

Tabla S3. Resumen efectos adversos observados con apremilast en ensayos clínicos y vida real

ESTEEM-1 y ESTEEM-2[6,9-15] (1)	
EA comunes (≥ 5% de los pacientes) (2)	
Diarrea	18,70%
Náuseas	16,50%
Infección tracto respiratorio superior	19,20%
Nasofaringitis	16,60%
Dolor de cabeza tensional	9,70%
EA graves	
EA cardiacos graves	0,80%
Cáncer	1,90%
Depresión	2,80%
Depresión grave	0,20%
Intención suicida (3)	0,10%
Infecciones	
Tracto urinario	0,20%
Apendicitis	0,30%
Neumonía	0,20%
Otras infecciones	≤ 0,1%
Otros	
Pérdida de peso, media (± SD)	−1,53% (± 6,0%)
Estudio LAPIS-PSO[16](4)	
EA comunes (≥ 5% de los pacientes)	
Diarrea	8,30%
Náuseas	1,20%
Dolor de cabeza	1,90%
Infección tracto respiratorio superior	0,90%

(1) Seguimiento hasta las 182 semanas. Perfil de seguridad de apremilast en los estudios ESTEEM-1 y ESTEEM-2 comparable al perfil observado en los estudios de fase III LIBERATE y PALACE-1, PALACE-2 y PALACE-37,8.

(2) En general, el porcentaje de pacientes que discontinuaron el tratamiento debido a alguno de estos EA fue muy bajo, ≤1% para cada uno de ellos.

(3) No se registró ningún caso de suicidio consumado.

(4) Parece que la incidencia global de EA con apremilast es menor en la práctica clínica real que la registrada en los ensayos clínicos durante el desarrollo del fármaco.

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