

Supplementary Material

Supplement to article titled: Clinically meaningful improvements in adolescents with moderate-to-severe atopic dermatitis treated with tralokinumab who did not achieve clear or almost clear skin at Week 16

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The authors have provided this Supplementary Material to provide readers additional information about their work.

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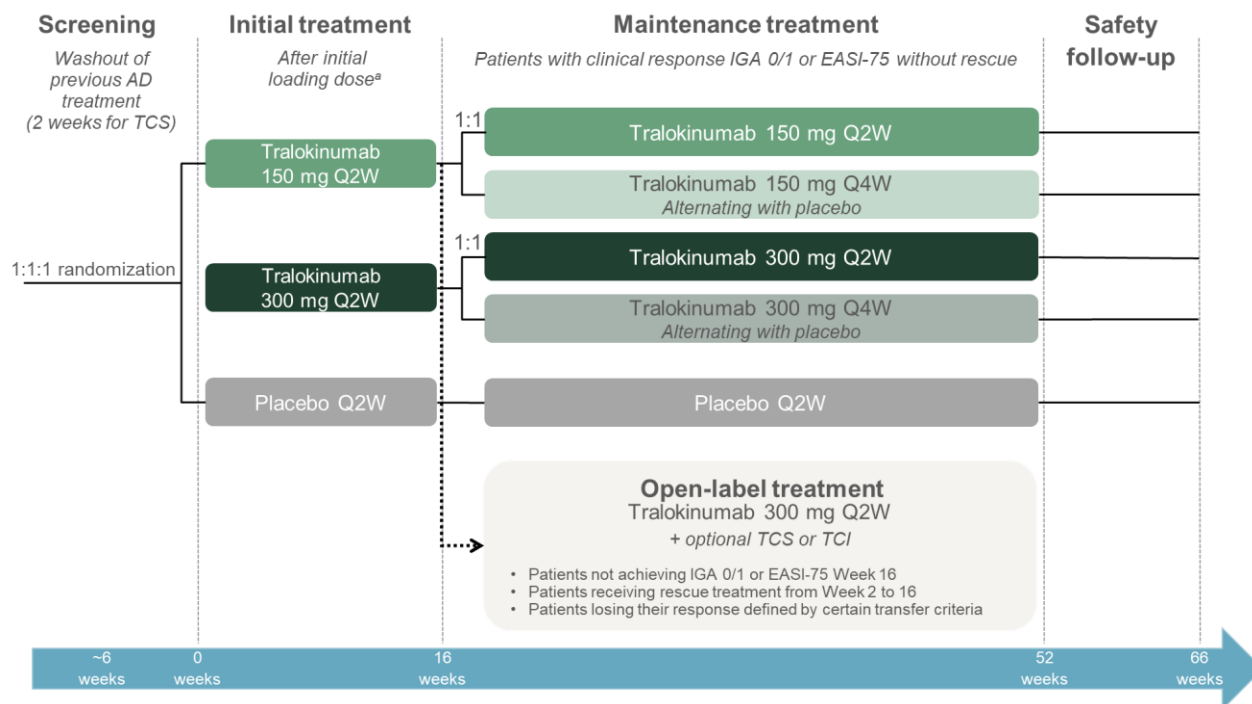
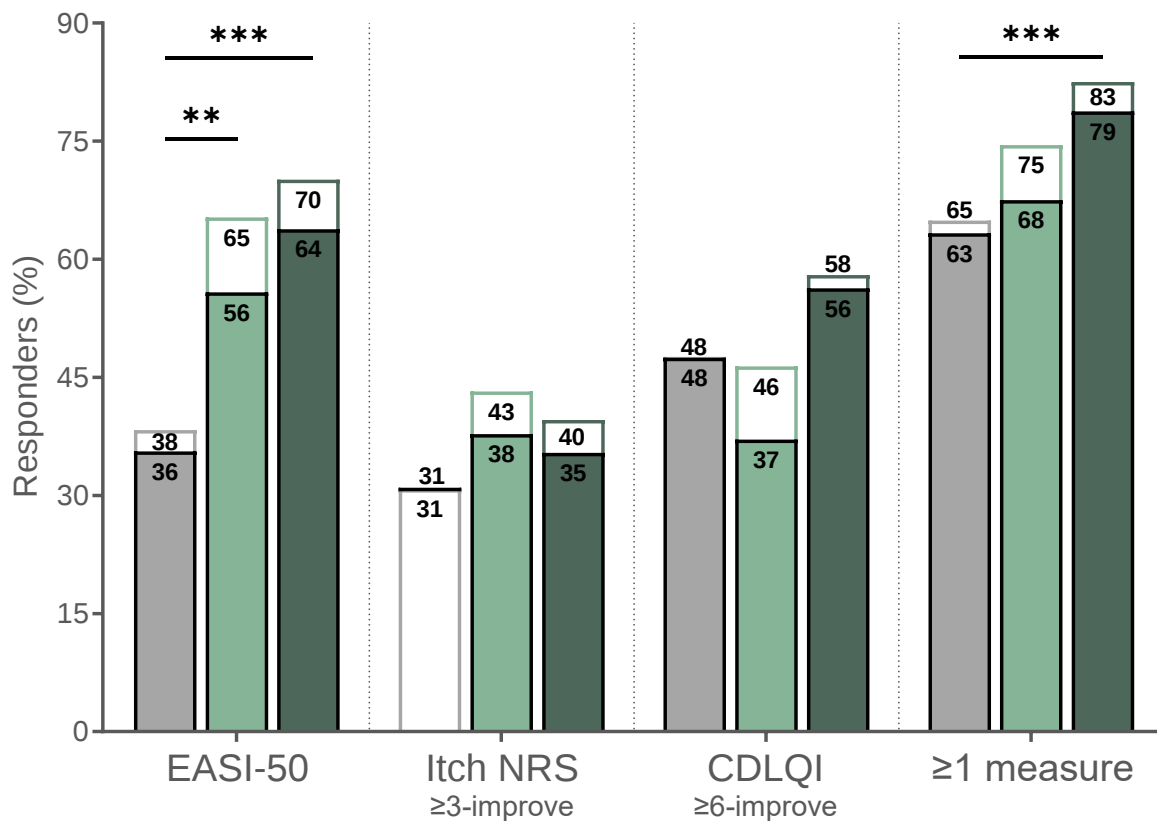


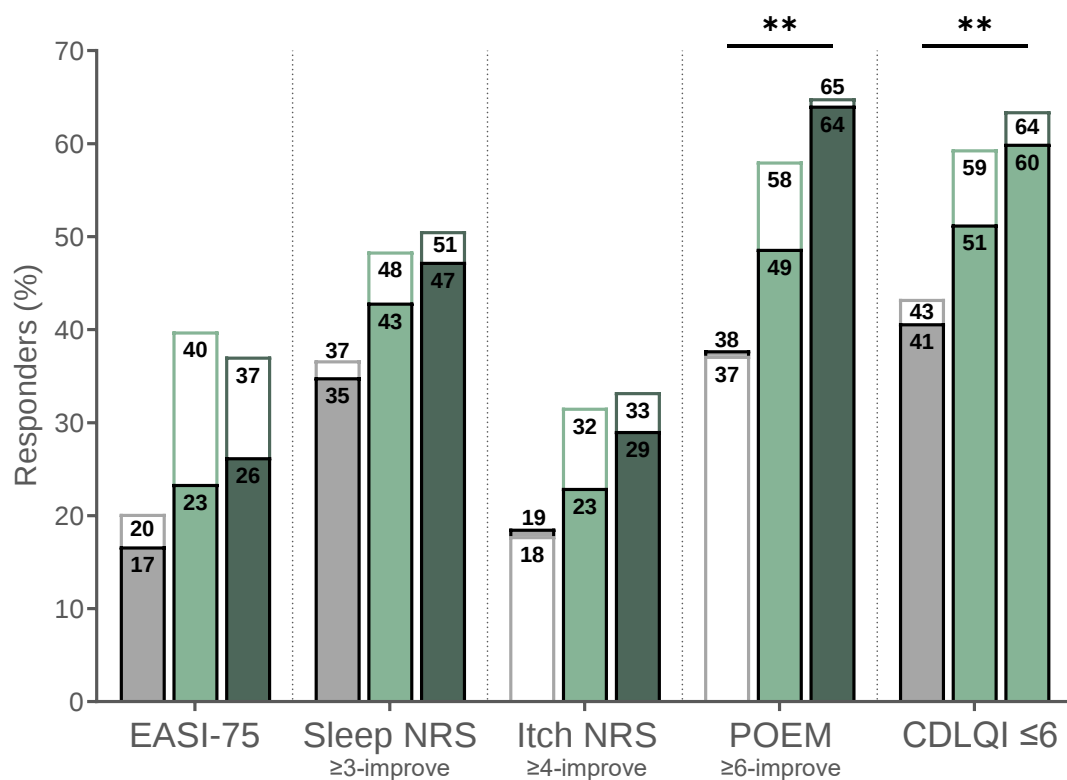
Figure S1. ECZTRA 6 trial design. ^aInitial loading dose on Day 0 was twice the dosage of their respective tralokinumab group.

AD, atopic dermatitis; EASI, Eczema Area Severity Index. EASI-75, at least 75% improvement in EASI; IGA, Investigator's Global Assessment; IGA 0/1, clear/almost clear skin; Q2W, every 2 weeks; Q4W, every 4 weeks; TCI, topical calcineurin inhibitors; TCS, topical corticosteroids.



	EASI-50	Itch NRS ≥3-improve	CDLQI ≥6-improve	≥1 measure
IGA >1 population, n				
Placebo	90	87	80	90
Tralokinumab 150 mg	77	74	70	77
Tralokinumab 300 mg	80	79	71	80
Total population, n				
Placebo	94	91	82	94
Tralokinumab 150 mg	98	95	84	98
Tralokinumab 300 mg	97	96	81	97

Figure S2. Percentages of IGA >1 patients who achieved clinically meaningful responses (EASI-50, ≥3-point improvement in itch NRS, ≥6-point improvement in CDLQI) at Week 16. Asterisks denote tralokinumab dose (150 or 300 mg) vs placebo in the IGA >1 population: * $P < 0.05$, ** $P < 0.01$, *** $P < 0.001$. Stacked (no fill) bars denote percentages for the total ECZTRA 6 population. Percentages of responders, rounded to nearest whole number, are listed within bars. Treatment policy estimand used data as observed, regardless of rescue medication and other intercurrent events, and multiple imputation for missing data. CDLQI, Children's Dermatology Life Quality Index; EASI, Eczema Area and Severity Index; EASI-50, at least 50% improvement in EASI; IGA, Investigator's Global Assessment; n, number of patients with available data; NRS, numeric rating scale.



	EASI-75	Sleep NRS ≥ 3 -improve	Itch NRS ≥ 4 -improve	POEM ≥ 6 -improve	CDLQI ≤ 6
IGA >1 population, n					
Placebo	90	86	86	82	86
Tralokinumab 150 mg	77	70	74	76	76
Tralokinumab 300 mg	80	74	79	78	80
Total population, n					
Placebo	94	90	90	86	90
Tralokinumab 150 mg	98	91	95	93	96
Tralokinumab 300 mg	97	89	96	94	96

Figure S3. Percentages of IGA >1 patients who achieved additional outcomes of interest at Week 16. Asterisks denote tralokinumab dose (150 or 300 mg) vs placebo in the IGA >1 population: * $P < 0.05$, ** $P < 0.01$, *** $P < 0.001$. Stacked (no fill) bars denote percentages for the total ECZTRA 6 population. Percentages of responders, rounded to nearest whole number, are listed within bars. Note that percentages of responders for 4-improvement in Itch NRS or ≥ 6 -improvement in POEM in the placebo group are as follows: IGA >1 population = 18.6%, total population = 17.8%; IGA >1 population = 37.8%, total population = 37.2%. Treatment policy estimand used data as observed, regardless of rescue medication and other intercurrent events, and multiple imputation for missing data. CDLQI, Children's Dermatology Life Quality Index; EASI, Eczema Area and Severity Index; EASI-75, at least 75% improvement in EASI; IGA, Investigator's Global Assessment; n, number of patients with available data; NRS, numeric rating scale; POEM, Patient Oriented Eczema Measure.

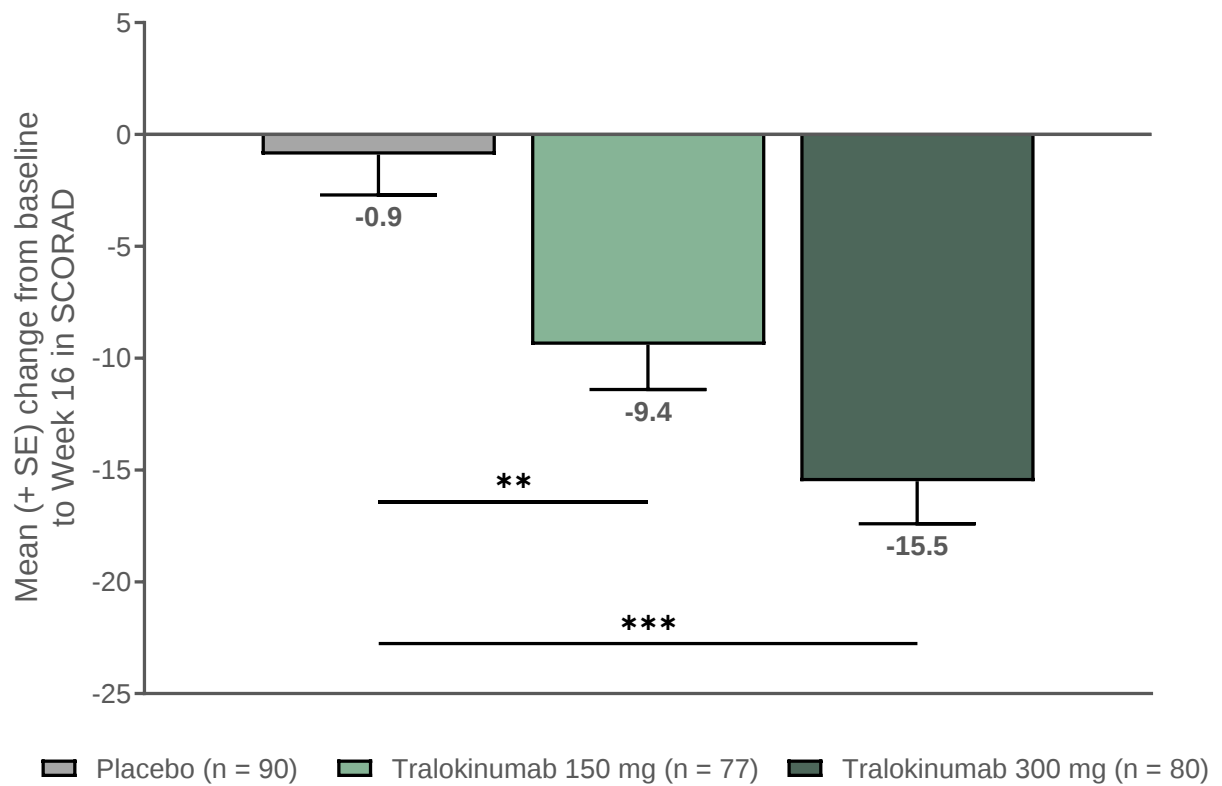


Figure S4. IGA >1 patients treated with tralokinumab achieved greater mean change from baseline to Week 16 in SCORAD compared with placebo. Asterisks denote tralokinumab dose (150 or 300 mg) vs placebo in the IGA >1 population: * $P < 0.05$, ** $P < 0.01$, *** $P < 0.001$. IGA, Investigator's Global Assessment; n, number of patients with available data; SCORAD, SCORing Atopic Dermatitis; SE, standard error.

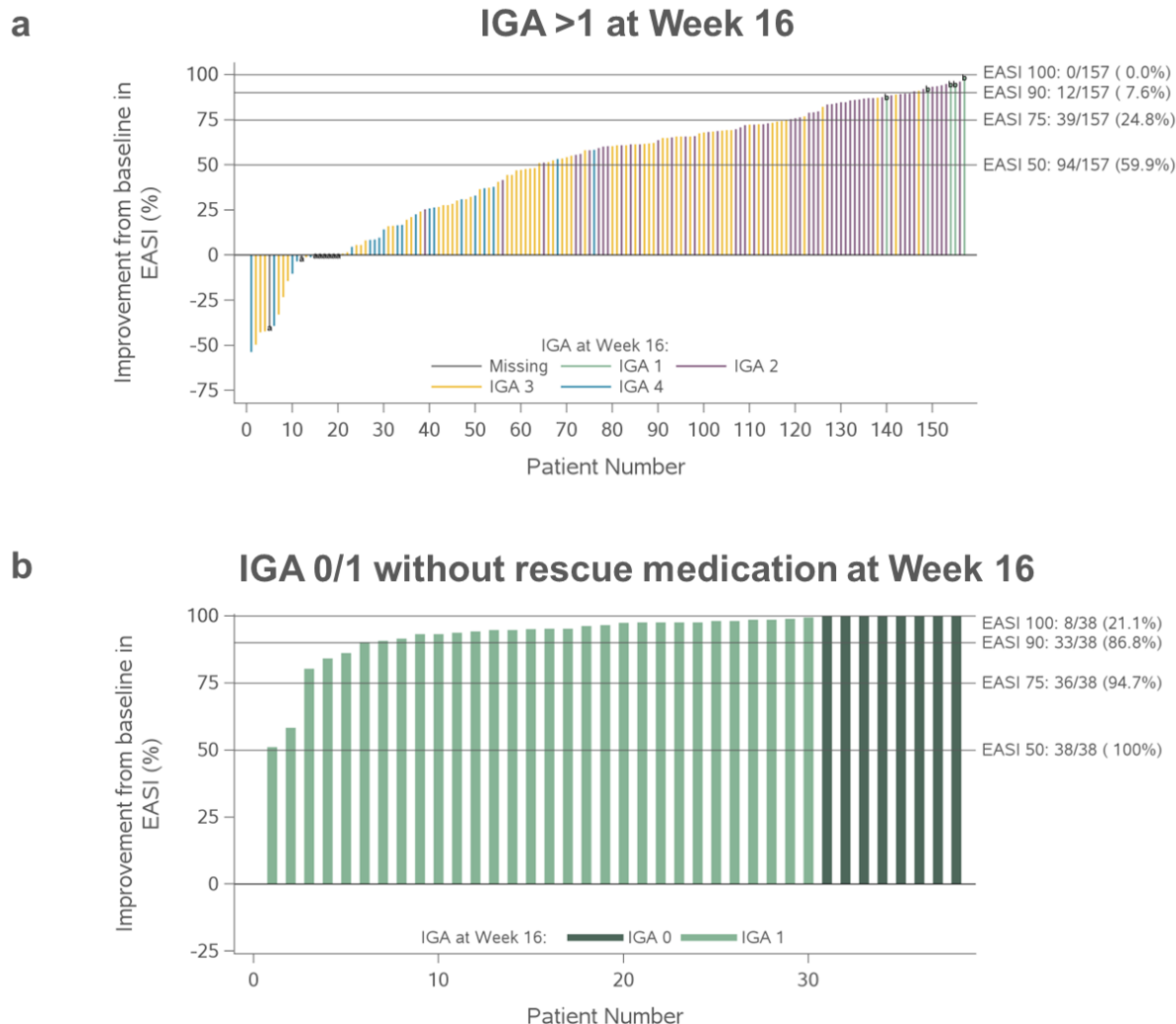


Figure S5. Improvement in EASI from baseline to Week 16 in tralokinumab-treated patients who showed (a) IGA >1 at Week 16 or (b) IGA 0/1 without rescue medication at Week 16. ^aWOCF used for missing data. ^bUse of rescue medication between Week 2 and Week 16.

EASI, Eczema Area and Severity Index; EASI-50/75/90/100, at least 50%/75%/90%/100% improvement in EASI; IGA, Investigator's Global Assessment; IGA 0/1/2/3/4, clear/almost clear/mild/moderate/severe; n, number of patients with available data; Q2W, every 2 weeks; TCI, topical calcineurin inhibitors; TCS, topical corticosteroids; WOCF, worst observation carried forward.

Table S1. Baseline characteristics for ECZTRA 6 patients who achieved IGA 0/1 without rescue medication at Week 16.

	IGA 0/1 ^a at Week 16		
	Placebo (N = 4)	Tralo 150 mg (N = 21)	Tralo 300 mg (N = 17)
Age (years), mean (SD)	16.0 (0.8)	14.7 (1.8)	14.6 (2.0)
Male, n (%)	1 (25.0)	13 (61.9)	5 (29.4)
Race, n (%)			
White	3 (75.0)	11 (52.4)	12 (70.6)
Black or African American	1 (25.0)	0 (0.0)	3 (17.6)
Asian	0 (0.0)	7 (33.3)	2 (11.8)
American Indian or Alaska Native	0 (0.0)	0 (0.0)	0 (0.0)
Native Hawaiian or Other Pacific Islander	0 (0.0)	0 (0.0)	0 (0.0)
Other	0 (0.0)	3 (14.3)	0 (0.0)
Body mass index (kg/m ²), mean (SD)	23.0 (5.2)	22.3 (3.5)	21.8 (3.6)
Duration of AD (years), mean (SD)	13.8 (4.6)	11.7 (4.6)	12.4 (3.5)
BSA involvement with AD (%), mean (SD)	52.0 (15.0)	44.7 (20.4)	38.1 (13.8)
IGA, n (%)			
IGA 3 (moderate)	3 (75.0)	17 (81.0)	12 (70.6)
IGA 4 (severe)	1 (25.0)	4 (19.0)	5 (29.4)
EASI, mean (SD)	27.8 (10.9)	26.7 (10.0)	25.7 (6.0)
Itch NRS, mean (SD)	6.7 (1.9)	7.5 (1.4)	7.9 (1.7)
CDLQI, mean (SD)	8.3 (6.9)	11.0 (6.8), N = 19	11.3 (8.6), N = 16
Sleep NRS, mean (SD)	6.4 (2.2)	6.8 (1.6)	6.1 (2.1)
POEM, mean (SD)	15.5 (6.5)	18.0 (7.4), N = 19	16.4 (7.1), N = 16
SCORAD, mean (SD)	63.1 (12.6)	64.7 (13.7)	65.9 (11.9)

^aPatients who achieved IGA 0/1 at Week 16 without rescue medication. Individual row N values are shown when different from respective total number of patients in group.

AD, atopic dermatitis; BSA, body surface area; CDLQI, Children's Dermatology Life Quality Index; EASI, Eczema Area and Severity Index; IGA, Investigator's Global Assessment; NRS, numeric rating scale; IGA 0/1, clear/almost clear skin; N, total number of patients per group; n, number of patients meeting indicated metric; POEM, Patient Oriented Eczema Measure; SCORAD, SCORing Atopic Dermatitis; SD, standard deviation.

Table S2. Rescue medication use by type during the initial 16-week treatment period in IGA >1 patients.

	IGA >1 ^a at Week 16		
	Placebo (N = 90)	Tralokinumab 150 mg (N = 77)	Tralokinumab 300 mg (N = 80)
Any rescue medication, n (%)	53 (58.9)	33 (42.9)	29 (36.3)
Topical, n (%)			
Corticosteroids	51 (56.7)	33 (42.9)	29 (36.3)
Other ^b	8 (8.9)	3 (3.9)	5 (6.3)
Systemic, n (%)			
Corticosteroids	5 (5.6)	1 (1.3)	1 (1.3)
Immunosuppressants ^c	1 (1.1)	0 (0.0)	1 (1.3)

^aPatients who did not achieve IGA 0/1 at Week 16 and/or used rescue medication. ^bIncludes pimecrolimus, tacrolimus, crisaborole. ^cIncludes methotrexate, cyclosporin, azathioprine, and mycophenolate.

IGA, Investigator's Global Assessment; IGA 0/1, clear/almost clear skin; N, total number of patients per group; n, number of patients meeting indicated metric.

Table S3. ECZTRA 6 trial investigators and institutions.

Country	Center Number	Investigator	Center Address
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	605-1070	Dr. Arjen Nikkels	Centre Hospitalier Universitaire de Liège Domaine du Sart Tilman B35 4000 LIEGE Belgium
	608-1377	Dr. Sven Lanssens	Dermatologie Maldegem Brugse Steenweg 181A 9990 Maldegem Belgium
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Table S4. Independent ethics committees and institutional review boards for ECZTRA 6 trial.

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Belgium	Ethics Committee Chairman: Prof. Dr. Phillipe Deron UZ Gent Corneel Heymanslaan, 10 B-9000 Gent, Belgium Ethics Committee Chairman: Dr. Jean-Marie Maloteaux Promenade de l'Alma 51 bte B1.43.03 1200 Bruxelles, Belgium Ethics Committee Chairman: Vincent Seutin Centre Hospitalier Universitaire Avenue de l'hôpital 1 Domaine du Sart Tilman B35 4000 Liege, Belgium Ethics Committee Chairman: Prof. dr. D. Michielsen Central Ethics Committee Dermatologie Maldegem Laarbeeklaan 101	Dr. Sofie De Schepper (600-0475) UZ Gent Corneel Heymanslaan, 10 Vijverpark - ground floor, entrance 52 B-9000 Gent, Belgium Dr. Pierre-Dominique Ghislain (601-1014) Cliniques Universitaires St-Luc Avenue Hippocrate, 10, Route 413 1200 Brussels Belgium Dr. Arjen Nikkels (605-1070) Centre Hospitalier Universitaire de Liège Domaine du Sart Tilman B35 4000 LIEGE Belgium Dr. Sven Lanssens (608-1377) Dermatologie Maldegem Brugse Steenweg 181A 9990 Maldegem Belgium

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Ethics Committee

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