

**Adalimumab in Japanese Patients with Active Ulcers of Pyoderma Gangrenosum:  
Final Analysis of a 52-Week Phase 3 Open-label Study**

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**Supplementary Material**

**Table S1.** Investigator Inflammation Assessment (From Wilkes *et al.* 2016, *J Am Acad Dermatol* <http://dx.doi.org/10.1016/j.jad.2016.07.049>)

<b>Severity rating score</b>		<b>Description</b>
<b>Erythema</b>		
0	None	No erythema
1	Slight	Mild pink color
2	Moderate	Moderate pink color
3	Severe	Reddish color
4	Very severe	Dark red or violaceous
<b>Border elevation</b>		
0	None	Border is flat with ulcer and surrounding skin, no elevation
1	Slight	Slight elevation of border above ulceration and surrounding skin
2	Moderate	Noticeable elevation of border above ulceration and surrounding skin
3	Severe	Significant elevation of border above ulceration and surrounding skin
4	Very severe	Border rolled high above ulceration and surrounding skin

**Table S2** Physician's Global Assessment Scale. (From Wilkes *et al.* 2016, *J Am Acad Dermatol* <http://dx.doi.org/10.1016/j.jad.2016.07.049>)

<b>Scale</b>	<b>Description</b>	
<b>0</b>	Completely clear	Except for possible residual hyperpigmentation
<b>1</b>	Almost clear	Very significant clearance (about 90%); however, patchy remnants of dusky erythema and/or very small ulceration
<b>2</b>	Marked improvement	Significant improvement (about 75%); however, a small amount of disease remaining (ie, remaining ulcers, although have decreased in size, minimal erythema, and/or barely perceptible border elevation)
<b>3</b>	Moderate improvement	Intermediate between slight and marked; representing about 50% improvement
<b>4</b>	Slight improvement	Some improvement (about 25%); however, significant disease remaining (ie, remaining ulcers with only minor decrease in size, erythema, or border elevation)
<b>5</b>	No change from baseline	
<b>6</b>	Worse	

**Table S3. Specification, measurement, and PGAR calculation of target ulcer**

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1a	Examination of all ulcers at the screening visit
1b	Specification of the target pyoderma gangrenosum (PG) ulcer; this does not change throughout the study  In the case of multiple PG ulcers, the target PG ulcer is the largest ulcer by area that can be photographed on a single plane
3	Photography of the target PG ulcer and all non-target PG ulcer(s) at specified visits
4a	Using digital photography of a patient's target PG ulcer, borders (and internal epithelialized regions, if any) delineated, and ulcer area calculated (cm <sup>2</sup> ) using computerized planimetry (by external vendor)
4b	Maximal width and height of the target PG ulcer and all non-target PG ulcers measured by the Investigator at specified visits
5	The PGAR (PG area reduction) calculated as the percentage area change in the target PG ulcer from baseline by digital planimetry

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PGAR 100	Pyoderma gangrenosum area reduction 100% (complete skin re-epithelialization)
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**Table S4.** Baseline demographics and disease characteristics of responders (achieving PGAR 100) and partial/non-responders at 26 weeks and 52 weeks

	26 Weeks		52 Weeks	
	Responders n=12	Partial/non-responders <sup>†</sup> n=10	Responders n=6	Partial/non-responders n=3
Female, n (%)	5 (41.7)	7 (70.0)	4 (66.7)	1 (33.3)
Age, mean (SD), y	48.6 (17.8)	65.7 (15.6)	56.5 (19.0)	69.0 (11.5)
BMI, mean (SD), kg/m <sup>2</sup>	25.2 (8.2)	25.9 (6.4)	29.0 (11.5)	29.6 (5.0)
Disease duration, mean (SD), y	4.8 (6.6)	1.5 (2.0)	5.5 (8.4)	2.6 (3.9)
Comorbidities, n (%)				
Hypertension	4 (33.3)	6 (60.0)	5 (83.3)	1 (33.3)
Hyperlipidemia	2 (16.7)	4 (40.0)	1 (16.7)	1 (33.3)
Hyperuricemia	2 (16.7)	3 (30.0)	2 (33.3)	2 (66.7)
Osteoporosis	0	4 (40.0)	1 (16.7)	1 (33.3)
Ulcerative colitis	3 (25.0)	1 (10.0)	1 (16.7)	0
Rheumatoid arthritis	1 (8.3)	2 (20.0)	0	1 (33.3)
Target PG ulcer area (digital planimetry), mean (SD), cm <sup>2</sup>	29.8 (25.2)	37.5 (25.8)	36.7 (22.3)	24.0 (18.7)
IIA, moderate to very severe, n (%)				
Erythema	10 (83.3)	6 (60.0)	4 (66.7)	2 (66.7)
Border elevation	8 (66.7)	7 (70.0)	5 (83.3)	2 (66.7)
Pain; NRS, mean (SD)	4.2 (3.2)	5.2 (2.5)	5.5 (3.3)	4.0 (1.0)
DLQI, mean (SD)	9.4 (8.5)	9.1 (5.8)	12.7 (9.4)	5.3 (3.5)
Corticosteroid use for PG, n (%) <sup>‡</sup>	8/11 (72.7)	5/5 (100%)	4/5 (80.0)	1/1 (100)

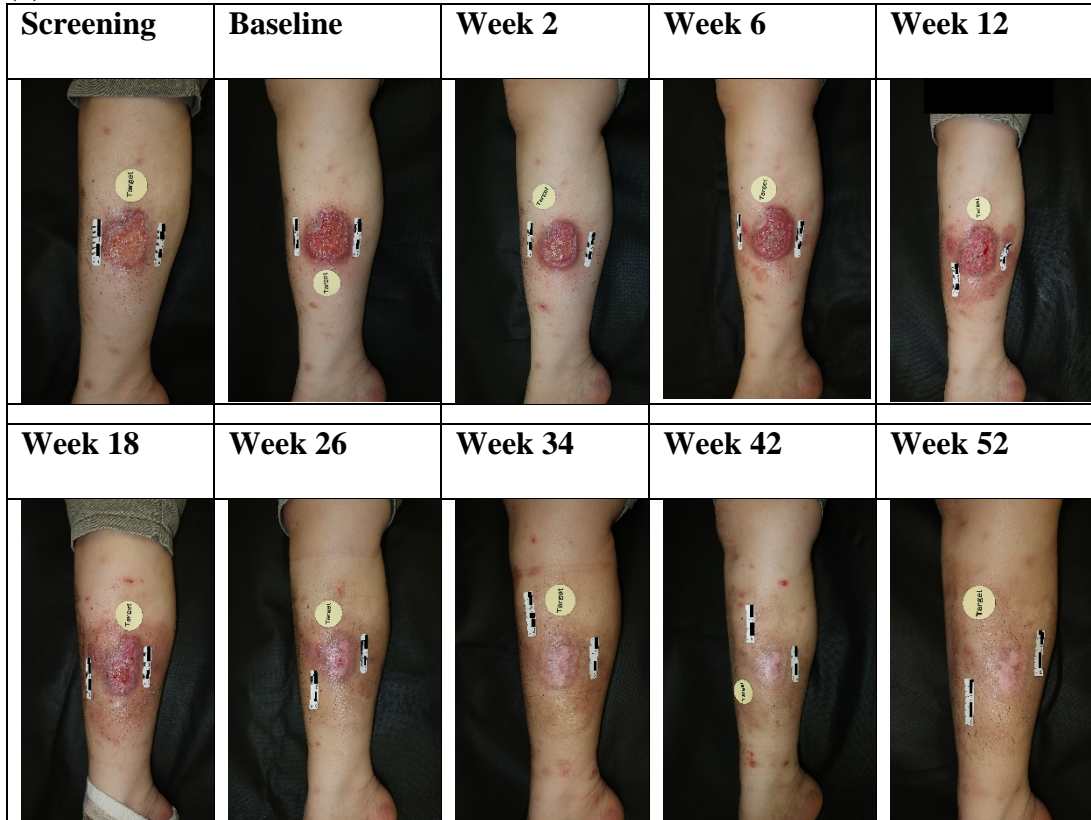
BMI, body mass index; DLQI, Dermatology Life Quality Index; IIA, investigator inflammation assessment; NRS, numeric rating scale; PG, pyoderma gangrenosum; PGAR 100, target PG ulcer area reduction 100 (defined as complete skin re-epithelialization); SD, standard deviation.

<sup>†</sup>Five of the 10 patients with partial or non-response to treatment discontinued before week 26 due to an adverse event or other reason.










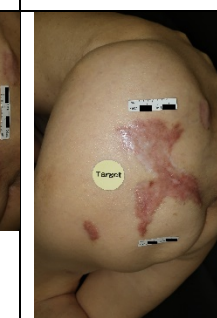
<sup>‡</sup>Of patients using concomitant corticosteroids.

**Figure S1.** Digital planimetry of Target PG ulcers during 52 weeks of treatment. (a) Patient 1; (b) Patient 2; (c) Patient 3.





(a)



(b)

Screening	Baseline	Week 2	Week 6	Week 12
				
Week 18	Week 26	Week 34	Week 42	Week 52
				

(c)

Screening	Baseline	Week 2	Week 6	Week 12
				
Week 18	Week 26	Week 34	Week 42	Week 52
