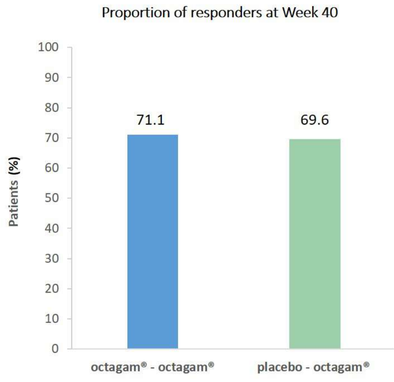
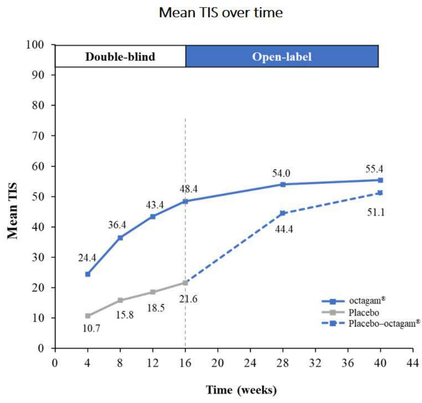
ProDERM secondary endpoints

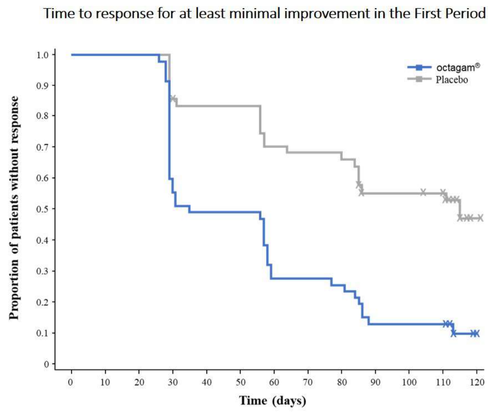
At the end of Extension Period (Week 40), during which all patients received octagam® treatment, the proportion of responders was similar for patients who had received octagam® throughout the study and patients who had received placebo in the First Period and octagam® in the Extension Period.



In the octagam® group, improvements in TIS were seen at Week 16 and maintained until Week 40. In the placebo group, the mean TIS increased after switching to octagam® at Week 16 to a level approaching that seen in the octagam® group by Week 40.



The time to at least minimal improvement was significantly shorter in the octagam® group than in the placebo group (median 35 vs 115 days, p < 0.0001).



Significant improvements from baseline to Week 16 were seen for octagam® versus placebo in various secondary endpoints.

	Least square (LS) mean change from baseline to Week 16		
Parameter	octagam®	Placebo	Difference in LS mean change (p value)
Extramuscular disease activity (MDAAT)	-2.1	-0.9	-1.2 (0.0010)
Physician Global Disease Activity (MDAAT)	-2.5	-1.1	-1.4 (< 0.0001)
Patient Global Disease Activity	-2.3	-1.3	-1.0 (0.0211)
MMT-8	15.1	6.5	8.6 (0.0001)
CDASI total activity score	-10.3	-2.3	-8.0 (< 0.0001)
CDASI total damage score	-0.7	-0.1	-0.6 (0.0304)
HAQ total score	-0.5	-0.1	-0.4 (0.0002)

Mean values for both the physical and mental health SF-36 scores improved from baseline to Week 16.

	Change from baseline to Week 16	
	octagam® N=47	Placebo N=48
Physical Health Score, mean [95% CI]	6.27 [3.59, 8.96]	2.39 [0.56, 4.22]
Mental Health Score, mean [95% CI]	3.36 [1.09, 5.64]	1.95 [-0.38, 4.28]

CDASI: cutaneous dermatomyositis disease area and severity index; CI: confidence interval; HAQ: Health Assessment Questionnaire; MDAAT: Myositis Disease Activity Assessment Tool; MMT-8: manual muscle testing-8; TIS: total improvement score.