Supplementary Table 1a. Baseline characteristics and treatment failure outcomes for individual subjects

Subject	New or Refractory DM	Treatment failure? (Yes/No)	Time to Treatment failure (days)	Gender	Age	Prednisone dosage at screening (duration)	Prednisone dosage at randomization	Other therapy at randomization (duration)
Etanercept-treated subjects								
10-4018	Refractory	Yes	189	F	60	40mg/d (2 months)	40mg/d	-
12-0006	New	Yes	358	M	21	0	60mg/d	-
12-0007	New	No	-	M	37	0	60mg/d	-
12-0008	Refractory	No	-	M	51	0 mg (was on prednisone in past but d/c secondary to side effects	0mg	-
13-0016	Refractory	No	-	F	30	40mg/d (≈1 month)	40mg/d	-
13-0017	Refractory	No	-	F	25	5mg/d (≈2.5 months)	5mg/d	Methotrexate 20 mg/week (≈4.5 months)
21-0001	Refractory	Yes	197	F	43	60mg/d (≈3 months)	60mg/d	-
21-0002	Refractory	Yes	85	M	61	60mg/d (≈2 months)	60mg/d	-
21-0003	Refractory	Yes	224	F	58	60mg/d (≈11.5 months)	60mg/d	Methotrexate 15 mg/week (≈11.5 months)
29-0061	New	No	-	M	34	40mg/d (< 2 months)	60mg/d	-
32-0001	Refractory	Yes	193	F	57	40mg/d (≈22 months)	60mg/d	Methotrexate 25 mg/week (≈21.5 months)
Placebo-Treated Subjects								
02-2101	Refractory	Yes	60	F	44	20mg/d (≈0.75	20mg/d	-

						month)		
02-2102	Refractory	Yes	172	F	52	25mg	25mg/d	-
10-4017	Refractory	Yes	79	M	50	40mg/d (≈1.5months)	40mg/d	Methotrexate 10mg/week (≈3.5months)
13-0015	New	Yes	168	F	25	60mg/d (≈1.5months)	60mg/d	-
28-0001	New	Yes	148	F	50	50mg (<2 months)	60 mg/d	-

Supplementary Table 1b. Baseline characteristics for individual subjects

Subject	Physician global activity assessment	Patient global activity assessment	Average MMT score	Average standardized MVICT score	Average % predicted normal MVICT score	MYOACT-Total	MYOACT – Muscle Disease Activity	MYOACT – Cutaneous Disease Activity	CDASI
Etanercept-Treated Subjects									
10-4018	4.05	4.85	4.16	-4.65	42.68	0.07500	3.70	4.50	14.5
12-0006	1.30	1.55	4.94	-0.53	90.05	0.07583	1.50	2.20	11.5
12-0007	2.55	5.00	5.00	-1.20	80.37	0.10417	0.65	3.15	16.0
12-0008	2.40	5.45	4.91	-2.98	58.15	0.14000	1.95	2.40	7.0
13-0016	6.45	7.45	3.44	-5.08	38.83	0.24083	5.70	5.35	11.0
13-0017	6.20	7.35	4.65	-4.27	45.05	0.23333	5.90	5.55	9.5
21-0001	4.35	1.05	4.30	-4.81	40.28	0.12000	5.10	7.00	22.5
21-0002	4.85	8.15	3.81	-6.05	33.84	0.07750	4.35	1.70	8.0
21-0003	1.75	5.45	4.51	-4.53	43.36	0.01667	1.90	0.00	0.0
29-0061	5.00	7.15	4.54	-7.58	34.52	0.15250	2.35	5.00	12.0
32-0001	5.40	5.70	4.79	-	-	0.21833	2.05	-0.3	19.0
Placebo-Treated Subjects									
02-2101	3.15	4.90	4.81	-2.58	62.14	0.09500	2.10	1.25	1.0
02-2102	1.00	4.45	4.06	-4.20	46.39	0.08416	1.25	1.35	3.5
10-4017	4.55	4.10	4.60	-4.97	40.10	0.09667	4.30	2.10	14.0
13-0015	7.35	8.55	3.55	-6.98	28.05	0.12250	3.30	1.35	4.5
28-0001	4.90	8.50	4.22	-3.85	48.73	0.14833	3.40	5.75	19.0

Supplementary Table 1c. Baseline characteristics and autoantibody data for individual subjects

Subject	HAQ	INQoL – Overall Quality of Life score	INQoL - Weakness score	SF-36 - Physical Component Summary	SF-36 - Mental Component Summary	Creatine Kinase (U/L)	Bone Density - lumbar spine Z-score	Autoantibodies? (Yes/No)
Etanercept-Treated Subjects								
10-4018	1.00	66.39	73.684	41.6619	49.1206	19	-0.6	Yes (ANA)
12-0006	0.25	23.06	34.211	41.7564	41.4870	90	1.0	No
12-0007	0.00	66.39	52.632	32.3958	47.7199	107	-	No
12-0008	1.06	55.83	73.684	33.1294	42.0635	213	-	No
13-0016	2.81	97.5	100.000	23.8398	18.6668	252	-3	No at baseline, but ANA positive at last visit
13-0017	1.13	57.22	68.421	21.8339	51.9058	1103	0.7	Yes (ANA, U1RNP)
21-0001	.88	37.50	26.316	39.4250	42.3775	27	-1	No
21-0002	2.00	83.61	100.000	24.5583	31.3556	6991	0.3	No
21-0003	2.69	77.22	81.579	22.4435	51.2279	35	-0.1	No at baseline, but ANA positive at last visit
29-0061	0.19	51.94	47.368	44.4971	35.1301	140	0.6	Yes (SSA, Jo-1)
32-0001	0.81	21.94	52.632	26.5811	53.3552	57	-.3	No
Placebo-Treated Subjects								
02-2101	0.25	54.44	34.211	28.7478	53.8412	87	0.1	No

02-2102	1.56	60.56	76.316	29.4734	26.8325	2162	-0.5	Yes (PM-Scl, Jo-1)
10-4017	0.06	48.89	18.421	47.6464	58.8911	1639	-2	No
13-0015	2.50	63.61	100.000	13.7193	60.0225	1446	-.1	No
28-0001	1.38	84.17	97.368	28.6531	35.5148	158	1.7	No at baseline, but ANA positive at end

Subject 28-0001 developed ovarian cancer

Abbreviations:

MMT = Manual Muscle Testing; MVICT = Maximum Voluntary Isometric Contraction Testing; MYOACT = Myositis Disease Activity Assessment Visual Analogue Scales; HAQ = Health Assessment Questionnaire; CDASI = Cutaneous Disease Activity Score Index; INQoL = Individualized Neuromuscular Quality of Life; ≈, approximately

Supplementary Table 2. Adverse Events

	Etanercept (n = 11)	Placebo (n = 5)
Cancer	**0**	**1 (Ovarian)**
Pregnancy and miscarriage	**1**	**0**
Upper respiratory infection	**5**	**1**
Urinary tract infection	**2**	**1**
Gastroenteritis / diarrhea	**3**	**3**
Zoster	**1**	**0**
Other infection	**6**	**3**
Fever	**1**	**1**
Worsening rash / pruritis	**5**	**1**
Interstitial lung disease	**1**	**0**
Musculoskeletal pain	**6**	**3**
Fatigue	**1**	**1**
Nausea	**3**	**2**
Abdominal pain	**0**	**2**
Constipation	**1**	**0**
Heartburn	**3**	**0**
Bronchospasm	**0**	**1**
Dyspnea	**1**	**2**
Vaginal bleeding	**0**	**1**

Acute psychosis	**1**	**0**
Depression	**2**	**0**
Anxiety	**1**	**0**
Tinnitus	**1**	**0**
Dizziness	**2**	**1**
Headache	**3**	**4**
Toothache	**3**	**0**
Hypertension	**3**	**1**
Cataracts	**1**	**0**
Blurred vision	**1**	**1**
Increased blood glucose	**0**	**1**

This Table shows the number of subjects in each treatment group experiencing one of the above adverse events (AE). There were no significant treatment group differences in frequencies of any AE.

Supplementary Table 3. Test-Retest Reliability of Outcome Measures

Outcome Variable	ICC	95% Lower Confidence Bound
Average MMT score	0.98	0.95
Average standardized MVICT score	0.90	0.78
Average percent of predicted normal MVICT score	0.91	0.79
Time to arise from a chair	0.95	0.88
Time to walk 30 feet	0.99	0.98
Physician global activity assessment	0.94	0.87
Patient global activity assessment	0.79	0.56
MYOACT score	0.90	0.77
CDASI score	0.96	0.90
Pruritis severity	0.91	0.79
HAQ score	0.96	0.92
SF-36 scores -Physical Component Summary -Mental Component Summary	 0.90 0.93	 0.79 0.85
INQoL Overall Quality of Life score	0.89	0.76

Abbreviations:

ICC = Intraclass Correlation Coefficient; MMT = Manual Muscle Testing; MVICT = Maximum Voluntary Isometric Contraction Testing; MYOACT = Myositis Disease Activity Assessment Visual Analogue Scales; HAQ = Health Assessment Questionnaire; CDASI = Cutaneous Disease Activity Score Index; INQoL = Individualized Neuromuscular Quality of Life

In order to assess test-retest reliability the outcome measures were performed on two consecutive days at the baseline visit by the same evaluator. Reliability was very good for the outcome measures studied.

Supplementary Table 4. Subjects Meeting IMACS Definitions of Improvement

Definition of Improvement (DOI)	Etanercept (Subjects meeting DOI)		Placebo (Subjects meeting DOI)	
	Week 24	Week 52	Week 24	Week 52
A1. 3 of any 6 core set measures improved by 20% or more, with no more than 2 worse by 25% or more, which cannot be MMT or MVICT	9 (82%)	6* (55%)	2 (40%)	3 (60%)
A2. Physician Global Activity improved by greater than 30% and MMT or MVICT improved by 1 – 15%, OR MMT or MVICT improved by greater than 15% and Physician Global Activity improved by greater than 10%, AND no more than 2 worse by 25% or more	9 (82%)	6* (55%)	2 (40%)	2 (40%)
A3a. MMT improved by at least 15%, OR Physician Global Activity improved by greater than 30% and MMT or MVICT improved by 1 – 15%, AND no more than 2 worse by 25% or more	9 (82%)	7* (64%)	2 (40%)	3 (60%)
A3b. 3 of any 6 measures improved by 20% or more, with no more than 2 worse by 25% or more	9 (82%)	7* (64%)	2 (40%)	3 (60%)
A5a. Physician Global Activity improved by greater than 30% and MMT or MVICT improved by 1 – 15%, OR MMT or MVICT improved by greater than 15% and Physician Global Activity improved by greater than 10%	9 (82%)	6* (55%)	2 (40%)	2 (40%)
A5b. 3 of any 6 measures improved by 15% or more, with no more than 1 worse by 25% or more, which cannot be MMT or MVICT	9 (82%)	6* (55%)	2 (40%)	2 (40%)

The 6 IMACS Core Set Measures referred to in the Table are Physical Global Activity Assessment, Patient Global Activity Assessment, Manual Muscle Testing, Extramuscular Assessment on MYOACT, Health Assessment Questionnaire, and muscle enzymes (eg., CK).

We modified from IMACS DOI criteria proposed by Rider LG, et al. (reference 29) by including the Average Percent of Predicted Normal MVICT score in addition to the MMT score for muscle strength testing.

Abbreviations:

MMT = Manual Muscle Testing; MVICT = Maximum Voluntary Isometric Contraction Testing