Dossier zur Nutzenbewertung gemäß § 35a SGB V

Efgartigimod (Vyvgart®)

argenx Germany GmbH

Separater Anhang 4-G

Behandlung der generalisierten Myasthenia gravis bei erwachsenen Patienten, die AChR-Antikörper positiv sind, zusätzlich zur Standardtherapie

Medizinischer Nutzen und
medizinischer Zusatznutzen,
Patientengruppen mit therapeutisch
bedeutsamem Zusatznutzen

Stand: 31.08.2022

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Table 1.1.1.2: Summary of Subgroup - ITT+

ANALYSIS SET: ITT+

	EFGARTIGIMOD (N=65)	PLACEBO (N=64)	ALL PATIENTS (N=129)
REGION (n %)			
n/N	65/65 (100.0)	64/64 (100.0)	129/129 (100.0)
EU	25 (38.5)	27 (42.2)	52 (40.3)
NON-EU	40 (61.5)	37 (57.8)	77 (59.7)
AGE CATEGORY (n %)			
n/N	65/65 (100.0)	64/64 (100.0)	129/129 (100.0)
18 - <65 years	57 (87.7)	51 (79.7)	108 (83.7)
>= 65 years	8 (12.3)	13 (20.3)	21 (16.3)
SEX (n %)			
n/N	65/65 (100.0)	64/64 (100.0)	129/129 (100.0)
Female	46 (70.8)	40 (62.5)	86 (66.7)
Male	19 (29.2)	24 (37.5)	43 (33.3)
RACE (n %)			
n/N	65/65 (100.0)	64/64 (100.0)	129/129 (100.0)
WHITE	54 (83.1)	56 (87.5)	110 (85.3)
NON-WHITE	11 (16.9)	8 (12.5)	19 (14.7)

EU include the following countries: Belgium, Czech Republic, Denmark, France, Germany, Hungary, Italy, Netherlands, Poland.
n is the number of patients with non-missing values, N is the total number of patients regardless of missing value status.
The denominator for the percentage of 'n/N' is the total number of patients, the denominator for the rest percentage calculation is the number of patients with non-missing values.
Program: /clinical/argx-113/mg/argx-113-1704/biostat/staging/gba/programs/t_baseline.sas, Version: 1.10

Table 1.1.1.2: Summary of Subgroup - ITT+

ANALYSIS SET: ITT+

	EFGARTIGIMOD (N=65)	PLACEBO (N=64)	ALL PATIENTS (N=129)
BASELINE MG-ADL TOTAL SCORE (n %)			
n/N	65/65 (100.0)	64/64 (100.0)	129/129 (100.0)
MILD (5-7)	16 (24.6)	18 (28.1)	34 (26.4)
MODERATE (8-9)	25 (38.5)	29 (45.3)	54 (41.9)
SEVERE (>=10)	24 (36.9)	17 (26.6)	41 (31.8)
CONCIMATANT TREATMENT (n %)			
n/N	65/65 (100.0)	64/64 (100.0)	129/129 (100.0)
NSID	38 (58.5)	37 (57.8)	75 (58.1)
NON-NSID	27 (41.5)	27 (42.2)	54 (41.9)
AChR-Ab STATUS (STRAT FACTOR) (n %)			
n/N	65/65 (100.0)	64/64 (100.0)	129/129 (100.0)
POSITIVE	65 (100.0)	64 (100.0)	129 (100.0)
THYMECTOMY PERFORMED FOR MG (n %)			
n/N	65/65 (100.0)	64/64 (100.0)	129/129 (100.0)
YES	45 (69.2)	30 (46.9)	75 (58.1)
NO	20 (30.8)	34 (53.1)	54 (41.9)

EU include the following countries: Belgium, Czech Republic, Denmark, France, Germany, Hungary, Italy, Netherlands, Poland.
n is the number of patients with non-missing values, N is the total number of patients regardless of missing value status.
The denominator for the percentage of 'n/N' is the total number of patients, the denominator for the rest percentage calculation is the number of patients with non-missing values.
Program: /clinical/argx-113/mg/argx-113-1704/biostat/staging/gba/programs/t_baseline.sas, Version: 1.10

Table 2.1.1.5: MG-ADL: Responders of 4-Point Reduction During First Cycle by Subgroup - ITT+

ANALYSIS SET: ITT+

	COCHRANE'S Q P-VALE	EFGARTIGIMOD (N=65) n (%)	PLACEBO (N=64) n (%)	ODDS RATIO (95% C.I.)	RELATIVE RISK (95% C.I.)	ARR (%) (95% C.I.)	P-VALUE*
REGION	0.911						
EU							
n/N1		25/25 (100.0)	27/27 (100.0)				
RESPONSE		18 (72.0)	10 (37.0)	4.371 (1.355; 14.105)	1.944 (1.122; 3.367)	35.0 (7.9; 55.7)	0.014
NO RESPONSE		7 (28.0)	17 (63.0)				
NON-EU							
n/N1		40/40 (100.0)	36/37 (97.3)				
RESPONSE		32 (80.0)	18 (50.0)	4.000 (1.452; 11.020)	1.600 (1.115; 2.297)	30.0 (8.6; 48.2)	0.008
NO RESPONSE		8 (20.0)	18 (50.0)				

ARR=Absolute Risk Reduction
n is the number of patients with non-missing values, N1 is the total number of patients in the corresponding analysis set, subgroup and cycle regardless of missing value status, N is the total number of patients in the analysis set.
0.5 is added if any cell count is zero for odds ratio and relative risk calculation
* P-value is from Fisher's exact test.
Program: /clinical/argx-113/mg/argx-113-1704/biostat/staging/gba/programs/t_responder_sub.sas, Version: 1.2

Table 2.1.1.5: MG-ADL: Responders of 4-Point Reduction During First Cycle by Subgroup - ITT+

ANALYSIS SET: ITT+

	COCHRANE'S Q P-VALE	EFGARTIGIMOD (N=65) n (%)	PLACEBO (N=64) n (%)	ODDS RATIO (95% C.I.)	RELATIVE RISK (95% C.I.)	ARR (%) (95% C.I.)	P-VALUE*
AGE CATEGORY	0.204						
18 - <65 years							
n/N1		57/57 (100.0)	51/51 (100.0)				
RESPONSE		44 (77.2)	26 (51.0)	3.254 (1.423; 7.442)	1.514 (1.117; 2.052)	26.2 (8.1; 42.3)	0.005
NO RESPONSE		13 (22.8)	25 (49.0)				
>= 65 years							
n/N1		8/8 (100.0)	12/13 (92.3)				
RESPONSE		6 (75.0)	2 (16.7)	15.000 (1.652; 136.172)	4.500 (1.194; 16.962)	58.3 (14.1; 79.8)	0.019
NO RESPONSE		2 (25.0)	10 (83.3)				

ARR=Absolute Risk Reduction
n is the number of patients with non-missing values, N1 is the total number of patients in the corresponding analysis set, subgroup and cycle regardless of missing value status, N is the total number of patients in the analysis set.
0.5 is added if any cell count is zero for odds ratio and relative risk calculation
* P-value is from Fisher's exact test.
Program: /clinical/argx-113/mg/argx-113-1704/biostat/staging/gba/programs/t_responder_sub.sas, Version: 1.2

Table 2.1.1.5: MG-ADL: Responders of 4-Point Reduction During First Cycle by Subgroup - ITT+

ANALYSIS SET: ITT+

	COCHRANE'S Q P-VALE	EFGARTIGIMOD (N=65) n (%)	PLACEBO (N=64) n (%)	ODDS RATIO (95% C.I.)	RELATIVE RISK (95% C.I.)	ARR (%) (95% C.I.)	P-VALUE*
SEX	0.818						
Female							
n/N1		46/46 (100.0)	40/40 (100.0)				
RESPONSE		36 (78.3)	18 (45.0)	4.400 (1.723; 11.236)	1.739 (1.195; 2.530)	33.3 (12.7; 50.4)	0.002
NO RESPONSE		10 (21.7)	22 (55.0)				
Male							
n/N1		19/19 (100.0)	23/24 (95.8)				
RESPONSE		14 (73.7)	10 (43.5)	3.640 (0.980; 13.523)	1.695 (0.990; 2.902)	30.2 (0.3; 53.2)	0.065
NO RESPONSE		5 (26.3)	13 (56.5)				

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0.5 is added if any cell count is zero for odds ratio and relative risk calculation
* P-value is from Fisher's exact test.
Program: /clinical/argx-113/mg/argx-113-1704/biostat/staging/gba/programs/t_responder_sub.sas, Version: 1.2

Table 2.1.1.5: MG-ADL: Responders of 4-Point Reduction During First Cycle by Subgroup - ITT+

ANALYSIS SET: ITT+

	COCHRANE'S Q P-VALE	EFGARTIGIMOD (N=65) n (%)	PLACEBO (N=64) n (%)	ODDS RATIO (95% C.I.)	RELATIVE RISK (95% C.I.)	ARR (%) (95% C.I.)	P-VALUE*
RACE	0.119						
WHITE							
n/N1		54/54 (100.0)	55/56 (98.2)				
RESPONSE		43 (79.6)	23 (41.8)	5.439 (2.320; 12.748)	1.904 (1.356; 2.674)	37.8 (19.6; 52.6)	<.001
NO RESPONSE		11 (20.4)	32 (58.2)				
NON-WHITE							
n/N1		11/11 (100.0)	8/8 (100.0)				
RESPONSE		7 (63.6)	5 (62.5)	1.050 (0.159; 6.924)	1.018 (0.506; 2.047)	1.1 (-35.8; 39.5)	1.000
NO RESPONSE		4 (36.4)	3 (37.5)				

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0.5 is added if any cell count is zero for odds ratio and relative risk calculation
* P-value is from Fisher's exact test.
Program: /clinical/argx-113/mg/argx-113-1704/biostat/staging/gba/programs/t_responder_sub.sas, Version: 1.2

Table 2.1.1.5: MG-ADL: Responders of 4-Point Reduction During First Cycle by Subgroup - ITT+

ANALYSIS SET: ITT+

	COCHRANE'S Q P-VALE	EFGARTIGIMOD (N=65) n (%)	PLACEBO (N=64) n (%)	ODDS RATIO (95% C.I.)	RELATIVE RISK (95% C.I.)	ARR (%) (95% C.I.)	P-VALUE*
BASELINE MG-ADL TOTAL SCORE	0.192						
MILD (5-7)							
n/N1		16/16 (100.0)	18/18 (100.0)				
RESPONSE		8 (50.0)	5 (27.8)	2.600 (0.627; 10.786)	1.800 (0.738; 4.390)	22.2 (-9.7; 49.0)	0.291
NO RESPONSE		8 (50.0)	13 (72.2)				
MODERATE (8-9)							
n/N1		25/25 (100.0)	29/29 (100.0)				
RESPONSE		23 (92.0)	13 (44.8)	14.154 (2.802; 71.497)	2.052 (1.348; 3.124)	47.2 (22.7; 64.6)	<.001
NO RESPONSE		2 (8.0)	16 (55.2)				
SEVERE (>=10)							
n/N1		24/24 (100.0)	16/17 (94.1)				
RESPONSE		19 (79.2)	10 (62.5)	2.280 (0.555; 9.361)	1.267 (0.823; 1.950)	16.7 (-10.7; 43.2)	0.295
NO RESPONSE		5 (20.8)	6 (37.5)				

ARR=Absolute Risk Reduction
n is the number of patients with non-missing values, N1 is the total number of patients in the corresponding analysis set, subgroup and cycle regardless of missing value status, N is the total number of patients in the analysis set.
0.5 is added if any cell count is zero for odds ratio and relative risk calculation
* P-value is from Fisher's exact test.
Program: /clinical/argx-113/mg/argx-113-1704/biostat/staging/gba/programs/t_responder_sub.sas, Version: 1.2

Table 2.1.1.5: MG-ADL: Responders of 4-Point Reduction During First Cycle by Subgroup - ITT+

ANALYSIS SET: ITT+

	COCHRANE'S Q P-VALE	EFGARTIGIMOD (N=65) n (%)	PLACEBO (N=64) n (%)	ODDS RATIO (95% C.I.)	RELATIVE RISK (95% C.I.)	ARR (%) (95% C.I.)	P-VALUE*
CONCIMATANT TREATMENT	0.932						
NSID							
n/N1		38/38 (100.0)	37/37 (100.0)				
RESPONSE		28 (73.7)	15 (40.5)	4.107 (1.548; 10.895)	1.818 (1.178; 2.805)	33.1 (10.8; 51.3)	0.005
NO RESPONSE		10 (26.3)	22 (59.5)				
NON-NSID							
n/N1		27/27 (100.0)	26/27 (96.3)				
RESPONSE		22 (81.5)	13 (50.0)	4.400 (1.275; 15.182)	1.630 (1.066; 2.491)	31.5 (5.9; 52.2)	0.021
NO RESPONSE		5 (18.5)	13 (50.0)				

ARR=Absolute Risk Reduction
n is the number of patients with non-missing values, N1 is the total number of patients in the corresponding analysis set, subgroup and cycle regardless of missing value status, N is the total number of patients in the analysis set.
0.5 is added if any cell count is zero for odds ratio and relative risk calculation
* P-value is from Fisher's exact test.
Program: /clinical/argx-113/mg/argx-113-1704/biostat/staging/gba/programs/t_responder_sub.sas, Version: 1.2

Table 2.1.1.5: MG-ADL: Responders of 4-Point Reduction During First Cycle by Subgroup - ITT+

ANALYSIS SET: ITT+

	COCHRANE'S Q P-VALE	EFGARTIGIMOD (N=65) n (%)	PLACEBO (N=64) n (%)	ODDS RATIO (95% C.I.)	RELATIVE RISK (95% C.I.)	ARR (%) (95% C.I.)	P-VALUE*
THYMECTOMY PERFORMED FOR MG	0.676						
YES							
n/N1		45/45 (100.0)	30/30 (100.0)				
RESPONSE		34 (75.6)	11 (36.7)	5.339 (1.951; 14.611)	2.061 (1.251; 3.393)	38.9 (16.1; 56.9)	0.002
NO RESPONSE		11 (24.4)	19 (63.3)				
NO							
n/N1		20/20 (100.0)	33/34 (97.1)				
RESPONSE		16 (80.0)	17 (51.5)	3.765 (1.035; 13.689)	1.553 (1.044; 2.310)	28.5 (1.6; 48.7)	0.046
NO RESPONSE		4 (20.0)	16 (48.5)				

ARR=Absolute Risk Reduction
n is the number of patients with non-missing values, N1 is the total number of patients in the corresponding analysis set, subgroup and cycle regardless of missing value status, N is the total number of patients in the analysis set.
0.5 is added if any cell count is zero for odds ratio and relative risk calculation
* P-value is from Fisher's exact test.
Program: /clinical/argx-113/mg/argx-113-1704/biostat/staging/gba/programs/t_responder_sub.sas, Version: 1.2

Table 2.1.5.4: MG-ADL: AUC between Baseline and Week 20 of Change From Baseline in Total MG-ADL Score by Subgroup - ITT+

ANALYSIS SET: ITT+

	Interaction P-value	EFGARTIGIMOD (N=65)	PLACEBO (N=64)
REGION	0.591		
EU			
n/N1 (%)		25/25 (100.0)	27/27 (100.0)
Mean (S.D.)		-47.7 (45.06)	-21.5 (40.06)
S.E.		9.01	7.71
95% C.I.		(-66.34; -29.14)	(-37.34; -5.65)
Median		-46.0	-17.5
Q1; Q3		(-80.0; -19.0)	(-45.0; 5.0)
Min; Max		(-149; 22)	(-106; 50)
Hedge's G		-0.61	
95% C.I.		(-1.156; -0.059)	
LS Mean (S.E.)		-46.8 (8.74)	-21.7 (8.45)
95% C.I.		(-64.35; -29.21)	(-38.64; -4.67)
LS Mean Differences (S.E.)		-25.1 (12.25)	
95% C.I.		(-49.77; -0.49)	
P-value		0.046	

S.D. = Standard Deviation; S.E. = Standard Error; AUC=Area Under the Curve; LS=Least Square
n is the number of patients with non-missing values, N1 is the total number of patients in the corresponding analysis set and subgroup regardless of missing value status, N is the total number of patients in the analysis set.
LS mean and LS mean difference is from an ANCOVA model with treatment, baseline score, Japanese/Non-Japanese and Standard Of Care(NSIDs/Non-NSIDs) as covariates. Interaction p-value is from the above ANCOVA model with additional factor/interaction of subgroup and subgroup by treatment.

Table 2.1.5.4: MG-ADL: AUC between Baseline and Week 20 of Change From Baseline in Total MG-ADL Score by Subgroup - ITT+

ANALYSIS SET: ITT+

	Interaction P-value	EFGARTIGIMOD (N=65)	PLACEBO (N=64)
REGION	0.591		
NON-EU			
n/N1 (%)		40/40 (100.0)	37/37 (100.0)
Mean (S.D.)		-67.5 (44.98)	-35.4 (44.45)
S.E.		7.11	7.31
95% C.I.		(-81.92; -53.15)	(-50.22; -20.58)
Median		-79.3	-39.5
Q1; Q3		(-99.3; -41.3)	(-62.5; -10.0)
Min; Max		(-150; 47)	(-151; 49)
Hedge's G		-0.71	
95% C.I.		(-1.168; -0.255)	
LS Mean (S.E.)		-50.7 (8.86)	-18.7 (9.15)
95% C.I.		(-68.37; -33.03)	(-36.89; -0.43)
LS Mean Differences (S.E.)		-32.0 (9.55)	
95% C.I.		(-51.08; -13.00)	
P-value		0.001	

S.D. = Standard Deviation; S.E. = Standard Error; AUC=Area Under the Curve; LS=Least Square
n is the number of patients with non-missing values, N1 is the total number of patients in the corresponding analysis set and subgroup regardless of missing value status, N is the total number of patients in the analysis set.
LS mean and LS mean difference is from an ANCOVA model with treatment, baseline score, Japanese/Non-Japanese and Standard Of Care(NSIDs/Non-NSIDs) as covariates. Interaction p-value is from the above ANCOVA model with additional factor/interaction of subgroup and subgroup by treatment.

Table 2.1.5.4: MG-ADL: AUC between Baseline and Week 20 of Change From Baseline in Total MG-ADL Score by Subgroup - ITT+

ANALYSIS SET: ITT+

	Interaction P-value	EFGARTIGIMOD (N=65)	PLACEBO (N=64)
AGE CATEGORY	0.071		
18 - <65 years			
n/N1 (%)		57/57 (100.0)	51/51 (100.0)
Mean (S.D.)		-58.1 (45.09)	-33.3 (42.90)
S.E.		5.97	6.01
95% C.I.		(-70.04; -46.11)	(-45.40; -21.27)
Median		-65.0	-37.5
Q1; Q3		(-89.4; -30.5)	(-62.5; -2.0)
Min; Max		(-149; 47)	(-151; 50)
Hedge's G		-0.56	
95% C.I.		(-0.940; -0.175)	
LS Mean (S.E.)		-40.4 (9.25)	-17.2 (9.65)
95% C.I.		(-58.75; -22.06)	(-36.34; 1.95)
LS Mean Differences (S.E.)		-23.2 (8.31)	
95% C.I.		(-39.69; -6.72)	
P-value		0.006	

S.D. = Standard Deviation; S.E. = Standard Error; AUC=Area Under the Curve; LS=Least Square
n is the number of patients with non-missing values, N1 is the total number of patients in the corresponding analysis set and subgroup regardless of missing value status, N is the total number of patients in the analysis set.
LS mean and LS mean difference is from an ANCOVA model with treatment, baseline score, Japanese/Non-Japanese and Standard Of Care(NSIDs/Non-NSIDs) as covariates. Interaction p-value is from the above ANCOVA model with additional factor/interaction of subgroup and subgroup by treatment.

Table 2.1.5.4: MG-ADL: AUC between Baseline and Week 20 of Change From Baseline in Total MG-ADL Score by Subgroup - ITT+

ANALYSIS SET: ITT+

	Interaction P-value	EFGARTIGIMOD (N=65)	PLACEBO (N=64)
AGE CATEGORY	0.071		
>= 65 years			
n/N1 (%)		8/8 (100.0)	13/13 (100.0)
Mean (S.D.)		-73.1 (51.01)	-14.6 (41.02)
S.E.		18.03	11.38
95% C.I.		(-115.72; -30.43)	(-39.39; 10.19)
Median		-82.8	-15.0
Q1; Q3		(-103.3; -34.8)	(-51.0; 16.0)
Min; Max		(-150; 7)	(-80; 49)
Hedge's G		-1.25	
95% C.I.		(-2.175; -0.323)	
LS Mean (S.E.)		-63.1 (19.19)	-2.9 (18.07)
95% C.I.		(-103.83; -22.45)	(-41.25; 35.37)
LS Mean Differences (S.E.)		-60.2 (19.01)	
95% C.I.		(-100.49; -19.91)	
P-value		0.006	

S.D. = Standard Deviation; S.E. = Standard Error; AUC=Area Under the Curve; LS=Least Square
n is the number of patients with non-missing values, N1 is the total number of patients in the corresponding analysis set and subgroup regardless of missing value status, N is the total number of patients in the analysis set.
LS mean and LS mean difference is from an ANCOVA model with treatment, baseline score, Japanese/Non-Japanese and Standard Of Care(NSIDs/Non-NSIDs) as covariates. Interaction p-value is from the above ANCOVA model with additional factor/interaction of subgroup and subgroup by treatment.

Table 2.1.5.4: MG-ADL: AUC between Baseline and Week 20 of Change From Baseline in Total MG-ADL Score by Subgroup - ITT+

ANALYSIS SET: ITT+

	Interaction P-value	EFGARTIGIMOD (N=65)	PLACEBO (N=64)
SEX	0.548		
Female			
n/N1 (%)		46/46 (100.0)	40/40 (100.0)
Mean (S.D.)		-61.7 (46.05)	-28.5 (42.62)
S.E.		6.79	6.74
95% C.I.		(-75.41; -48.06)	(-42.09; -14.83)
Median		-66.0	-25.8
Q1; Q3		(-99.0; -37.5)	(-48.3; -4.5)
Min; Max		(-149; 47)	(-151; 50)
Hedge's G		-0.74	
95% C.I.		(-1.175; -0.307)	
LS Mean (S.E.)		-45.4 (10.04)	-12.9 (10.92)
95% C.I.		(-65.35; -25.40)	(-34.60; 8.87)
LS Mean Differences (S.E.)		-32.5 (9.53)	
95% C.I.		(-51.47; -13.55)	
P-value		0.001	

S.D. = Standard Deviation; S.E. = Standard Error; AUC=Area Under the Curve; LS=Least Square
n is the number of patients with non-missing values, N1 is the total number of patients in the corresponding analysis set and subgroup regardless of missing value status, N is the total number of patients in the analysis set.
LS mean and LS mean difference is from an ANCOVA model with treatment, baseline score, Japanese/Non-Japanese and Standard Of Care(NSIDs/Non-NSIDs) as covariates. Interaction p-value is from the above ANCOVA model with additional factor/interaction of subgroup and subgroup by treatment.

Table 2.1.5.4: MG-ADL: AUC between Baseline and Week 20 of Change From Baseline in Total MG-ADL Score by Subgroup - ITT+

ANALYSIS SET: ITT+

	Interaction P-value	EFGARTIGIMOD (N=65)	PLACEBO (N=64)
SEX	0.548		
Male			
n/N1 (%)		19/19 (100.0)	24/24 (100.0)
Mean (S.D.)		-55.5 (45.76)	-31.3 (44.18)
S.E.		10.50	9.02
95% C.I.		(-77.58; -33.47)	(-49.97; -12.66)
Median		-54.5	-39.3
Q1; Q3		(-88.0; -19.0)	(-65.8; 6.8)
Min; Max		(-150; 20)	(-106; 48)
Hedge's G		-0.53	
95% C.I.		(-1.131; 0.072)	
LS Mean (S.E.)		-37.7 (15.79)	-15.7 (14.61)
95% C.I.		(-69.63; -5.70)	(-45.32; 13.84)
LS Mean Differences (S.E.)		-21.9 (13.36)	
95% C.I.		(-48.98; 5.12)	
P-value		0.109	

S.D. = Standard Deviation; S.E. = Standard Error; AUC=Area Under the Curve; LS=Least Square
n is the number of patients with non-missing values, N1 is the total number of patients in the corresponding analysis set and subgroup regardless of missing value status, N is the total number of patients in the analysis set.
LS mean and LS mean difference is from an ANCOVA model with treatment, baseline score, Japanese/Non-Japanese and Standard Of Care(NSIDs/Non-NSIDs) as covariates. Interaction p-value is from the above ANCOVA model with additional factor/interaction of subgroup and subgroup by treatment.

Table 2.1.5.4: MG-ADL: AUC between Baseline and Week 20 of Change From Baseline in Total MG-ADL Score by Subgroup - ITT+

ANALYSIS SET: ITT+

	Interaction P-value	EFGARTIGIMOD (N=65)	PLACEBO (N=64)
RACE	0.428		
WHITE			
n/N1 (%)		54/54 (100.0)	56/56 (100.0)
Mean (S.D.)		-62.4 (46.72)	-29.4 (43.80)
S.E.		6.36	5.85
95% C.I.		(-75.14; -49.64)	(-41.18; -17.72)
Median		-66.0	-26.9
Q1; Q3		(-99.0; -33.0)	(-55.8; 1.3)
Min; Max		(-150; 47)	(-151; 50)
Hedge's G		-0.72	
95% C.I.		(-1.106; -0.339)	
LS Mean (S.E.)		-61.2 (6.15)	-30.0 (6.02)
95% C.I.		(-73.41; -49.03)	(-41.93; -18.06)
LS Mean Differences (S.E.)		-31.2 (8.59)	
95% C.I.		(-48.26; -14.19)	
P-value		<.001	

S.D. = Standard Deviation; S.E. = Standard Error; AUC=Area Under the Curve; LS=Least Square
n is the number of patients with non-missing values, N1 is the total number of patients in the corresponding analysis set and subgroup regardless of missing value status, N is the total number of patients in the analysis set.
LS mean and LS mean difference is from an ANCOVA model with treatment, baseline score, Japanese/Non-Japanese and Standard Of Care(NSIDs/Non-NSIDs) as covariates. Interaction p-value is from the above ANCOVA model with additional factor/interaction of subgroup and subgroup by treatment.

Table 2.1.5.4: MG-ADL: AUC between Baseline and Week 20 of Change From Baseline in Total MG-ADL Score by Subgroup - ITT+

ANALYSIS SET: ITT+

	Interaction P-value	EFGARTIGIMOD (N=65)	PLACEBO (N=64)
RACE	0.428		
NON-WHITE			
n/N1 (%)		11/11 (100.0)	8/8 (100.0)
Mean (S.D.)		-47.8 (39.99)	-30.1 (38.43)
S.E.		12.06	13.59
95% C.I.		(-74.66; -20.93)	(-62.26; 1.99)
Median		-52.0	-39.0
Q1; Q3		(-88.3; -12.0)	(-58.6; -12.9)
Min; Max		(-91; 27)	(-68; 48)
Hedge's G		-0.43	
95% C.I.		(-1.309; 0.452)	
LS Mean (S.E.)		-45.0 (8.38)	-32.6 (10.20)
95% C.I.		(-62.97; -27.02)	(-54.49; -10.74)
LS Mean Differences (S.E.)		-12.4 (12.70)	
95% C.I.		(-39.62; 14.86)	
P-value		0.346	

S.D. = Standard Deviation; S.E. = Standard Error; AUC=Area Under the Curve; LS=Least Square
n is the number of patients with non-missing values, N1 is the total number of patients in the corresponding analysis set and subgroup regardless of missing value status, N is the total number of patients in the analysis set.
LS mean and LS mean difference is from an ANCOVA model with treatment, baseline score, Japanese/Non-Japanese and Standard Of Care(NSIDs/Non-NSIDs) as covariates. Interaction p-value is from the above ANCOVA model with additional factor/interaction of subgroup and subgroup by treatment.

Table 2.1.5.4: MG-ADL: AUC between Baseline and Week 20 of Change From Baseline in Total MG-ADL Score by Subgroup - ITT+

ANALYSIS SET: ITT+

	Interaction P-value	EFGARTIGIMOD (N=65)	PLACEBO (N=64)
BASELINE MG-ADL TOTAL SCORE	0.499		
MILD (5-7)			
n/N1 (%)		16/16 (100.0)	18/18 (100.0)
Mean (S.D.)		-32.0 (44.37)	-14.7 (39.23)
S.E.		11.09	9.25
95% C.I.		(-55.64; -8.36)	(-34.24; 4.77)
Median		-34.5	-11.3
Q1; Q3		(-59.8; 2.0)	(-47.0; 16.0)
Min; Max		(-112; 47)	(-81; 48)
Hedge's G		-0.40	
95% C.I.		(-1.069; 0.260)	
LS Mean (S.E.)		-19.8 (13.21)	0.9 (12.94)
95% C.I.		(-46.82; 7.20)	(-25.59; 27.34)
LS Mean Differences (S.E.)		-20.7 (14.37)	
95% C.I.		(-50.07; 8.70)	
P-value		0.161	

S.D. = Standard Deviation; S.E. = Standard Error; AUC=Area Under the Curve; LS=Least Square
n is the number of patients with non-missing values, N1 is the total number of patients in the corresponding analysis set and subgroup regardless of missing value status, N is the total number of patients in the analysis set.
LS mean and LS mean difference is from an ANCOVA model with treatment, baseline score, Japanese/Non-Japanese and Standard Of Care(NSIDs/Non-NSIDs) as covariates. Interaction p-value is from the above ANCOVA model with additional factor/interaction of subgroup and subgroup by treatment.

Table 2.1.5.4: MG-ADL: AUC between Baseline and Week 20 of Change From Baseline in Total MG-ADL Score by Subgroup - ITT+

ANALYSIS SET: ITT+

	Interaction P-value	EFGARTIGIMOD (N=65)	PLACEBO (N=64)
BASELINE MG-ADL TOTAL SCORE	0.499		
MODERATE (8-9)			
n/N1 (%)		25/25 (100.0)	29/29 (100.0)
Mean (S.D.)		-70.2 (32.85)	-31.0 (44.47)
S.E.		6.57	8.26
95% C.I.		(-83.76; -56.64)	(-47.90; -14.07)
Median		-67.5	-33.5
Q1; Q3		(-94.5; -48.0)	(-55.0; -10.0)
Min; Max		(-126; 20)	(-151; 50)
Hedge's G		-0.98	
95% C.I.		(-1.536; -0.419)	
LS Mean (S.E.)		-54.4 (16.47)	-14.5 (15.65)
95% C.I.		(-87.49; -21.29)	(-45.91; 17.01)
LS Mean Differences (S.E.)		-39.9 (11.25)	
95% C.I.		(-62.55; -17.33)	
P-value		<.001	

S.D. = Standard Deviation; S.E. = Standard Error; AUC=Area Under the Curve; LS=Least Square
n is the number of patients with non-missing values, N1 is the total number of patients in the corresponding analysis set and subgroup regardless of missing value status, N is the total number of patients in the analysis set.
LS mean and LS mean difference is from an ANCOVA model with treatment, baseline score, Japanese/Non-Japanese and Standard Of Care(NSIDs/Non-NSIDs) as covariates. Interaction p-value is from the above ANCOVA model with additional factor/interaction of subgroup and subgroup by treatment.

Table 2.1.5.4: MG-ADL: AUC between Baseline and Week 20 of Change From Baseline in Total MG-ADL Score by Subgroup - ITT+

ANALYSIS SET: ITT+

	Interaction P-value	EFGARTIGIMOD (N=65)	PLACEBO (N=64)
BASELINE MG-ADL TOTAL SCORE	0.499		
SEVERE (>=10)			
n/N1 (%)		24/24 (100.0)	17/17 (100.0)
Mean (S.D.)		-67.8 (51.75)	-42.7 (41.36)
S.E.		10.56	10.03
95% C.I.		(-89.68; -45.97)	(-63.99; -21.46)
Median		-79.3	-49.5
Q1; Q3		(-103.0; -19.3)	(-68.3; -13.0)
Min; Max		(-150; 22)	(-124; 37)
Hedge's G		-0.52	
95% C.I.		(-1.135; 0.104)	
LS Mean (S.E.)		-57.3 (16.08)	-30.1 (18.36)
95% C.I.		(-89.94; -24.71)	(-67.31; 7.17)
LS Mean Differences (S.E.)		-27.3 (15.74)	
95% C.I.		(-59.19; 4.67)	
P-value		0.092	

S.D. = Standard Deviation; S.E. = Standard Error; AUC=Area Under the Curve; LS=Least Square
n is the number of patients with non-missing values, N1 is the total number of patients in the corresponding analysis set and subgroup regardless of missing value status, N is the total number of patients in the analysis set.
LS mean and LS mean difference is from an ANCOVA model with treatment, baseline score, Japanese/Non-Japanese and Standard Of Care(NSIDs/Non-NSIDs) as covariates. Interaction p-value is from the above ANCOVA model with additional factor/interaction of subgroup and subgroup by treatment.

Table 2.1.5.4: MG-ADL: AUC between Baseline and Week 20 of Change From Baseline in Total MG-ADL Score by Subgroup - ITT+

ANALYSIS SET: ITT+

	Interaction P-value	EFGARTIGIMOD (N=65)	PLACEBO (N=64)
CONCIMATANT TREATMENT	0.855		
NSID			
n/N1 (%)		38/38 (100.0)	37/37 (100.0)
Mean (S.D.)		-60.5 (43.51)	-30.4 (46.30)
S.E.		7.06	7.61
95% C.I.		(-74.77; -46.17)	(-45.85; -14.98)
Median		-62.3	-33.5
Q1; Q3		(-94.5; -38.5)	(-55.0; 2.5)
Min; Max		(-137; 27)	(-151; 49)
Hedge's G		-0.66	
95% C.I.		(-1.123; -0.202)	
LS Mean (S.E.)		-43.1 (9.72)	-12.8 (10.06)
95% C.I.		(-62.50; -23.75)	(-32.84; 7.26)
LS Mean Differences (S.E.)		-30.3 (9.94)	
95% C.I.		(-50.17; -10.51)	
P-value		0.003	

S.D. = Standard Deviation; S.E. = Standard Error; AUC=Area Under the Curve; LS=Least Square
n is the number of patients with non-missing values, N1 is the total number of patients in the corresponding analysis set and subgroup regardless of missing value status, N is the total number of patients in the analysis set.
LS mean and LS mean difference is from an ANCOVA model with treatment, baseline score, Japanese/Non-Japanese and Standard Of Care(NSIDs/Non-NSIDs) as covariates. Interaction p-value is from the above ANCOVA model with additional factor/interaction of subgroup and subgroup by treatment.

Table 2.1.5.4: MG-ADL: AUC between Baseline and Week 20 of Change From Baseline in Total MG-ADL Score by Subgroup - ITT+

ANALYSIS SET: ITT+

	Interaction P-value	EFGARTIGIMOD (N=65)	PLACEBO (N=64)
CONCIMATANT TREATMENT	0.855		
NON-NSID			
n/N1 (%)		27/27 (100.0)	27/27 (100.0)
Mean (S.D.)		-59.1 (49.45)	-28.3 (38.54)
S.E.		9.52	7.42
95% C.I.		(-78.71; -39.58)	(-43.57; -13.08)
Median		-66.0	-26.0
Q1; Q3		(-90.5; -19.5)	(-56.5; -3.5)
Min; Max		(-150; 47)	(-106; 50)
Hedge's G		-0.69	
95% C.I.		(-1.227; -0.144)	
LS Mean (S.E.)		-51.9 (16.82)	-25.2 (17.23)
95% C.I.		(-85.73; -18.14)	(-59.79; 9.41)
LS Mean Differences (S.E.)		-26.8 (11.96)	
95% C.I.		(-50.76; -2.74)	
P-value		0.030	

S.D. = Standard Deviation; S.E. = Standard Error; AUC=Area Under the Curve; LS=Least Square
n is the number of patients with non-missing values, N1 is the total number of patients in the corresponding analysis set and subgroup regardless of missing value status, N is the total number of patients in the analysis set.
LS mean and LS mean difference is from an ANCOVA model with treatment, baseline score, Japanese/Non-Japanese and Standard Of Care(NSIDs/Non-NSIDs) as covariates. Interaction p-value is from the above ANCOVA model with additional factor/interaction of subgroup and subgroup by treatment.

Table 2.1.5.4: MG-ADL: AUC between Baseline and Week 20 of Change From Baseline in Total MG-ADL Score by Subgroup - ITT+

ANALYSIS SET: ITT+

	Interaction P-value	EFGARTIGIMOD (N=65)	PLACEBO (N=64)
THYMECTOMY PERFORMED FOR MG	0.976		
YES			
n/N1 (%)		45/45 (100.0)	30/30 (100.0)
Mean (S.D.)		-59.0 (46.21)	-30.6 (41.11)
S.E.		6.89	7.51
95% C.I.		(-72.88; -45.12)	(-45.91; -15.21)
Median		-66.0	-29.5
Q1; Q3		(-94.5; -26.0)	(-62.5; 2.5)
Min; Max		(-149; 47)	(-124; 37)
Hedge's G		-0.64	
95% C.I.		(-1.105; -0.168)	
LS Mean (S.E.)		-38.6 (10.43)	-10.4 (12.53)
95% C.I.		(-59.41; -17.81)	(-35.37; 14.59)
LS Mean Differences (S.E.)		-28.2 (10.10)	
95% C.I.		(-48.37; -8.07)	
P-value		0.007	

S.D. = Standard Deviation; S.E. = Standard Error; AUC=Area Under the Curve; LS=Least Square
n is the number of patients with non-missing values, N1 is the total number of patients in the corresponding analysis set and subgroup regardless of missing value status, N is the total number of patients in the analysis set.
LS mean and LS mean difference is from an ANCOVA model with treatment, baseline score, Japanese/Non-Japanese and Standard Of Care(NSIDs/Non-NSIDs) as covariates. Interaction p-value is from the above ANCOVA model with additional factor/interaction of subgroup and subgroup by treatment.

Table 2.1.5.4: MG-ADL: AUC between Baseline and Week 20 of Change From Baseline in Total MG-ADL Score by Subgroup - ITT+

ANALYSIS SET: ITT+

	Interaction P-value	EFGARTIGIMOD (N=65)	PLACEBO (N=64)
THYMECTOMY PERFORMED FOR MG	0.976		
NO			
n/N1 (%)		20/20 (100.0)	34/34 (100.0)
Mean (S.D.)		-62.0 (45.64)	-28.6 (44.99)
S.E.		10.21	7.72
95% C.I.		(-83.34; -40.62)	(-44.33; -12.93)
Median		-63.0	-28.1
Q1; Q3		(-85.0; -35.8)	(-55.0; -3.5)
Min; Max		(-150; 22)	(-151; 50)
Hedge's G		-0.73	
95% C.I.		(-1.288; -0.165)	
LS Mean (S.E.)		-52.3 (14.55)	-22.1 (12.36)
95% C.I.		(-81.49; -23.03)	(-46.94; 2.73)
LS Mean Differences (S.E.)		-30.2 (12.75)	
95% C.I.		(-55.77; -4.54)	
P-value		0.022	

S.D. = Standard Deviation; S.E. = Standard Error; AUC=Area Under the Curve; LS=Least Square
n is the number of patients with non-missing values, N1 is the total number of patients in the corresponding analysis set and subgroup regardless of missing value status, N is the total number of patients in the analysis set.
LS mean and LS mean difference is from an ANCOVA model with treatment, baseline score, Japanese/Non-Japanese and Standard Of Care(NSIDs/Non-NSIDs) as covariates. Interaction p-value is from the above ANCOVA model with additional factor/interaction of subgroup and subgroup by treatment.

Table 2.2.1.5: QMG: Responders of 6-Point Reduction During First Cycle by Subgroup - ITT+

ANALYSIS SET: ITT+

	COCHRANE'S Q P-VALE	EFGARTIGIMOD (N=65) n (%)	PLACEBO (N=64) n (%)	ODDS RATIO (95% C.I.)	RELATIVE RISK (95% C.I.)	ARR (%) (95% C.I.)	P-VALUE*
REGION	0.379						
EU							
n/N1		25/25 (100.0)	27/27 (100.0)				
RESPONSE		17 (68.0)	4 (14.8)	12.219 (3.155; 47.326)	4.590 (1.787; 11.793)	53.2 (26.8; 70.5)	<.001
NO RESPONSE		8 (32.0)	23 (85.2)				
NON-EU							
n/N1		40/40 (100.0)	36/37 (97.3)				
RESPONSE		29 (72.5)	3 (8.3)	29.000 (7.365; 114.195)	8.700 (2.896; 26.139)	64.2 (43.7; 76.8)	<.001
NO RESPONSE		11 (27.5)	33 (91.7)				

ARR=Absolute Risk Reduction
n is the number of patients with non-missing values, N1 is the total number of patients in the corresponding analysis set, subgroup and cycle regardless of missing value status, N is the total number of patients in the analysis set.
0.5 is added if any cell count is zero for odds ratio and relative risk calculation
* P-value is from Fisher's exact test.
Program: /clinical/argx-113/mg/argx-113-1704/biostat/staging/gba/programs/t_responder_sub.sas, Version: 1.2

Table 2.2.1.5: QMG: Responders of 6-Point Reduction During First Cycle by Subgroup - ITT+

ANALYSIS SET: ITT+

	COCHRANE'S Q P-VALE	EFGARTIGIMOD (N=65) n (%)	PLACEBO (N=64) n (%)	ODDS RATIO (95% C.I.)	RELATIVE RISK (95% C.I.)	ARR (%) (95% C.I.)	P-VALUE*
AGE CATEGORY	0.326						
18 - <65 years							
n/N1		57/57 (100.0)	51/51 (100.0)				
RESPONSE		39 (68.4)	6 (11.8)	16.250 (5.868; 45.001)	5.816 (2.687; 12.586)	56.7 (39.3; 68.9)	<.001
NO RESPONSE		18 (31.6)	45 (88.2)				
>= 65 years							
n/N1		8/8 (100.0)	12/13 (92.3)				
RESPONSE		7 (87.5)	1 (8.3)	77.000 (4.114; 1441.049)	10.500 (1.579; 69.832)	79.2 (35.3; 91.5)	0.001
NO RESPONSE		1 (12.5)	11 (91.7)				

ARR=Absolute Risk Reduction
n is the number of patients with non-missing values, N1 is the total number of patients in the corresponding analysis set, subgroup and cycle regardless of missing value status, N is the total number of patients in the analysis set.
0.5 is added if any cell count is zero for odds ratio and relative risk calculation
* P-value is from Fisher's exact test.
Program: /clinical/argx-113/mg/argx-113-1704/biostat/staging/gba/programs/t_responder_sub.sas, Version: 1.2

Table 2.2.1.5: QMG: Responders of 6-Point Reduction During First Cycle by Subgroup - ITT+

ANALYSIS SET: ITT+

	COCHRANE'S Q P-VALE	EFGARTIGIMOD (N=65) n (%)	PLACEBO (N=64) n (%)	ODDS RATIO (95% C.I.)	RELATIVE RISK (95% C.I.)	ARR (%) (95% C.I.)	P-VALUE*
SEX	0.068						
Female							
n/N1		46/46 (100.0)	40/40 (100.0)				
RESPONSE		30 (65.2)	6 (15.0)	10.625 (3.685; 30.635)	4.348 (2.019; 9.365)	50.2 (30.0; 64.7)	<.001
NO RESPONSE		16 (34.8)	34 (85.0)				
Male							
n/N1		19/19 (100.0)	23/24 (95.8)				
RESPONSE		16 (84.2)	1 (4.3)	117.333 (11.156; 1234.014)	19.368 (2.820; 133.005)	79.9 (52.5; 90.7)	<.001
NO RESPONSE		3 (15.8)	22 (95.7)				

ARR=Absolute Risk Reduction
n is the number of patients with non-missing values, N1 is the total number of patients in the corresponding analysis set, subgroup and cycle regardless of missing value status, N is the total number of patients in the analysis set.
0.5 is added if any cell count is zero for odds ratio and relative risk calculation
* P-value is from Fisher's exact test.
Program: /clinical/argx-113/mg/argx-113-1704/biostat/staging/gba/programs/t_responder_sub.sas, Version: 1.2

Table 2.2.1.5: QMG: Responders of 6-Point Reduction During First Cycle by Subgroup - ITT+

ANALYSIS SET: ITT+

	COCHRANE'S Q P-VALE	EFGARTIGIMOD (N=65) n (%)	PLACEBO (N=64) n (%)	ODDS RATIO (95% C.I.)	RELATIVE RISK (95% C.I.)	ARR (%) (95% C.I.)	P-VALUE*
RACE	1.000						
WHITE							
n/N1		54/54 (100.0)	55/56 (98.2)				
RESPONSE		40 (74.1)	7 (12.7)	19.592 (7.210; 53.236)	5.820 (2.862; 11.836)	61.3 (44.1; 73.1)	<.001
NO RESPONSE		14 (25.9)	48 (87.3)				
NON-WHITE							
n/N1		11/11 (100.0)	8/8 (100.0)				
RESPONSE		6 (54.5)	0 (0.0)	20.091 (0.933; 432.754)	9.750 (0.627; 151.532)	54.5 (12.6; 78.7)	0.018
NO RESPONSE		5 (45.5)	8 (100.0)				

ARR=Absolute Risk Reduction
n is the number of patients with non-missing values, N1 is the total number of patients in the corresponding analysis set, subgroup and cycle regardless of missing value status, N is the total number of patients in the analysis set.
0.5 is added if any cell count is zero for odds ratio and relative risk calculation
* P-value is from Fisher's exact test.
Program: /clinical/argx-113/mg/argx-113-1704/biostat/staging/gba/programs/t_responder_sub.sas, Version: 1.2

Table 2.2.1.5: QMG: Responders of 6-Point Reduction During First Cycle by Subgroup - ITT+

ANALYSIS SET: ITT+

	COCHRANE'S Q P-VALE	EFGARTIGIMOD (N=65) n (%)	PLACEBO (N=64) n (%)	ODDS RATIO (95% C.I.)	RELATIVE RISK (95% C.I.)	ARR (%) (95% C.I.)	P-VALUE*
BASELINE MG-ADL TOTAL SCORE	0.651						
MILD (5-7)							
n/N1		16/16 (100.0)	18/18 (100.0)				
RESPONSE		10 (62.5)	1 (5.6)	28.333 (2.967; 270.574)	11.250 (1.613; 78.458)	56.9 (25.7; 76.5)	0.001
NO RESPONSE		6 (37.5)	17 (94.4)				
MODERATE (8-9)							
n/N1		25/25 (100.0)	29/29 (100.0)				
RESPONSE		21 (84.0)	4 (13.8)	32.813 (7.304; 147.414)	6.090 (2.413; 15.371)	70.2 (45.1; 82.9)	<.001
NO RESPONSE		4 (16.0)	25 (86.2)				
SEVERE (>=10)							
n/N1		24/24 (100.0)	16/17 (94.1)				
RESPONSE		15 (62.5)	2 (12.5)	11.667 (2.139; 63.638)	5.000 (1.319; 18.960)	50.0 (19.3; 68.7)	0.003
NO RESPONSE		9 (37.5)	14 (87.5)				

ARR=Absolute Risk Reduction
n is the number of patients with non-missing values, N1 is the total number of patients in the corresponding analysis set, subgroup and cycle regardless of missing value status, N is the total number of patients in the analysis set.
0.5 is added if any cell count is zero for odds ratio and relative risk calculation
* P-value is from Fisher's exact test.
Program: /clinical/argx-113/mg/argx-113-1704/biostat/staging/gba/programs/t_responder_sub.sas, Version: 1.2

Table 2.2.1.5: QMG: Responders of 6-Point Reduction During First Cycle by Subgroup - ITT+

ANALYSIS SET: ITT+

	COCHRANE'S Q P-VALE	EFGARTIGIMOD (N=65) n (%)	PLACEBO (N=64) n (%)	ODDS RATIO (95% C.I.)	RELATIVE RISK (95% C.I.)	ARR (%) (95% C.I.)	P-VALUE*
CONCIMATANT TREATMENT	0.901						
NSID							
n/N1		38/38 (100.0)	37/37 (100.0)				
RESPONSE		25 (65.8)	3 (8.1)	21.795 (5.608; 84.699)	8.114 (2.678; 24.589)	57.7 (37.0; 71.7)	<.001
NO RESPONSE		13 (34.2)	34 (91.9)				
NON-NSID							
n/N1		27/27 (100.0)	26/27 (96.3)				
RESPONSE		21 (77.8)	4 (15.4)	19.250 (4.750; 78.011)	5.056 (2.007; 12.733)	62.4 (36.5; 77.2)	<.001
NO RESPONSE		6 (22.2)	22 (84.6)				

ARR=Absolute Risk Reduction
n is the number of patients with non-missing values, N1 is the total number of patients in the corresponding analysis set, subgroup and cycle regardless of missing value status, N is the total number of patients in the analysis set.
0.5 is added if any cell count is zero for odds ratio and relative risk calculation
* P-value is from Fisher's exact test.
Program: /clinical/argx-113/mg/argx-113-1704/biostat/staging/gba/programs/t_responder_sub.sas, Version: 1.2

Table 2.2.1.5: QMG: Responders of 6-Point Reduction During First Cycle by Subgroup - ITT+

ANALYSIS SET: ITT+

	COCHRANE'S Q P-VALE	EFGARTIGIMOD (N=65) n (%)	PLACEBO (N=64) n (%)	ODDS RATIO (95% C.I.)	RELATIVE RISK (95% C.I.)	ARR (%) (95% C.I.)	P-VALUE*
THYMECTOMY PERFORMED FOR MG	0.277						
YES							
n/N1		45/45 (100.0)	30/30 (100.0)				
RESPONSE		30 (66.7)	4 (13.3)	13.000 (3.832; 44.103)	5.000 (1.962; 12.741)	53.3 (31.4; 67.7)	<.001
NO RESPONSE		15 (33.3)	26 (86.7)				
NO							
n/N1		20/20 (100.0)	33/34 (97.1)				
RESPONSE		16 (80.0)	3 (9.1)	40.000 (7.954; 201.163)	8.800 (2.926; 26.462)	70.9 (44.9; 84.2)	<.001
NO RESPONSE		4 (20.0)	30 (90.9)				

ARR=Absolute Risk Reduction
n is the number of patients with non-missing values, N1 is the total number of patients in the corresponding analysis set, subgroup and cycle regardless of missing value status, N is the total number of patients in the analysis set.
0.5 is added if any cell count is zero for odds ratio and relative risk calculation
* P-value is from Fisher's exact test.
Program: /clinical/argx-113/mg/argx-113-1704/biostat/staging/gba/programs/t_responder_sub.sas, Version: 1.2

Table 2.2.5.4: QMG: AUC between Baseline and Week 20 of Change From Baseline in Total QMG Score by Subgroup - ITT+

ANALYSIS SET: ITT+

	Interaction P-value	EFGARTIGIMOD (N=65)	PLACEBO (N=64)
REGION	0.823		
EU			
n/N1 (%)		25/25 (100.0)	25/27 (92.6)
Mean (S.D.)		-74.1 (80.98)	-15.9 (58.24)
S.E.		16.20	11.65
95% C.I.		(-107.56; -40.70)	(-39.98; 8.09)
Median		-76.5	-31.0
Q1; Q3		(-107.5; -35.0)	(-59.5; 31.0)
Min; Max		(-243; 67)	(-119; 130)
Hedge's G		-0.81	
95% C.I.		(-1.380; -0.244)	
LS Mean (S.E.)		-72.8 (13.65)	-17.4 (13.69)
95% C.I.		(-100.30; -45.36)	(-44.99; 10.11)
LS Mean Differences (S.E.)		-55.4 (19.32)	
95% C.I.		(-94.28; -16.49)	
P-value		0.006	

S.D. = Standard Deviation; S.E. = Standard Error; AUC=Area Under the Curve; LS=Least Square
n is the number of patients with non-missing values, N1 is the total number of patients in the corresponding analysis set and subgroup regardless of missing value status, N is the total number of patients in the analysis set.
LS mean and LS mean difference is from an ANCOVA model with treatment, baseline score, Japanese/Non-Japanese and Standard Of Care(NSIDs/Non-NSIDs) as covariates. Interaction p-value is from the above ANCOVA model with additional factor/interaction of subgroup and subgroup by treatment.

Table 2.2.5.4: QMG: AUC between Baseline and Week 20 of Change From Baseline in Total QMG Score by Subgroup - ITT+

ANALYSIS SET: ITT+

	Interaction P-value	EFGARTIGIMOD (N=65)	PLACEBO (N=64)
REGION	0.823		
NON-EU			
n/N1 (%)		40/40 (100.0)	37/37 (100.0)
Mean (S.D.)		-84.9 (74.77)	-21.9 (49.90)
S.E.		11.82	8.20
95% C.I.		(-108.83; -61.00)	(-38.57; -5.30)
Median		-87.8	-16.5
Q1; Q3		(-144.1; -11.0)	(-58.0; 3.1)
Min; Max		(-216; 33)	(-103; 93)
Hedge's G		-0.97	
95% C.I.		(-1.442; -0.505)	
LS Mean (S.E.)		-66.7 (12.67)	-4.8 (13.38)
95% C.I.		(-91.91; -41.40)	(-31.43; 21.91)
LS Mean Differences (S.E.)		-61.9 (13.47)	
95% C.I.		(-88.75; -35.04)	
P-value		<.001	

S.D. = Standard Deviation; S.E. = Standard Error; AUC=Area Under the Curve; LS=Least Square
n is the number of patients with non-missing values, N1 is the total number of patients in the corresponding analysis set and subgroup regardless of missing value status, N is the total number of patients in the analysis set.
LS mean and LS mean difference is from an ANCOVA model with treatment, baseline score, Japanese/Non-Japanese and Standard Of Care(NSIDs/Non-NSIDs) as covariates. Interaction p-value is from the above ANCOVA model with additional factor/interaction of subgroup and subgroup by treatment.

Table 2.2.5.4: QMG: AUC between Baseline and Week 20 of Change From Baseline in Total QMG Score by Subgroup - ITT+

ANALYSIS SET: ITT+

	Interaction P-value	EFGARTIGIMOD (N=65)	PLACEBO (N=64)
AGE CATEGORY	0.410		
18 - <65 years			
n/N1 (%)		57/57 (100.0)	49/51 (96.1)
Mean (S.D.)		-79.6 (77.22)	-21.2 (54.61)
S.E.		10.23	7.80
95% C.I.		(-100.04; -59.06)	(-36.90; -5.53)
Median		-84.0	-31.0
Q1; Q3		(-132.5; -11.5)	(-67.5; 14.0)
Min; Max		(-243; 67)	(-119; 130)
Hedge's G		-0.86	
95% C.I.		(-1.251; -0.459)	
LS Mean (S.E.)		-56.5 (14.16)	-1.0 (15.06)
95% C.I.		(-84.61; -28.44)	(-30.84; 28.92)
LS Mean Differences (S.E.)		-55.6 (12.43)	
95% C.I.		(-80.22; -30.91)	
P-value		<.001	

S.D. = Standard Deviation; S.E. = Standard Error; AUC=Area Under the Curve; LS=Least Square
n is the number of patients with non-missing values, N1 is the total number of patients in the corresponding analysis set and subgroup regardless of missing value status, N is the total number of patients in the analysis set.
LS mean and LS mean difference is from an ANCOVA model with treatment, baseline score, Japanese/Non-Japanese and Standard Of Care(NSIDs/Non-NSIDs) as covariates. Interaction p-value is from the above ANCOVA model with additional factor/interaction of subgroup and subgroup by treatment.

Table 2.2.5.4: QMG: AUC between Baseline and Week 20 of Change From Baseline in Total QMG Score by Subgroup - ITT+

ANALYSIS SET: ITT+

	Interaction P-value	EFGARTIGIMOD (N=65)	PLACEBO (N=64)
AGE CATEGORY	0.410		
>= 65 years			
n/N1 (%)		8/8 (100.0)	13/13 (100.0)
Mean (S.D.)		-89.4 (77.96)	-13.1 (48.10)
S.E.		27.56	13.34
95% C.I.		(-154.59; -24.23)	(-42.20; 15.93)
Median		-59.2	-12.8
Q1; Q3		(-157.5; -34.5)	(-56.0; 1.0)
Min; Max		(-210; -3)	(-87; 77)
Hedge's G		-1.20	
95% C.I.		(-2.124; -0.283)	
LS Mean (S.E.)		-92.2 (25.55)	-15.1 (24.04)
95% C.I.		(-146.37; -38.03)	(-66.07; 35.87)
LS Mean Differences (S.E.)		-77.1 (25.37)	
95% C.I.		(-130.87; -23.32)	
P-value		0.008	

S.D. = Standard Deviation; S.E. = Standard Error; AUC=Area Under the Curve; LS=Least Square
n is the number of patients with non-missing values, N1 is the total number of patients in the corresponding analysis set and subgroup regardless of missing value status, N is the total number of patients in the analysis set.
LS mean and LS mean difference is from an ANCOVA model with treatment, baseline score, Japanese/Non-Japanese and Standard Of Care(NSIDs/Non-NSIDs) as covariates. Interaction p-value is from the above ANCOVA model with additional factor/interaction of subgroup and subgroup by treatment.

Table 2.2.5.4: QMG: AUC between Baseline and Week 20 of Change From Baseline in Total QMG Score by Subgroup - ITT+

ANALYSIS SET: ITT+

	Interaction P-value	EFGARTIGIMOD (N=65)	PLACEBO (N=64)
SEX	0.757		
Female			
n/N1 (%)		46/46 (100.0)	40/40 (100.0)
Mean (S.D.)		-81.1 (83.02)	-24.1 (50.54)
S.E.		12.24	7.99
95% C.I.		(-105.76; -56.45)	(-40.25; -7.92)
Median		-81.7	-26.8
Q1; Q3		(-149.0; -3.0)	(-65.0; 5.5)
Min; Max		(-243; 43)	(-103; 130)
Hedge's G		-0.81	
95% C.I.		(-1.246; -0.372)	
LS Mean (S.E.)		-66.8 (15.60)	-11.2 (17.12)
95% C.I.		(-97.79; -35.72)	(-45.31; 22.84)
LS Mean Differences (S.E.)		-55.5 (14.15)	
95% C.I.		(-83.67; -27.37)	
P-value		<.001	

S.D. = Standard Deviation; S.E. = Standard Error; AUC=Area Under the Curve; LS=Least Square
n is the number of patients with non-missing values, N1 is the total number of patients in the corresponding analysis set and subgroup regardless of missing value status, N is the total number of patients in the analysis set.
LS mean and LS mean difference is from an ANCOVA model with treatment, baseline score, Japanese/Non-Japanese and Standard Of Care(NSIDs/Non-NSIDs) as covariates. Interaction p-value is from the above ANCOVA model with additional factor/interaction of subgroup and subgroup by treatment.

Table 2.2.5.4: QMG: AUC between Baseline and Week 20 of Change From Baseline in Total QMG Score by Subgroup - ITT+

ANALYSIS SET: ITT+

	Interaction P-value	EFGARTIGIMOD (N=65)	PLACEBO (N=64)
SEX	0.757		
Male			
n/N1 (%)		19/19 (100.0)	22/24 (91.7)
Mean (S.D.)		-80.0 (61.02)	-11.2 (57.58)
S.E.		14.00	12.28
95% C.I.		(-109.36; -50.54)	(-36.75; 14.30)
Median		-69.5	-21.9
Q1; Q3		(-132.5; -40.5)	(-56.0; 32.0)
Min; Max		(-210; 67)	(-119; 93)
Hedge's G		-1.14	
95% C.I.		(-1.789; -0.488)	
LS Mean (S.E.)		-63.3 (21.38)	2.8 (19.89)
95% C.I.		(-106.71; -19.99)	(-37.53; 43.13)
LS Mean Differences (S.E.)		-66.1 (18.44)	
95% C.I.		(-103.53; -28.76)	
P-value		<.001	

S.D. = Standard Deviation; S.E. = Standard Error; AUC=Area Under the Curve; LS=Least Square
n is the number of patients with non-missing values, N1 is the total number of patients in the corresponding analysis set and subgroup regardless of missing value status, N is the total number of patients in the analysis set.
LS mean and LS mean difference is from an ANCOVA model with treatment, baseline score, Japanese/Non-Japanese and Standard Of Care(NSIDs/Non-NSIDs) as covariates. Interaction p-value is from the above ANCOVA model with additional factor/interaction of subgroup and subgroup by treatment.

Table 2.2.5.4: QMG: AUC between Baseline and Week 20 of Change From Baseline in Total QMG Score by Subgroup - ITT+

ANALYSIS SET: ITT+

	Interaction P-value	EFGARTIGIMOD (N=65)	PLACEBO (N=64)
RACE	0.848		
WHITE			
n/N1 (%)		54/54 (100.0)	55/56 (98.2)
Mean (S.D.)		-85.4 (78.73)	-22.6 (53.81)
S.E.		10.71	7.26
95% C.I.		(-106.88; -63.90)	(-37.18; -8.09)
Median		-81.7	-31.0
Q1; Q3		(-146.0; -32.5)	(-67.5; 18.0)
Min; Max		(-243; 67)	(-119; 130)
Hedge's G		-0.93	
95% C.I.		(-1.318; -0.533)	
LS Mean (S.E.)		-84.0 (8.93)	-25.1 (8.82)
95% C.I.		(-101.72; -66.31)	(-42.64; -7.66)
LS Mean Differences (S.E.)		-58.9 (12.55)	
95% C.I.		(-83.74; -33.98)	
P-value		<.001	

S.D. = Standard Deviation; S.E. = Standard Error; AUC=Area Under the Curve; LS=Least Square
n is the number of patients with non-missing values, N1 is the total number of patients in the corresponding analysis set and subgroup regardless of missing value status, N is the total number of patients in the analysis set.
LS mean and LS mean difference is from an ANCOVA model with treatment, baseline score, Japanese/Non-Japanese and Standard Of Care(NSIDs/Non-NSIDs) as covariates. Interaction p-value is from the above ANCOVA model with additional factor/interaction of subgroup and subgroup by treatment.

Table 2.2.5.4: QMG: AUC between Baseline and Week 20 of Change From Baseline in Total QMG Score by Subgroup - ITT+

ANALYSIS SET: ITT+

	Interaction P-value	EFGARTIGIMOD (N=65)	PLACEBO (N=64)
RACE	0.848		
NON-WHITE			
n/N1 (%)		11/11 (100.0)	7/8 (87.5)
Mean (S.D.)		-58.1 (64.70)	4.9 (41.87)
S.E.		19.51	15.83
95% C.I.		(-101.54; -14.61)	(-33.80; 43.65)
Median		-53.3	-6.7
Q1; Q3		(-132.5; 4.5)	(-16.5; 14.0)
Min; Max		(-142; 26)	(-36; 93)
Hedge's G		-1.05	
95% C.I.		(-2.014; -0.083)	
LS Mean (S.E.)		-58.2 (13.91)	-5.5 (17.58)
95% C.I.		(-88.25; -28.17)	(-43.44; 32.51)
LS Mean Differences (S.E.)		-52.7 (21.76)	
95% C.I.		(-99.75; -5.73)	
P-value		0.031	

S.D. = Standard Deviation; S.E. = Standard Error; AUC=Area Under the Curve; LS=Least Square
n is the number of patients with non-missing values, N1 is the total number of patients in the corresponding analysis set and subgroup regardless of missing value status, N is the total number of patients in the analysis set.
LS mean and LS mean difference is from an ANCOVA model with treatment, baseline score, Japanese/Non-Japanese and Standard Of Care(NSIDs/Non-NSIDs) as covariates. Interaction p-value is from the above ANCOVA model with additional factor/interaction of subgroup and subgroup by treatment.

Table 2.2.5.4: QMG: AUC between Baseline and Week 20 of Change From Baseline in Total QMG Score by Subgroup - ITT+

ANALYSIS SET: ITT+

	Interaction P-value	EFGARTIGIMOD (N=65)	PLACEBO (N=64)
BASELINE MG-ADL TOTAL SCORE	0.285		
MILD (5-7)			
n/N1 (%)		16/16 (100.0)	18/18 (100.0)
Mean (S.D.)		-60.3 (80.31)	-12.7 (54.50)
S.E.		20.08	12.85
95% C.I.		(-103.04; -17.46)	(-39.80; 14.41)
Median		-44.0	-27.8
Q1; Q3		(-121.5; 0.8)	(-52.2; 31.0)
Min; Max		(-243; 67)	(-93; 93)
Hedge's G		-0.68	
95% C.I.		(-1.362; -0.007)	
LS Mean (S.E.)		-40.0 (21.56)	8.5 (21.10)
95% C.I.		(-84.14; 4.07)	(-34.64; 51.66)
LS Mean Differences (S.E.)		-48.5 (22.38)	
95% C.I.		(-94.33; -2.77)	
P-value		0.038	

S.D. = Standard Deviation; S.E. = Standard Error; AUC=Area Under the Curve; LS=Least Square
n is the number of patients with non-missing values, N1 is the total number of patients in the corresponding analysis set and subgroup regardless of missing value status, N is the total number of patients in the analysis set.
LS mean and LS mean difference is from an ANCOVA model with treatment, baseline score, Japanese/Non-Japanese and Standard Of Care(NSIDs/Non-NSIDs) as covariates. Interaction p-value is from the above ANCOVA model with additional factor/interaction of subgroup and subgroup by treatment.

Table 2.2.5.4: QMG: AUC between Baseline and Week 20 of Change From Baseline in Total QMG Score by Subgroup - ITT+

ANALYSIS SET: ITT+

	Interaction P-value	EFGARTIGIMOD (N=65)	PLACEBO (N=64)
BASELINE MG-ADL TOTAL SCORE	0.285		
MODERATE (8-9)			
n/N1 (%)		25/25 (100.0)	28/29 (96.6)
Mean (S.D.)		-100.1 (67.18)	-19.4 (54.79)
S.E.		13.44	10.35
95% C.I.		(-127.85; -72.39)	(-40.64; 1.85)
Median		-94.0	-22.6
Q1; Q3		(-132.5; -53.3)	(-57.0; 14.0)
Min; Max		(-235; 43)	(-119; 130)
Hedge's G		-1.31	
95% C.I.		(-1.892; -0.719)	
LS Mean (S.E.)		-98.1 (23.53)	-18.9 (22.72)
95% C.I.		(-145.36; -50.75)	(-64.59; 26.79)
LS Mean Differences (S.E.)		-79.2 (16.24)	
95% C.I.		(-111.81; -46.51)	
P-value		<.001	

S.D. = Standard Deviation; S.E. = Standard Error; AUC=Area Under the Curve; LS=Least Square
n is the number of patients with non-missing values, N1 is the total number of patients in the corresponding analysis set and subgroup regardless of missing value status, N is the total number of patients in the analysis set.
LS mean and LS mean difference is from an ANCOVA model with treatment, baseline score, Japanese/Non-Japanese and Standard Of Care(NSIDs/Non-NSIDs) as covariates. Interaction p-value is from the above ANCOVA model with additional factor/interaction of subgroup and subgroup by treatment.

Table 2.2.5.4: QMG: AUC between Baseline and Week 20 of Change From Baseline in Total QMG Score by Subgroup - ITT+

ANALYSIS SET: ITT+

	Interaction P-value	EFGARTIGIMOD (N=65)	PLACEBO (N=64)
BASELINE MG-ADL TOTAL SCORE SEVERE (>=10)	0.285		
n/N1 (%)		24/24 (100.0)	16/17 (94.1)
Mean (S.D.)		-74.3 (82.10)	-27.4 (50.44)
S.E.		16.76	12.61
95% C.I.		(-108.95; -39.62)	(-54.31; -0.55)
Median		-67.3	-26.5
Q1; Q3		(-137.6; -0.7)	(-72.3; 16.0)
Min; Max		(-210; 42)	(-103; 56)
Hedge's G		-0.64	
95% C.I.		(-1.280; -0.008)	
LS Mean (S.E.)		-55.0 (23.47)	-12.1 (27.34)
95% C.I.		(-102.62; -7.31)	(-67.58; 43.43)
LS Mean Differences (S.E.)		-42.9 (22.80)	
95% C.I.		(-89.17; 3.39)	
P-value		0.068	

S.D. = Standard Deviation; S.E. = Standard Error; AUC=Area Under the Curve; LS=Least Square
n is the number of patients with non-missing values, N1 is the total number of patients in the corresponding analysis set and subgroup regardless of missing value status, N is the total number of patients in the analysis set.
LS mean and LS mean difference is from an ANCOVA model with treatment, baseline score, Japanese/Non-Japanese and Standard Of Care(NSIDs/Non-NSIDs) as covariates. Interaction p-value is from the above ANCOVA model with additional factor/interaction of subgroup and subgroup by treatment.

Table 2.2.5.4: QMG: AUC between Baseline and Week 20 of Change From Baseline in Total QMG Score by Subgroup - ITT+

ANALYSIS SET: ITT+

	Interaction P-value	EFGARTIGIMOD (N=65)	PLACEBO (N=64)
CONCIMATANT TREATMENT	0.949		
NSID			
n/N1 (%)		38/38 (100.0)	35/37 (94.6)
Mean (S.D.)		-74.5 (73.97)	-14.2 (51.91)
S.E.		12.00	8.77
95% C.I.		(-98.83; -50.20)	(-32.08; 3.59)
Median		-70.8	-14.5
Q1; Q3		(-123.5; -6.5)	(-49.0; 31.0)
Min; Max		(-235; 67)	(-119; 93)
Hedge's G		-0.93	
95% C.I.		(-1.405; -0.448)	
LS Mean (S.E.)		-57.1 (13.35)	2.2 (14.05)
95% C.I.		(-83.78; -30.52)	(-25.82; 30.25)
LS Mean Differences (S.E.)		-59.4 (13.71)	
95% C.I.		(-86.71; -32.02)	
P-value		<.001	

S.D. = Standard Deviation; S.E. = Standard Error; AUC=Area Under the Curve; LS=Least Square
n is the number of patients with non-missing values, N1 is the total number of patients in the corresponding analysis set and subgroup regardless of missing value status, N is the total number of patients in the analysis set.
LS mean and LS mean difference is from an ANCOVA model with treatment, baseline score, Japanese/Non-Japanese and Standard Of Care(NSIDs/Non-NSIDs) as covariates. Interaction p-value is from the above ANCOVA model with additional factor/interaction of subgroup and subgroup by treatment.

Table 2.2.5.4: QMG: AUC between Baseline and Week 20 of Change From Baseline in Total QMG Score by Subgroup - ITT+

ANALYSIS SET: ITT+

	Interaction P-value	EFGARTIGIMOD (N=65)	PLACEBO (N=64)
CONCIMATANT TREATMENT	0.949		
NON-NSID			
n/N1 (%)		27/27 (100.0)	27/27 (100.0)
Mean (S.D.)		-89.6 (81.13)	-26.4 (54.68)
S.E.		15.61	10.52
95% C.I.		(-121.66; -57.47)	(-47.99; -4.73)
Median		-91.0	-42.5
Q1; Q3		(-142.2; -17.0)	(-67.5; 1.0)
Min; Max		(-243; 43)	(-89; 130)
Hedge's G		-0.90	
95% C.I.		(-1.453; -0.348)	
LS Mean (S.E.)		-68.4 (28.02)	-8.3 (29.20)
95% C.I.		(-124.72; -12.16)	(-66.97; 50.34)
LS Mean Differences (S.E.)		-60.1 (18.97)	
95% C.I.		(-98.22; -22.03)	
P-value		0.003	

S.D. = Standard Deviation; S.E. = Standard Error; AUC=Area Under the Curve; LS=Least Square
n is the number of patients with non-missing values, N1 is the total number of patients in the corresponding analysis set and subgroup regardless of missing value status, N is the total number of patients in the analysis set.
LS mean and LS mean difference is from an ANCOVA model with treatment, baseline score, Japanese/Non-Japanese and Standard Of Care(NSIDs/Non-NSIDs) as covariates. Interaction p-value is from the above ANCOVA model with additional factor/interaction of subgroup and subgroup by treatment.

Table 2.2.5.4: QMG: AUC between Baseline and Week 20 of Change From Baseline in Total QMG Score by Subgroup - ITT+

ANALYSIS SET: ITT+

	Interaction P-value	EFGARTIGIMOD (N=65)	PLACEBO (N=64)
THYMECTOMY PERFORMED FOR MG	0.494		
YES			
n/N1 (%)		45/45 (100.0)	29/30 (96.7)
Mean (S.D.)		-73.1 (75.64)	-21.6 (50.74)
S.E.		11.28	9.42
95% C.I.		(-95.84; -50.40)	(-40.86; -2.26)
Median		-79.4	-29.0
Q1; Q3		(-122.5; -3.0)	(-58.0; 14.0)
Min; Max		(-235; 67)	(-119; 80)
Hedge's G		-0.76	
95% C.I.		(-1.239; -0.283)	
LS Mean (S.E.)		-58.9 (15.94)	-5.8 (19.04)
95% C.I.		(-90.69; -27.11)	(-43.78; 32.18)
LS Mean Differences (S.E.)		-53.1 (15.19)	
95% C.I.		(-83.41; -22.79)	
P-value		<.001	

S.D. = Standard Deviation; S.E. = Standard Error; AUC=Area Under the Curve; LS=Least Square
n is the number of patients with non-missing values, N1 is the total number of patients in the corresponding analysis set and subgroup regardless of missing value status, N is the total number of patients in the analysis set.
LS mean and LS mean difference is from an ANCOVA model with treatment, baseline score, Japanese/Non-Japanese and Standard Of Care(NSIDs/Non-NSIDs) as covariates. Interaction p-value is from the above ANCOVA model with additional factor/interaction of subgroup and subgroup by treatment.

Table 2.2.5.4: QMG: AUC between Baseline and Week 20 of Change From Baseline in Total QMG Score by Subgroup - ITT+

ANALYSIS SET: ITT+

	Interaction P-value	EFGARTIGIMOD (N=65)	PLACEBO (N=64)
THYMECTOMY PERFORMED FOR MG	0.494		
NO			
n/N1 (%)		20/20 (100.0)	33/34 (97.1)
Mean (S.D.)		-98.0 (78.44)	-17.7 (55.69)
S.E.		17.54	9.69
95% C.I.		(-134.68; -61.26)	(-37.48; 2.02)
Median		-83.8	-16.5
Q1; Q3		(-165.9; -43.5)	(-59.5; 10.0)
Min; Max		(-243; 42)	(-103; 130)
Hedge's G		-1.21	
95% C.I.		(-1.808; -0.620)	
LS Mean (S.E.)		-74.9 (20.97)	-3.3 (19.18)
95% C.I.		(-117.05; -32.74)	(-41.85; 35.27)
LS Mean Differences (S.E.)		-71.6 (18.65)	
95% C.I.		(-109.10; -34.12)	
P-value		<.001	

S.D. = Standard Deviation; S.E. = Standard Error; AUC=Area Under the Curve; LS=Least Square
n is the number of patients with non-missing values, N1 is the total number of patients in the corresponding analysis set and subgroup regardless of missing value status, N is the total number of patients in the analysis set.
LS mean and LS mean difference is from an ANCOVA model with treatment, baseline score, Japanese/Non-Japanese and Standard Of Care(NSIDs/Non-NSIDs) as covariates. Interaction p-value is from the above ANCOVA model with additional factor/interaction of subgroup and subgroup by treatment.

Table 2.3.1.5: MGC: Responders of 8-Point Reduction During First Cycle by Subgroup - ITT+

ANALYSIS SET: ITT+

	COCHRANE'S Q P-VALE	EFGARTIGIMOD (N=65) n (%)	PLACEBO (N=64) n (%)	ODDS RATIO (95% C.I.)	RELATIVE RISK (95% C.I.)	ARR (%) (95% C.I.)	P-VALUE*
REGION	0.187						
EU							
n/N1		25/25 (100.0)	27/27 (100.0)				
RESPONSE		17 (68.0)	9 (33.3)	4.250 (1.332; 13.562)	2.040 (1.123; 3.707)	34.7 (7.5; 55.5)	0.025
NO RESPONSE		8 (32.0)	18 (66.7)				
NON-EU							
n/N1		40/40 (100.0)	36/37 (97.3)				
RESPONSE		30 (75.0)	7 (19.4)	12.429 (4.168; 37.057)	3.857 (1.937; 7.679)	55.6 (33.8; 70.1)	<.001
NO RESPONSE		10 (25.0)	29 (80.6)				

ARR=Absolute Risk Reduction
n is the number of patients with non-missing values, N1 is the total number of patients in the corresponding analysis set, subgroup and cycle regardless of missing value status, N is the total number of patients in the analysis set.
0.5 is added if any cell count is zero for odds ratio and relative risk calculation
* P-value is from Fisher's exact test.
Program: /clinical/argx-113/mg/argx-113-1704/biostat/staging/gba/programs/t_responder_sub.sas, Version: 1.2

Table 2.3.1.5: MGC: Responders of 8-Point Reduction During First Cycle by Subgroup - ITT+

ANALYSIS SET: ITT+

	COCHRANE'S Q P-VALE	EFGARTIGIMOD (N=65) n (%)	PLACEBO (N=64) n (%)	ODDS RATIO (95% C.I.)	RELATIVE RISK (95% C.I.)	ARR (%) (95% C.I.)	P-VALUE*
AGE CATEGORY	0.456						
18 - <65 years							
n/N1		57/57 (100.0)	51/51 (100.0)				
RESPONSE		42 (73.7)	15 (29.4)	6.720 (2.893; 15.610)	2.505 (1.593; 3.939)	44.3 (25.7; 58.7)	<.001
NO RESPONSE		15 (26.3)	36 (70.6)				
>= 65 years							
n/N1		8/8 (100.0)	12/13 (92.3)				
RESPONSE		5 (62.5)	1 (8.3)	18.333 (1.508; 222.875)	7.500 (1.065; 52.809)	54.2 (12.3; 78.9)	0.018
NO RESPONSE		3 (37.5)	11 (91.7)				

ARR=Absolute Risk Reduction
n is the number of patients with non-missing values, N1 is the total number of patients in the corresponding analysis set, subgroup and cycle regardless of missing value status, N is the total number of patients in the analysis set.
0.5 is added if any cell count is zero for odds ratio and relative risk calculation
* P-value is from Fisher's exact test.
Program: /clinical/argx-113/mg/argx-113-1704/biostat/staging/gba/programs/t_responder_sub.sas, Version: 1.2

Table 2.3.1.5: MGC: Responders of 8-Point Reduction During First Cycle by Subgroup - ITT+

ANALYSIS SET: ITT+

	COCHRANE'S Q P-VALE	EFGARTIGIMOD (N=65) n (%)	PLACEBO (N=64) n (%)	ODDS RATIO (95% C.I.)	RELATIVE RISK (95% C.I.)	ARR (%) (95% C.I.)	P-VALUE*
SEX	0.719						
Female							
n/N1		46/46 (100.0)	40/40 (100.0)				
RESPONSE		35 (76.1)	11 (27.5)	8.388 (3.180; 22.126)	2.767 (1.631; 4.694)	48.6 (27.8; 63.7)	<.001
NO RESPONSE		11 (23.9)	29 (72.5)				
Male							
n/N1		19/19 (100.0)	23/24 (95.8)				
RESPONSE		12 (63.2)	5 (21.7)	6.171 (1.583; 24.054)	2.905 (1.244; 6.784)	41.4 (11.5; 62.8)	0.011
NO RESPONSE		7 (36.8)	18 (78.3)				

ARR=Absolute Risk Reduction
n is the number of patients with non-missing values, N1 is the total number of patients in the corresponding analysis set, subgroup and cycle regardless of missing value status, N is the total number of patients in the analysis set.
0.5 is added if any cell count is zero for odds ratio and relative risk calculation
* P-value is from Fisher's exact test.
Program: /clinical/argx-113/mg/argx-113-1704/biostat/staging/gba/programs/t_responder_sub.sas, Version: 1.2

Table 2.3.1.5: MGC: Responders of 8-Point Reduction During First Cycle by Subgroup - ITT+

ANALYSIS SET: ITT+

	COCHRANE'S Q P-VALE	EFGARTIGIMOD (N=65) n (%)	PLACEBO (N=64) n (%)	ODDS RATIO (95% C.I.)	RELATIVE RISK (95% C.I.)	ARR (%) (95% C.I.)	P-VALUE*
RACE	0.396						
WHITE							
n/N1		54/54 (100.0)	55/56 (98.2)				
RESPONSE		41 (75.9)	14 (25.5)	9.236 (3.869; 22.051)	2.983 (1.852; 4.804)	50.5 (32.3; 64.0)	<.001
NO RESPONSE		13 (24.1)	41 (74.5)				
NON-WHITE							
n/N1		11/11 (100.0)	8/8 (100.0)				
RESPONSE		6 (54.5)	2 (25.0)	3.600 (0.491; 26.398)	2.182 (0.585; 8.134)	29.5 (-13.6; 59.6)	0.352
NO RESPONSE		5 (45.5)	6 (75.0)				

ARR=Absolute Risk Reduction
n is the number of patients with non-missing values, N1 is the total number of patients in the corresponding analysis set, subgroup and cycle regardless of missing value status, N is the total number of patients in the analysis set.
0.5 is added if any cell count is zero for odds ratio and relative risk calculation
* P-value is from Fisher's exact test.
Program: /clinical/argx-113/mg/argx-113-1704/biostat/staging/gba/programs/t_responder_sub.sas, Version: 1.2

Table 2.3.1.5: MGC: Responders of 8-Point Reduction During First Cycle by Subgroup - ITT+

ANALYSIS SET: ITT+

	COCHRANE'S Q P-VALE	EFGARTIGIMOD (N=65) n (%)	PLACEBO (N=64) n (%)	ODDS RATIO (95% C.I.)	RELATIVE RISK (95% C.I.)	ARR (%) (95% C.I.)	P-VALUE*
BASELINE MG-ADL TOTAL SCORE	0.105						
MILD (5-7)							
n/N1		16/16 (100.0)	18/18 (100.0)				
RESPONSE		6 (37.5)	4 (22.2)	2.100 (0.467; 9.440)	1.688 (0.578; 4.925)	15.3 (-14.6; 42.6)	0.457
NO RESPONSE		10 (62.5)	14 (77.8)				
MODERATE (8-9)							
n/N1		25/25 (100.0)	29/29 (100.0)				
RESPONSE		20 (80.0)	8 (27.6)	10.500 (2.937; 37.545)	2.900 (1.558; 5.398)	52.4 (26.1; 69.4)	<.001
NO RESPONSE		5 (20.0)	21 (72.4)				
SEVERE (>=10)							
n/N1		24/24 (100.0)	16/17 (94.1)				
RESPONSE		21 (87.5)	4 (25.0)	21.000 (4.007; 110.057)	3.500 (1.478; 8.288)	62.5 (31.8; 79.4)	<.001
NO RESPONSE		3 (12.5)	12 (75.0)				

ARR=Absolute Risk Reduction
n is the number of patients with non-missing values, N1 is the total number of patients in the corresponding analysis set, subgroup and cycle regardless of missing value status, N is the total number of patients in the analysis set.
0.5 is added if any cell count is zero for odds ratio and relative risk calculation
* P-value is from Fisher's exact test.
Program: /clinical/argx-113/mg/argx-113-1704/biostat/staging/gba/programs/t_responder_sub.sas, Version: 1.2

Table 2.3.1.5: MGC: Responders of 8-Point Reduction During First Cycle by Subgroup - ITT+

ANALYSIS SET: ITT+

	COCHRANE'S Q P-VALE	EFGARTIGIMOD (N=65) n (%)	PLACEBO (N=64) n (%)	ODDS RATIO (95% C.I.)	RELATIVE RISK (95% C.I.)	ARR (%) (95% C.I.)	P-VALUE*
CONCIMATANT TREATMENT	0.652						
NSID							
n/N1		38/38 (100.0)	37/37 (100.0)				
RESPONSE		24 (63.2)	7 (18.9)	7.347 (2.560; 21.083)	3.338 (1.641; 6.789)	44.2 (22.2; 60.7)	<.001
NO RESPONSE		14 (36.8)	30 (81.1)				
NON-NSID							
n/N1		27/27 (100.0)	26/27 (96.3)				
RESPONSE		23 (85.2)	9 (34.6)	10.861 (2.860; 41.241)	2.461 (1.418; 4.271)	50.6 (24.5; 68.2)	<.001
NO RESPONSE		4 (14.8)	17 (65.4)				

ARR=Absolute Risk Reduction
n is the number of patients with non-missing values, N1 is the total number of patients in the corresponding analysis set, subgroup and cycle regardless of missing value status, N is the total number of patients in the analysis set.
0.5 is added if any cell count is zero for odds ratio and relative risk calculation
* P-value is from Fisher's exact test.
Program: /clinical/argx-113/mg/argx-113-1704/biostat/staging/gba/programs/t_responder_sub.sas, Version: 1.2

Table 2.3.1.5: MGC: Responders of 8-Point Reduction During First Cycle by Subgroup - ITT+

ANALYSIS SET: ITT+

	COCHRANE'S Q P-VALE	EFGARTIGIMOD (N=65) n (%)	PLACEBO (N=64) n (%)	ODDS RATIO (95% C.I.)	RELATIVE RISK (95% C.I.)	ARR (%) (95% C.I.)	P-VALUE*
THYMECTOMY PERFORMED FOR MG	0.295						
YES							
n/N1		45/45 (100.0)	30/30 (100.0)				
RESPONSE		29 (64.4)	6 (20.0)	7.250 (2.455; 21.413)	3.222 (1.525; 6.807)	44.4 (21.8; 60.6)	<.001
NO RESPONSE		16 (35.6)	24 (80.0)				
NO							
n/N1		20/20 (100.0)	33/34 (97.1)				
RESPONSE		18 (90.0)	10 (30.3)	20.700 (4.021; 106.572)	2.970 (1.735; 5.085)	59.7 (33.3; 74.5)	<.001
NO RESPONSE		2 (10.0)	23 (69.7)				

ARR=Absolute Risk Reduction
n is the number of patients with non-missing values, N1 is the total number of patients in the corresponding analysis set, subgroup and cycle regardless of missing value status, N is the total number of patients in the analysis set.
0.5 is added if any cell count is zero for odds ratio and relative risk calculation
* P-value is from Fisher's exact test.
Program: /clinical/argx-113/mg/argx-113-1704/biostat/staging/gba/programs/t_responder_sub.sas, Version: 1.2

Table 2.3.5.4: MGC: AUC between Baseline and Week 20 of Change From Baseline in Total MGC Score by Subgroup - ITT+

ANALYSIS SET: ITT+

	Interaction P-value	EFGARTIGIMOD (N=65)	PLACEBO (N=64)
REGION	0.547		
EU			
n/N1 (%)		25/25 (100.0)	27/27 (100.0)
Mean (S.D.)		-111.8 (110.77)	-59.4 (87.14)
S.E.		22.15	16.77
95% C.I.		(-157.51; -66.06)	(-93.92; -24.98)
Median		-105.0	-57.5
Q1; Q3		(-169.4; -48.0)	(-108.0; -30.6)
Min; Max		(-286; 143)	(-228; 239)
Hedge's G		-0.52	
95% C.I.		(-1.065; 0.025)	
LS Mean (S.E.)		-109.7 (18.44)	-62.7 (17.89)
95% C.I.		(-146.82; -72.64)	(-98.64; -26.70)
LS Mean Differences (S.E.)		-47.1 (25.66)	
95% C.I.		(-98.66; 4.54)	
P-value		0.073	

S.D. = Standard Deviation; S.E. = Standard Error; AUC=Area Under the Curve; LS=Least Square
n is the number of patients with non-missing values, N1 is the total number of patients in the corresponding analysis set and subgroup regardless of missing value status, N is the total number of patients in the analysis set.
LS mean and LS mean difference is from an ANCOVA model with treatment, baseline score, Japanese/Non-Japanese and Standard Of Care(NSIDs/Non-NSIDs) as covariates. Interaction p-value is from the above ANCOVA model with additional factor/interaction of subgroup and subgroup by treatment.

Table 2.3.5.4: MGC: AUC between Baseline and Week 20 of Change From Baseline in Total MGC Score by Subgroup - ITT+

ANALYSIS SET: ITT+

	Interaction P-value	EFGARTIGIMOD (N=65)	PLACEBO (N=64)
REGION	0.547		
NON-EU			
n/N1 (%)		40/40 (100.0)	37/37 (100.0)
Mean (S.D.)		-136.5 (108.21)	-69.4 (91.67)
S.E.		17.11	15.07
95% C.I.		(-171.08; -101.86)	(-99.95; -38.82)
Median		-126.8	-61.5
Q1; Q3		(-214.3; -44.5)	(-103.0; -13.0)
Min; Max		(-334; 128)	(-319; 140)
Hedge's G		-0.66	
95% C.I.		(-1.115; -0.205)	
LS Mean (S.E.)		-114.0 (19.34)	-47.6 (20.08)
95% C.I.		(-152.58; -75.47)	(-87.60; -7.52)
LS Mean Differences (S.E.)		-66.5 (20.42)	
95% C.I.		(-107.18; -25.75)	
P-value		0.002	

S.D. = Standard Deviation; S.E. = Standard Error; AUC=Area Under the Curve; LS=Least Square
n is the number of patients with non-missing values, N1 is the total number of patients in the corresponding analysis set and subgroup regardless of missing value status, N is the total number of patients in the analysis set.
LS mean and LS mean difference is from an ANCOVA model with treatment, baseline score, Japanese/Non-Japanese and Standard Of Care(NSIDs/Non-NSIDs) as covariates. Interaction p-value is from the above ANCOVA model with additional factor/interaction of subgroup and subgroup by treatment.

Table 2.3.5.4: MGC: AUC between Baseline and Week 20 of Change From Baseline in Total MGC Score by Subgroup - ITT+

ANALYSIS SET: ITT+

	Interaction P-value	EFGARTIGIMOD (N=65)	PLACEBO (N=64)
AGE CATEGORY	0.484		
18 - <65 years			
n/N1 (%)		57/57 (100.0)	51/51 (100.0)
Mean (S.D.)		-128.2 (110.18)	-66.9 (90.52)
S.E.		14.59	12.67
95% C.I.		(-157.46; -98.99)	(-92.37; -41.45)
Median		-123.5	-53.5
Q1; Q3		(-209.0; -51.0)	(-108.0; -13.0)
Min; Max		(-334; 143)	(-319; 239)
Hedge's G		-0.60	
95% C.I.		(-0.984; -0.217)	
LS Mean (S.E.)		-103.3 (20.31)	-48.4 (21.43)
95% C.I.		(-143.59; -63.02)	(-90.91; -5.88)
LS Mean Differences (S.E.)		-54.9 (17.99)	
95% C.I.		(-90.59; -19.23)	
P-value		0.003	

S.D. = Standard Deviation; S.E. = Standard Error; AUC=Area Under the Curve; LS=Least Square
n is the number of patients with non-missing values, N1 is the total number of patients in the corresponding analysis set and subgroup regardless of missing value status, N is the total number of patients in the analysis set.
LS mean and LS mean difference is from an ANCOVA model with treatment, baseline score, Japanese/Non-Japanese and Standard Of Care(NSIDs/Non-NSIDs) as covariates. Interaction p-value is from the above ANCOVA model with additional factor/interaction of subgroup and subgroup by treatment.

Table 2.3.5.4: MGC: AUC between Baseline and Week 20 of Change From Baseline in Total MGC Score by Subgroup - ITT+

ANALYSIS SET: ITT+

	Interaction P-value	EFGARTIGIMOD (N=65)	PLACEBO (N=64)
AGE CATEGORY	0.484		
>= 65 years			
n/N1 (%)		8/8 (100.0)	13/13 (100.0)
Mean (S.D.)		-118.1 (106.88)	-58.5 (87.13)
S.E.		37.79	24.17
95% C.I.		(-207.41; -28.70)	(-111.11; -5.81)
Median		-109.1	-88.5
Q1; Q3		(-203.0; -26.3)	(-103.0; -33.8)
Min; Max		(-280; 12)	(-180; 140)
Hedge's G		-0.60	
95% C.I.		(-1.468; 0.262)	
LS Mean (S.E.)		-125.2 (39.57)	-30.2 (35.09)
95% C.I.		(-209.11; -41.33)	(-104.55; 44.24)
LS Mean Differences (S.E.)		-95.1 (38.90)	
95% C.I.		(-177.53; -12.61)	
P-value		0.026	

S.D. = Standard Deviation; S.E. = Standard Error; AUC=Area Under the Curve; LS=Least Square
n is the number of patients with non-missing values, N1 is the total number of patients in the corresponding analysis set and subgroup regardless of missing value status, N is the total number of patients in the analysis set.
LS mean and LS mean difference is from an ANCOVA model with treatment, baseline score, Japanese/Non-Japanese and Standard Of Care(NSIDs/Non-NSIDs) as covariates. Interaction p-value is from the above ANCOVA model with additional factor/interaction of subgroup and subgroup by treatment.

Table 2.3.5.4: MGC: AUC between Baseline and Week 20 of Change From Baseline in Total MGC Score by Subgroup - ITT+

ANALYSIS SET: ITT+

	Interaction P-value	EFGARTIGIMOD (N=65)	PLACEBO (N=64)
SEX	0.646		
Female			
n/N1 (%)		46/46 (100.0)	40/40 (100.0)
Mean (S.D.)		-135.3 (111.40)	-65.8 (92.06)
S.E.		16.42	14.56
95% C.I.		(-168.43; -102.27)	(-95.27; -36.38)
Median		-124.0	-51.3
Q1; Q3		(-219.5; -53.0)	(-99.0; -16.5)
Min; Max		(-334; 143)	(-319; 239)
Hedge's G		-0.67	
95% C.I.		(-1.101; -0.238)	
LS Mean (S.E.)		-112.1 (22.49)	-47.8 (24.84)
95% C.I.		(-156.81; -67.33)	(-97.24; 1.59)
LS Mean Differences (S.E.)		-64.2 (20.87)	
95% C.I.		(-105.76; -22.73)	
P-value		0.003	

S.D. = Standard Deviation; S.E. = Standard Error; AUC=Area Under the Curve; LS=Least Square
n is the number of patients with non-missing values, N1 is the total number of patients in the corresponding analysis set and subgroup regardless of missing value status, N is the total number of patients in the analysis set.
LS mean and LS mean difference is from an ANCOVA model with treatment, baseline score, Japanese/Non-Japanese and Standard Of Care(NSIDs/Non-NSIDs) as covariates. Interaction p-value is from the above ANCOVA model with additional factor/interaction of subgroup and subgroup by treatment.

Table 2.3.5.4: MGC: AUC between Baseline and Week 20 of Change From Baseline in Total MGC Score by Subgroup - ITT+

ANALYSIS SET: ITT+

	Interaction P-value	EFGARTIGIMOD (N=65)	PLACEBO (N=64)
SEX	0.646		
Male			
n/N1 (%)		19/19 (100.0)	24/24 (100.0)
Mean (S.D.)		-106.7 (103.03)	-64.1 (86.21)
S.E.		23.64	17.60
95% C.I.		(-156.37; -57.05)	(-100.54; -27.74)
Median		-106.0	-79.4
Q1; Q3		(-159.5; -26.5)	(-111.5; -19.6)
Min; Max		(-302; 86)	(-228; 140)
Hedge's G		-0.44	
95% C.I.		(-1.043; 0.154)	
LS Mean (S.E.)		-88.8 (30.47)	-40.6 (28.01)
95% C.I.		(-150.53; -27.14)	(-97.33; 16.05)
LS Mean Differences (S.E.)		-48.2 (25.79)	
95% C.I.		(-100.40; 4.01)	
P-value		0.069	

S.D. = Standard Deviation; S.E. = Standard Error; AUC=Area Under the Curve; LS=Least Square
n is the number of patients with non-missing values, N1 is the total number of patients in the corresponding analysis set and subgroup regardless of missing value status, N is the total number of patients in the analysis set.
LS mean and LS mean difference is from an ANCOVA model with treatment, baseline score, Japanese/Non-Japanese and Standard Of Care(NSIDs/Non-NSIDs) as covariates. Interaction p-value is from the above ANCOVA model with additional factor/interaction of subgroup and subgroup by treatment.

Table 2.3.5.4: MGC: AUC between Baseline and Week 20 of Change From Baseline in Total MGC Score by Subgroup - ITT+

ANALYSIS SET: ITT+

	Interaction P-value	EFGARTIGIMOD (N=65)	PLACEBO (N=64)
RACE	0.665		
WHITE			
n/N1 (%)		54/54 (100.0)	56/56 (100.0)
Mean (S.D.)		-133.5 (106.26)	-66.8 (90.01)
S.E.		14.46	12.03
95% C.I.		(-162.46; -104.45)	(-90.95; -42.74)
Median		-120.1	-59.5
Q1; Q3		(-213.5; -53.0)	(-109.5; -21.8)
Min; Max		(-334; 143)	(-319; 239)
Hedge's G		-0.67	
95% C.I.		(-1.054; -0.291)	
LS Mean (S.E.)		-131.5 (12.67)	-70.1 (12.41)
95% C.I.		(-156.63; -106.38)	(-94.66; -45.47)
LS Mean Differences (S.E.)		-61.4 (17.69)	
95% C.I.		(-96.52; -26.36)	
P-value		<.001	

S.D. = Standard Deviation; S.E. = Standard Error; AUC=Area Under the Curve; LS=Least Square
n is the number of patients with non-missing values, N1 is the total number of patients in the corresponding analysis set and subgroup regardless of missing value status, N is the total number of patients in the analysis set.
LS mean and LS mean difference is from an ANCOVA model with treatment, baseline score, Japanese/Non-Japanese and Standard Of Care(NSIDs/Non-NSIDs) as covariates. Interaction p-value is from the above ANCOVA model with additional factor/interaction of subgroup and subgroup by treatment.

Table 2.3.5.4: MGC: AUC between Baseline and Week 20 of Change From Baseline in Total MGC Score by Subgroup - ITT+

ANALYSIS SET: ITT+

	Interaction P-value	EFGARTIGIMOD (N=65)	PLACEBO (N=64)
RACE	0.665		
NON-WHITE			
n/N1 (%)		11/11 (100.0)	8/8 (100.0)
Mean (S.D.)		-95.2 (121.95)	-53.6 (88.41)
S.E.		36.77	31.26
95% C.I.		(-177.11; -13.26)	(-127.56; 20.27)
Median		-104.5	-51.6
Q1; Q3		(-154.0; -12.0)	(-79.4; -10.6)
Min; Max		(-302; 128)	(-228; 82)
Hedge's G		-0.36	
95% C.I.		(-1.240; 0.515)	
LS Mean (S.E.)		-101.2 (24.34)	-61.4 (29.26)
95% C.I.		(-153.44; -49.05)	(-124.14; 1.35)
LS Mean Differences (S.E.)		-39.8 (36.57)	
95% C.I.		(-118.28; 38.59)	
P-value		0.294	

S.D. = Standard Deviation; S.E. = Standard Error; AUC=Area Under the Curve; LS=Least Square
n is the number of patients with non-missing values, N1 is the total number of patients in the corresponding analysis set and subgroup regardless of missing value status, N is the total number of patients in the analysis set.
LS mean and LS mean difference is from an ANCOVA model with treatment, baseline score, Japanese/Non-Japanese and Standard Of Care(NSIDs/Non-NSIDs) as covariates. Interaction p-value is from the above ANCOVA model with additional factor/interaction of subgroup and subgroup by treatment.

Table 2.3.5.4: MGC: AUC between Baseline and Week 20 of Change From Baseline in Total MGC Score by Subgroup - ITT+

ANALYSIS SET: ITT+

	Interaction P-value	EFGARTIGIMOD (N=65)	PLACEBO (N=64)
BASELINE MG-ADL TOTAL SCORE	0.446		
MILD (5-7)			
n/N1 (%)		16/16 (100.0)	18/18 (100.0)
Mean (S.D.)		-67.4 (127.10)	-48.5 (71.85)
S.E.		31.77	16.93
95% C.I.		(-135.13; 0.32)	(-84.25; -12.79)
Median		-52.0	-48.3
Q1; Q3		(-157.5; -15.0)	(-103.0; -30.6)
Min; Max		(-274; 143)	(-159; 140)
Hedge's G		-0.18	
95% C.I.		(-0.841; 0.477)	
LS Mean (S.E.)		-48.4 (31.13)	-18.8 (29.45)
95% C.I.		(-112.06; 15.27)	(-79.05; 41.39)
LS Mean Differences (S.E.)		-29.6 (32.84)	
95% C.I.		(-96.74; 37.61)	
P-value		0.375	

S.D. = Standard Deviation; S.E. = Standard Error; AUC=Area Under the Curve; LS=Least Square
n is the number of patients with non-missing values, N1 is the total number of patients in the corresponding analysis set and subgroup regardless of missing value status, N is the total number of patients in the analysis set.
LS mean and LS mean difference is from an ANCOVA model with treatment, baseline score, Japanese/Non-Japanese and Standard Of Care(NSIDs/Non-NSIDs) as covariates. Interaction p-value is from the above ANCOVA model with additional factor/interaction of subgroup and subgroup by treatment.

Table 2.3.5.4: MGC: AUC between Baseline and Week 20 of Change From Baseline in Total MGC Score by Subgroup - ITT+

ANALYSIS SET: ITT+

	Interaction P-value	EFGARTIGIMOD (N=65)	PLACEBO (N=64)
BASELINE MG-ADL TOTAL SCORE	0.446		
MODERATE (8-9)			
n/N1 (%)		25/25 (100.0)	29/29 (100.0)
Mean (S.D.)		-157.7 (89.82)	-70.9 (101.76)
S.E.		17.96	18.90
95% C.I.		(-194.78; -120.63)	(-109.56; -32.15)
Median		-158.0	-64.5
Q1; Q3		(-213.5; -102.0)	(-112.0; -33.8)
Min; Max		(-334; 12)	(-319; 239)
Hedge's G		-0.89	
95% C.I.		(-1.441; -0.334)	
LS Mean (S.E.)		-126.1 (35.98)	-49.7 (35.27)
95% C.I.		(-198.42; -53.81)	(-120.60; 21.15)
LS Mean Differences (S.E.)		-76.4 (24.72)	
95% C.I.		(-126.06; -26.72)	
P-value		0.003	

S.D. = Standard Deviation; S.E. = Standard Error; AUC=Area Under the Curve; LS=Least Square
n is the number of patients with non-missing values, N1 is the total number of patients in the corresponding analysis set and subgroup regardless of missing value status, N is the total number of patients in the analysis set.
LS mean and LS mean difference is from an ANCOVA model with treatment, baseline score, Japanese/Non-Japanese and Standard Of Care(NSIDs/Non-NSIDs) as covariates. Interaction p-value is from the above ANCOVA model with additional factor/interaction of subgroup and subgroup by treatment.

Table 2.3.5.4: MGC: AUC between Baseline and Week 20 of Change From Baseline in Total MGC Score by Subgroup - ITT+

ANALYSIS SET: ITT+

	Interaction P-value	EFGARTIGIMOD (N=65)	PLACEBO (N=64)
BASELINE MG-ADL TOTAL SCORE	0.446		
SEVERE (>=10)			
n/N1 (%)		24/24 (100.0)	17/17 (100.0)
Mean (S.D.)		-134.7 (102.74)	-73.2 (85.44)
S.E.		20.97	20.72
95% C.I.		(-178.07; -91.30)	(-117.12; -29.26)
Median		-118.0	-61.5
Q1; Q3		(-199.3; -42.9)	(-103.0; -2.0)
Min; Max		(-315; 31)	(-256; 29)
Hedge's G		-0.63	
95% C.I.		(-1.252; -0.004)	
LS Mean (S.E.)		-127.4 (31.67)	-70.2 (36.20)
95% C.I.		(-191.65; -63.18)	(-143.58; 3.24)
LS Mean Differences (S.E.)		-57.2 (30.36)	
95% C.I.		(-118.83; 4.33)	
P-value		0.067	

S.D. = Standard Deviation; S.E. = Standard Error; AUC=Area Under the Curve; LS=Least Square
n is the number of patients with non-missing values, N1 is the total number of patients in the corresponding analysis set and subgroup regardless of missing value status, N is the total number of patients in the analysis set.
LS mean and LS mean difference is from an ANCOVA model with treatment, baseline score, Japanese/Non-Japanese and Standard Of Care(NSIDs/Non-NSIDs) as covariates. Interaction p-value is from the above ANCOVA model with additional factor/interaction of subgroup and subgroup by treatment.

Table 2.3.5.4: MGC: AUC between Baseline and Week 20 of Change From Baseline in Total MGC Score by Subgroup - ITT+

ANALYSIS SET: ITT+

	Interaction P-value	EFGARTIGIMOD (N=65)	PLACEBO (N=64)
CONCIMATANT TREATMENT	0.706		
NSID			
n/N1 (%)		38/38 (100.0)	37/37 (100.0)
Mean (S.D.)		-112.5 (118.08)	-62.0 (76.26)
S.E.		19.16	12.54
95% C.I.		(-151.32; -73.70)	(-87.40; -36.55)
Median		-104.5	-53.5
Q1; Q3		(-199.0; -35.5)	(-97.5; -30.6)
Min; Max		(-334; 143)	(-319; 82)
Hedge's G		-0.50	
95% C.I.		(-0.957; -0.047)	
LS Mean (S.E.)		-85.2 (20.30)	-30.7 (20.97)
95% C.I.		(-125.71; -44.75)	(-72.48; 11.13)
LS Mean Differences (S.E.)		-54.6 (20.53)	
95% C.I.		(-95.50; -13.62)	
P-value		0.010	

S.D. = Standard Deviation; S.E. = Standard Error; AUC=Area Under the Curve; LS=Least Square
n is the number of patients with non-missing values, N1 is the total number of patients in the corresponding analysis set and subgroup regardless of missing value status, N is the total number of patients in the analysis set.
LS mean and LS mean difference is from an ANCOVA model with treatment, baseline score, Japanese/Non-Japanese and Standard Of Care(NSIDs/Non-NSIDs) as covariates. Interaction p-value is from the above ANCOVA model with additional factor/interaction of subgroup and subgroup by treatment.

Table 2.3.5.4: MGC: AUC between Baseline and Week 20 of Change From Baseline in Total MGC Score by Subgroup - ITT+

ANALYSIS SET: ITT+

	Interaction P-value	EFGARTIGIMOD (N=65)	PLACEBO (N=64)
CONCIMATANT TREATMENT	0.706		
NON-NSID			
n/N1 (%)		27/27 (100.0)	27/27 (100.0)
Mean (S.D.)		-147.3 (93.13)	-69.6 (105.84)
S.E.		17.92	20.37
95% C.I.		(-184.17; -110.49)	(-111.47; -27.74)
Median		-124.5	-67.5
Q1; Q3		(-231.5; -54.0)	(-142.0; -10.0)
Min; Max		(-311; -19)	(-256; 239)
Hedge's G		-0.77	
95% C.I.		(-1.314; -0.223)	
LS Mean (S.E.)		-152.5 (36.95)	-87.9 (38.25)
95% C.I.		(-226.70; -78.28)	(-164.70; -11.05)
LS Mean Differences (S.E.)		-64.6 (25.64)	
95% C.I.		(-116.10; -13.12)	
P-value		0.015	

S.D. = Standard Deviation; S.E. = Standard Error; AUC=Area Under the Curve; LS=Least Square
n is the number of patients with non-missing values, N1 is the total number of patients in the corresponding analysis set and subgroup regardless of missing value status, N is the total number of patients in the analysis set.
LS mean and LS mean difference is from an ANCOVA model with treatment, baseline score, Japanese/Non-Japanese and Standard Of Care(NSIDs/Non-NSIDs) as covariates. Interaction p-value is from the above ANCOVA model with additional factor/interaction of subgroup and subgroup by treatment.

Table 2.3.5.4: MGC: AUC between Baseline and Week 20 of Change From Baseline in Total MGC Score by Subgroup - ITT+

ANALYSIS SET: ITT+

	Interaction P-value	EFGARTIGIMOD (N=65)	PLACEBO (N=64)
THYMECTOMY PERFORMED FOR MG	0.317		
YES			
n/N1 (%)		45/45 (100.0)	30/30 (100.0)
Mean (S.D.)		-110.6 (111.42)	-57.4 (62.04)
S.E.		16.61	11.33
95% C.I.		(-144.03; -77.08)	(-80.58; -34.24)
Median		-102.0	-48.5
Q1; Q3		(-199.0; -38.0)	(-103.0; -13.0)
Min; Max		(-334; 143)	(-241; 41)
Hedge's G		-0.55	
95% C.I.		(-1.020; -0.088)	
LS Mean (S.E.)		-84.6 (21.05)	-37.4 (25.44)
95% C.I.		(-126.58; -42.62)	(-88.15; 13.31)
LS Mean Differences (S.E.)		-47.2 (20.04)	
95% C.I.		(-87.15; -7.21)	
P-value		0.021	

S.D. = Standard Deviation; S.E. = Standard Error; AUC=Area Under the Curve; LS=Least Square
n is the number of patients with non-missing values, N1 is the total number of patients in the corresponding analysis set and subgroup regardless of missing value status, N is the total number of patients in the analysis set.
LS mean and LS mean difference is from an ANCOVA model with treatment, baseline score, Japanese/Non-Japanese and Standard Of Care(NSIDs/Non-NSIDs) as covariates. Interaction p-value is from the above ANCOVA model with additional factor/interaction of subgroup and subgroup by treatment.

Table 2.3.5.4: MGC: AUC between Baseline and Week 20 of Change From Baseline in Total MGC Score by Subgroup - ITT+

ANALYSIS SET: ITT+

	Interaction P-value	EFGARTIGIMOD (N=65)	PLACEBO (N=64)
THYMECTOMY PERFORMED FOR MG	0.317		
NO			
n/N1 (%)		20/20 (100.0)	34/34 (100.0)
Mean (S.D.)		-163.9 (95.92)	-72.1 (108.22)
S.E.		21.45	18.56
95% C.I.		(-208.83; -119.04)	(-109.82; -34.30)
Median		-155.8	-71.8
Q1; Q3		(-246.8; -104.8)	(-138.5; -36.5)
Min; Max		(-315; -26)	(-319; 239)
Hedge's G		-0.87	
95% C.I.		(-1.440; -0.303)	
LS Mean (S.E.)		-148.0 (31.61)	-65.4 (27.27)
95% C.I.		(-211.47; -84.44)	(-120.24; -10.63)
LS Mean Differences (S.E.)		-82.5 (27.33)	
95% C.I.		(-137.44; -27.60)	
P-value		0.004	

S.D. = Standard Deviation; S.E. = Standard Error; AUC=Area Under the Curve; LS=Least Square
n is the number of patients with non-missing values, N1 is the total number of patients in the corresponding analysis set and subgroup regardless of missing value status, N is the total number of patients in the analysis set.
LS mean and LS mean difference is from an ANCOVA model with treatment, baseline score, Japanese/Non-Japanese and Standard Of Care(NSIDs/Non-NSIDs) as covariates. Interaction p-value is from the above ANCOVA model with additional factor/interaction of subgroup and subgroup by treatment.

Table 2.4.1.9: EQ-VAS: Responders of 15-Point Increase During First Cycle by Subgroup - ITT+

ANALYSIS SET: ITT+

	COCHRANE'S Q P-VALE	EFGARTIGIMOD (N=65) n (%)	PLACEBO (N=64) n (%)	ODDS RATIO (95% C.I.)	RELATIVE RISK (95% C.I.)	ARR (%) (95% C.I.)	P-VALUE*
REGION	0.977						
EU							
n/N1		25/25 (100.0)	27/27 (100.0)				
RESPONSE		16 (64.0)	8 (29.6)	4.222 (1.322; 13.490)	2.160 (1.126; 4.143)	34.4 (7.3; 55.3)	0.025
NO RESPONSE		9 (36.0)	19 (70.4)				
NON-EU							
n/N1		40/40 (100.0)	36/37 (97.3)				
RESPONSE		28 (70.0)	13 (36.1)	4.128 (1.582; 10.772)	1.938 (1.200; 3.131)	33.9 (11.4; 52.0)	0.005
NO RESPONSE		12 (30.0)	23 (63.9)				

ARR=Absolute Risk Reduction
n is the number of patients with non-missing values, N1 is the total number of patients in the corresponding analysis set, subgroup and cycle regardless of missing value status, N is the total number of patients in the analysis set.
0.5 is added if any cell count is zero for odds ratio and relative risk calculation
* P-value is from Fisher's exact test.
Program: /clinical/argx-113/mg/argx-113-1704/biostat/staging/gba/programs/t_responder_sub.sas, Version: 1.2

Table 2.4.1.9: EQ-VAS: Responders of 15-Point Increase During First Cycle by Subgroup - ITT+

ANALYSIS SET: ITT+

	COCHRANE'S Q P-VALE	EFGARTIGIMOD (N=65) n (%)	PLACEBO (N=64) n (%)	ODDS RATIO (95% C.I.)	RELATIVE RISK (95% C.I.)	ARR (%) (95% C.I.)	P-VALUE*
AGE CATEGORY	0.168						
18 - <65 years							
n/N1		57/57 (100.0)	51/51 (100.0)				
RESPONSE		37 (64.9)	18 (35.3)	3.392 (1.538; 7.481)	1.839 (1.211; 2.793)	29.6 (10.7; 45.7)	0.004
NO RESPONSE		20 (35.1)	33 (64.7)				
>= 65 years							
n/N1		8/8 (100.0)	12/13 (92.3)				
RESPONSE		7 (87.5)	3 (25.0)	21.000 (1.777; 248.103)	3.500 (1.269; 9.652)	62.5 (17.9; 81.6)	0.020
NO RESPONSE		1 (12.5)	9 (75.0)				

ARR=Absolute Risk Reduction
n is the number of patients with non-missing values, N1 is the total number of patients in the corresponding analysis set, subgroup and cycle regardless of missing value status, N is the total number of patients in the analysis set.
0.5 is added if any cell count is zero for odds ratio and relative risk calculation
* P-value is from Fisher's exact test.
Program: /clinical/argx-113/mg/argx-113-1704/biostat/staging/gba/programs/t_responder_sub.sas, Version: 1.2

Table 2.4.1.9: EQ-VAS: Responders of 15-Point Increase During First Cycle by Subgroup - ITT+

ANALYSIS SET: ITT+

	COCHRANE'S Q P-VALE	EFGARTIGIMOD (N=65) n (%)	PLACEBO (N=64) n (%)	ODDS RATIO (95% C.I.)	RELATIVE RISK (95% C.I.)	ARR (%) (95% C.I.)	P-VALUE*
SEX	0.058						
Female							
n/N1		46/46 (100.0)	40/40 (100.0)				
RESPONSE		29 (63.0)	16 (40.0)	2.559 (1.071; 6.114)	1.576 (1.016; 2.446)	23.0 (1.9; 41.5)	0.051
NO RESPONSE		17 (37.0)	24 (60.0)				
Male							
n/N1		19/19 (100.0)	23/24 (95.8)				
RESPONSE		15 (78.9)	5 (21.7)	13.500 (3.065; 59.460)	3.632 (1.616; 8.159)	57.2 (27.2; 74.6)	<.001
NO RESPONSE		4 (21.1)	18 (78.3)				

ARR=Absolute Risk Reduction
n is the number of patients with non-missing values, N1 is the total number of patients in the corresponding analysis set, subgroup and cycle regardless of missing value status, N is the total number of patients in the analysis set.
0.5 is added if any cell count is zero for odds ratio and relative risk calculation
* P-value is from Fisher's exact test.
Program: /clinical/argx-113/mg/argx-113-1704/biostat/staging/gba/programs/t_responder_sub.sas, Version: 1.2

Table 2.4.1.9: EQ-VAS: Responders of 15-Point Increase During First Cycle by Subgroup - ITT+

ANALYSIS SET: ITT+

	COCHRANE'S Q P-VALE	EFGARTIGIMOD (N=65) n (%)	PLACEBO (N=64) n (%)	ODDS RATIO (95% C.I.)	RELATIVE RISK (95% C.I.)	ARR (%) (95% C.I.)	P-VALUE*
RACE	0.194						
WHITE							
n/N1		54/54 (100.0)	55/56 (98.2)				
RESPONSE		39 (72.2)	18 (32.7)	5.344 (2.355; 12.130)	2.207 (1.460; 3.337)	39.5 (20.9; 54.4)	<.001
NO RESPONSE		15 (27.8)	37 (67.3)				
NON-WHITE							
n/N1		11/11 (100.0)	8/8 (100.0)				
RESPONSE		5 (45.5)	3 (37.5)	1.389 (0.216; 8.916)	1.212 (0.402; 3.657)	8.0 (-32.1; 43.6)	1.000
NO RESPONSE		6 (54.5)	5 (62.5)				

ARR=Absolute Risk Reduction
n is the number of patients with non-missing values, N1 is the total number of patients in the corresponding analysis set, subgroup and cycle regardless of missing value status, N is the total number of patients in the analysis set.
0.5 is added if any cell count is zero for odds ratio and relative risk calculation
* P-value is from Fisher's exact test.
Program: /clinical/argx-113/mg/argx-113-1704/biostat/staging/gba/programs/t_responder_sub.sas, Version: 1.2

Table 2.4.1.9: EQ-VAS: Responders of 15-Point Increase During First Cycle by Subgroup - ITT+

ANALYSIS SET: ITT+

	COCHRANE'S Q P-VALE	EFGARTIGIMOD (N=65) n (%)	PLACEBO (N=64) n (%)	ODDS RATIO (95% C.I.)	RELATIVE RISK (95% C.I.)	ARR (%) (95% C.I.)	P-VALUE*
BASELINE MG-ADL TOTAL SCORE	0.651						
MILD (5-7)							
n/N1		16/16 (100.0)	18/18 (100.0)				
RESPONSE		11 (68.8)	4 (22.2)	7.700 (1.661; 35.692)	3.094 (1.226; 7.804)	46.5 (13.0; 68.1)	0.014
NO RESPONSE		5 (31.3)	14 (77.8)				
MODERATE (8-9)							
n/N1		25/25 (100.0)	29/29 (100.0)				
RESPONSE		18 (72.0)	13 (44.8)	3.165 (1.013; 9.888)	1.606 (1.002; 2.575)	27.2 (0.8; 48.6)	0.057
NO RESPONSE		7 (28.0)	16 (55.2)				
SEVERE (>=10)							
n/N1		24/24 (100.0)	16/17 (94.1)				
RESPONSE		15 (62.5)	4 (25.0)	5.000 (1.231; 20.301)	2.500 (1.013; 6.171)	37.5 (6.0; 59.6)	0.027
NO RESPONSE		9 (37.5)	12 (75.0)				

ARR=Absolute Risk Reduction
n is the number of patients with non-missing values, N1 is the total number of patients in the corresponding analysis set, subgroup and cycle regardless of missing value status, N is the total number of patients in the analysis set.
0.5 is added if any cell count is zero for odds ratio and relative risk calculation
* P-value is from Fisher's exact test.
Program: /clinical/argx-113/mg/argx-113-1704/biostat/staging/gba/programs/t_responder_sub.sas, Version: 1.2

Table 2.4.1.9: EQ-VAS: Responders of 15-Point Increase During First Cycle by Subgroup - ITT+

ANALYSIS SET: ITT+

	COCHRANE'S Q P-VALE	EFGARTIGIMOD (N=65) n (%)	PLACEBO (N=64) n (%)	ODDS RATIO (95% C.I.)	RELATIVE RISK (95% C.I.)	ARR (%) (95% C.I.)	P-VALUE*
CONCIMATANT TREATMENT	0.594						
NSID							
n/N1		38/38 (100.0)	37/37 (100.0)				
RESPONSE		24 (63.2)	12 (32.4)	3.571 (1.377; 9.263)	1.947 (1.152; 3.291)	30.7 (8.1; 49.3)	0.011
NO RESPONSE		14 (36.8)	25 (67.6)				
NON-NSID							
n/N1		27/27 (100.0)	26/27 (96.3)				
RESPONSE		20 (74.1)	9 (34.6)	5.397 (1.657; 17.573)	2.140 (1.206; 3.797)	39.5 (12.6; 59.3)	0.006
NO RESPONSE		7 (25.9)	17 (65.4)				

ARR=Absolute Risk Reduction
n is the number of patients with non-missing values, N1 is the total number of patients in the corresponding analysis set, subgroup and cycle regardless of missing value status, N is the total number of patients in the analysis set.
0.5 is added if any cell count is zero for odds ratio and relative risk calculation
* P-value is from Fisher's exact test.
Program: /clinical/argx-113/mg/argx-113-1704/biostat/staging/gba/programs/t_responder_sub.sas, Version: 1.2

Table 2.4.1.9: EQ-VAS: Responders of 15-Point Increase During First Cycle by Subgroup - ITT+

ANALYSIS SET: ITT+

	COCHRANE'S Q P-VALE	EFGARTIGIMOD (N=65) n (%)	PLACEBO (N=64) n (%)	ODDS RATIO (95% C.I.)	RELATIVE RISK (95% C.I.)	ARR (%) (95% C.I.)	P-VALUE*
THYMECTOMY PERFORMED FOR MG	0.182						
YES							
n/N1		45/45 (100.0)	30/30 (100.0)				
RESPONSE		29 (64.4)	12 (40.0)	2.719 (1.049; 7.043)	1.611 (0.988; 2.627)	24.4 (1.5; 44.2)	0.058
NO RESPONSE		16 (35.6)	18 (60.0)				
NO							
n/N1		20/20 (100.0)	33/34 (97.1)				
RESPONSE		15 (75.0)	9 (27.3)	8.000 (2.248; 28.469)	2.750 (1.491; 5.071)	47.7 (20.1; 66.2)	0.001
NO RESPONSE		5 (25.0)	24 (72.7)				

ARR=Absolute Risk Reduction
n is the number of patients with non-missing values, N1 is the total number of patients in the corresponding analysis set, subgroup and cycle regardless of missing value status, N is the total number of patients in the analysis set.
0.5 is added if any cell count is zero for odds ratio and relative risk calculation
* P-value is from Fisher's exact test.
Program: /clinical/argx-113/mg/argx-113-1704/biostat/staging/gba/programs/t_responder_sub.sas, Version: 1.2

Table 2.4.5.4: EQ-VAS: AUC between Baseline and Week 20 of Change From Baseline in EQ-VAS Score by Subgroup - ITT+

ANALYSIS SET: ITT+

	Interaction P-value	EFGARTIGIMOD (N=65)	PLACEBO (N=64)
REGION	0.418		
EU			
n/N1 (%)		25/25 (100.0)	27/27 (100.0)
Mean (S.D.)		171.6 (259.55)	76.2 (172.16)
S.E.		51.91	33.13
95% C.I.		(64.47; 278.75)	(8.10; 144.31)
Median		154.0	67.5
Q1; Q3		(-5.0; 365.0)	(-30.0; 167.5)
Min; Max		(-328; 653)	(-280; 500)
Hedge's G		0.43	
95% C.I.		(-0.112; 0.972)	
LS Mean (S.E.)		161.8 (36.42)	90.4 (35.28)
95% C.I.		(88.60; 235.05)	(19.49; 161.36)
LS Mean Differences (S.E.)		71.4 (50.67)	
95% C.I.		(-30.47; 173.28)	
P-value		0.165	

S.D. = Standard Deviation; S.E. = Standard Error; AUC=Area Under the Curve; LS=Least Square
n is the number of patients with non-missing values, N1 is the total number of patients in the corresponding analysis set and subgroup regardless of missing value status, N is the total number of patients in the analysis set.
LS mean and LS mean difference is from an ANCOVA model with treatment, baseline score, Japanese/Non-Japanese and Standard Of Care(NSIDs/Non-NSIDs) as covariates. Interaction p-value is from the above ANCOVA model with additional factor/interaction of subgroup and subgroup by treatment.

Table 2.4.5.4: EQ-VAS: AUC between Baseline and Week 20 of Change From Baseline in EQ-VAS Score by Subgroup - ITT+

ANALYSIS SET: ITT+

	Interaction P-value	EFGARTIGIMOD (N=65)	PLACEBO (N=64)
REGION	0.418		
NON-EU			
n/N1 (%)		40/40 (100.0)	37/37 (100.0)
Mean (S.D.)		190.6 (288.21)	95.9 (225.17)
S.E.		45.57	37.02
95% C.I.		(98.42; 282.77)	(20.86; 171.01)
Median		145.0	86.1
Q1; Q3		(3.0; 289.5)	(6.5; 200.0)
Min; Max		(-445; 1002)	(-493; 813)
Hedge's G		0.36	
95% C.I.		(-0.086; 0.807)	
LS Mean (S.E.)		181.3 (49.27)	46.3 (50.92)
95% C.I.		(83.09; 279.53)	(-55.19; 147.84)
LS Mean Differences (S.E.)		135.0 (53.67)	
95% C.I.		(28.00; 241.98)	
P-value		0.014	

S.D. = Standard Deviation; S.E. = Standard Error; AUC=Area Under the Curve; LS=Least Square
n is the number of patients with non-missing values, N1 is the total number of patients in the corresponding analysis set and subgroup regardless of missing value status, N is the total number of patients in the analysis set.
LS mean and LS mean difference is from an ANCOVA model with treatment, baseline score, Japanese/Non-Japanese and Standard Of Care(NSIDs/Non-NSIDs) as covariates. Interaction p-value is from the above ANCOVA model with additional factor/interaction of subgroup and subgroup by treatment.

Table 2.4.5.4: EQ-VAS: AUC between Baseline and Week 20 of Change From Baseline in EQ-VAS Score by Subgroup - ITT+

ANALYSIS SET: ITT+

	Interaction P-value	EFGARTIGIMOD (N=65)	PLACEBO (N=64)
AGE CATEGORY	0.063		
18 - <65 years			
n/N1 (%)		57/57 (100.0)	51/51 (100.0)
Mean (S.D.)		154.9 (268.63)	99.1 (193.02)
S.E.		35.58	27.03
95% C.I.		(83.61; 226.16)	(44.77; 153.34)
Median		128.0	99.0
Q1; Q3		(-9.0; 280.0)	(0.0; 200.0)
Min; Max		(-445; 1002)	(-405; 813)
Hedge's G		0.23	
95% C.I.		(-0.142; 0.611)	
LS Mean (S.E.)		118.3 (44.51)	35.4 (46.39)
95% C.I.		(30.06; 206.61)	(-56.59; 127.43)
LS Mean Differences (S.E.)		82.9 (39.95)	
95% C.I.		(3.68; 162.14)	
P-value		0.040	

S.D. = Standard Deviation; S.E. = Standard Error; AUC=Area Under the Curve; LS=Least Square
n is the number of patients with non-missing values, N1 is the total number of patients in the corresponding analysis set and subgroup regardless of missing value status, N is the total number of patients in the analysis set.
LS mean and LS mean difference is from an ANCOVA model with treatment, baseline score, Japanese/Non-Japanese and Standard Of Care(NSIDs/Non-NSIDs) as covariates. Interaction p-value is from the above ANCOVA model with additional factor/interaction of subgroup and subgroup by treatment.

Table 2.4.5.4: EQ-VAS: AUC between Baseline and Week 20 of Change From Baseline in EQ-VAS Score by Subgroup - ITT+

ANALYSIS SET: ITT+

	Interaction P-value	EFGARTIGIMOD (N=65)	PLACEBO (N=64)
AGE CATEGORY	0.063		
>= 65 years			
n/N1 (%)		8/8 (100.0)	13/13 (100.0)
Mean (S.D.)		385.7 (252.72)	42.7 (242.58)
S.E.		89.35	67.28
95% C.I.		(174.43; 596.98)	(-103.88; 189.31)
Median		392.0	51.0
Q1; Q3		(168.8; 561.5)	(-28.3; 165.0)
Min; Max		(60; 781)	(-493; 443)
Hedge's G		1.34	
95% C.I.		(0.399; 2.274)	
LS Mean (S.E.)		354.0 (112.11)	91.4 (99.46)
95% C.I.		(116.29; 591.61)	(-119.48; 302.20)
LS Mean Differences (S.E.)		262.6 (109.94)	
95% C.I.		(29.52; 495.66)	
P-value		0.030	

S.D. = Standard Deviation; S.E. = Standard Error; AUC=Area Under the Curve; LS=Least Square
n is the number of patients with non-missing values, N1 is the total number of patients in the corresponding analysis set and subgroup regardless of missing value status, N is the total number of patients in the analysis set.
LS mean and LS mean difference is from an ANCOVA model with treatment, baseline score, Japanese/Non-Japanese and Standard Of Care(NSIDs/Non-NSIDs) as covariates. Interaction p-value is from the above ANCOVA model with additional factor/interaction of subgroup and subgroup by treatment.

Table 2.4.5.4: EQ-VAS: AUC between Baseline and Week 20 of Change From Baseline in EQ-VAS Score by Subgroup - ITT+

ANALYSIS SET: ITT+

	Interaction P-value	EFGARTIGIMOD (N=65)	PLACEBO (N=64)
SEX	0.175		
Female			
n/N1 (%)		46/46 (100.0)	40/40 (100.0)
Mean (S.D.)		156.2 (233.59)	130.3 (174.81)
S.E.		34.44	27.64
95% C.I.		(86.85; 225.59)	(74.42; 186.24)
Median		150.0	154.0
Q1; Q3		(-30.6; 290.0)	(26.3; 232.8)
Min; Max		(-445; 653)	(-405; 500)
Hedge's G		0.12	
95% C.I.		(-0.297; 0.543)	
LS Mean (S.E.)		125.3 (43.27)	62.9 (46.57)
95% C.I.		(39.21; 211.38)	(-29.72; 155.61)
LS Mean Differences (S.E.)		62.3 (41.08)	
95% C.I.		(-19.40; 144.09)	
P-value		0.133	

S.D. = Standard Deviation; S.E. = Standard Error; AUC=Area Under the Curve; LS=Least Square
n is the number of patients with non-missing values, N1 is the total number of patients in the corresponding analysis set and subgroup regardless of missing value status, N is the total number of patients in the analysis set.
LS mean and LS mean difference is from an ANCOVA model with treatment, baseline score, Japanese/Non-Japanese and Standard Of Care(NSIDs/Non-NSIDs) as covariates. Interaction p-value is from the above ANCOVA model with additional factor/interaction of subgroup and subgroup by treatment.

Table 2.4.5.4: EQ-VAS: AUC between Baseline and Week 20 of Change From Baseline in EQ-VAS Score by Subgroup - ITT+

ANALYSIS SET: ITT+

	Interaction P-value	EFGARTIGIMOD (N=65)	PLACEBO (N=64)
SEX	0.175		
Male			
n/N1 (%)		19/19 (100.0)	24/24 (100.0)
Mean (S.D.)		248.8 (356.77)	16.4 (229.88)
S.E.		81.85	46.92
95% C.I.		(76.88; 420.80)	(-80.66; 113.48)
Median		118.0	8.3
Q1; Q3		(60.0; 530.6)	(-53.3; 68.8)
Min; Max		(-328; 1002)	(-493; 813)
Hedge's G		0.78	
95% C.I.		(0.167; 1.393)	
LS Mean (S.E.)		193.0 (95.75)	38.6 (84.89)
95% C.I.		(-0.81; 386.88)	(-133.23; 210.46)
LS Mean Differences (S.E.)		154.4 (79.31)	
95% C.I.		(-6.13; 314.97)	
P-value		0.059	

S.D. = Standard Deviation; S.E. = Standard Error; AUC=Area Under the Curve; LS=Least Square
n is the number of patients with non-missing values, N1 is the total number of patients in the corresponding analysis set and subgroup regardless of missing value status, N is the total number of patients in the analysis set.
LS mean and LS mean difference is from an ANCOVA model with treatment, baseline score, Japanese/Non-Japanese and Standard Of Care(NSIDs/Non-NSIDs) as covariates. Interaction p-value is from the above ANCOVA model with additional factor/interaction of subgroup and subgroup by treatment.

Table 2.4.5.4: EQ-VAS: AUC between Baseline and Week 20 of Change From Baseline in EQ-VAS Score by Subgroup - ITT+

ANALYSIS SET: ITT+

	Interaction P-value	EFGARTIGIMOD (N=65)	PLACEBO (N=64)
RACE	0.839		
WHITE			
n/N1 (%)		54/54 (100.0)	56/56 (100.0)
Mean (S.D.)		188.6 (266.79)	85.1 (179.45)
S.E.		36.31	23.98
95% C.I.		(115.77; 261.41)	(37.09; 133.21)
Median		168.8	72.5
Q1; Q3		(22.5; 365.0)	(-2.5; 194.4)
Min; Max		(-445; 810)	(-493; 500)
Hedge's G		0.45	
95% C.I.		(0.077; 0.829)	
LS Mean (S.E.)		193.0 (26.99)	89.3 (26.44)
95% C.I.		(139.46; 246.49)	(36.89; 141.71)
LS Mean Differences (S.E.)		103.7 (37.63)	
95% C.I.		(29.08; 178.28)	
P-value		0.007	

S.D. = Standard Deviation; S.E. = Standard Error; AUC=Area Under the Curve; LS=Least Square
n is the number of patients with non-missing values, N1 is the total number of patients in the corresponding analysis set and subgroup regardless of missing value status, N is the total number of patients in the analysis set.
LS mean and LS mean difference is from an ANCOVA model with treatment, baseline score, Japanese/Non-Japanese and Standard Of Care(NSIDs/Non-NSIDs) as covariates. Interaction p-value is from the above ANCOVA model with additional factor/interaction of subgroup and subgroup by treatment.

Table 2.4.5.4: EQ-VAS: AUC between Baseline and Week 20 of Change From Baseline in EQ-VAS Score by Subgroup - ITT+

ANALYSIS SET: ITT+

	Interaction P-value	EFGARTIGIMOD (N=65)	PLACEBO (N=64)
RACE	0.839		
NON-WHITE			
n/N1 (%)		11/11 (100.0)	8/8 (100.0)
Mean (S.D.)		157.3 (328.72)	104.9 (343.93)
S.E.		99.11	121.60
95% C.I.		(-63.54; 378.13)	(-182.68; 392.39)
Median		5.0	109.4
Q1; Q3		(-32.0; 197.2)	(-165.2; 209.0)
Min; Max		(-88; 1002)	(-280; 813)
Hedge's G		0.15	
95% C.I.		(-0.722; 1.021)	
LS Mean (S.E.)		220.1 (95.81)	10.8 (109.52)
95% C.I.		(14.64; 425.60)	(-224.08; 245.71)
LS Mean Differences (S.E.)		209.3 (144.79)	
95% C.I.		(-101.23; 519.84)	
P-value		0.170	

S.D. = Standard Deviation; S.E. = Standard Error; AUC=Area Under the Curve; LS=Least Square
n is the number of patients with non-missing values, N1 is the total number of patients in the corresponding analysis set and subgroup regardless of missing value status, N is the total number of patients in the analysis set.
LS mean and LS mean difference is from an ANCOVA model with treatment, baseline score, Japanese/Non-Japanese and Standard Of Care(NSIDs/Non-NSIDs) as covariates. Interaction p-value is from the above ANCOVA model with additional factor/interaction of subgroup and subgroup by treatment.

Table 2.4.5.4: EQ-VAS: AUC between Baseline and Week 20 of Change From Baseline in EQ-VAS Score by Subgroup - ITT+

ANALYSIS SET: ITT+

	Interaction P-value	EFGARTIGIMOD (N=65)	PLACEBO (N=64)
BASELINE MG-ADL TOTAL SCORE	0.498		
MILD (5-7)			
n/N1 (%)		16/16 (100.0)	18/18 (100.0)
Mean (S.D.)		113.0 (245.36)	48.1 (168.35)
S.E.		61.34	39.68
95% C.I.		(-17.77; 243.71)	(-35.61; 131.83)
Median		105.3	84.5
Q1; Q3		(-69.8; 279.5)	(6.0; 120.0)
Min; Max		(-328; 593)	(-493; 294)
Hedge's G		0.30	
95% C.I.		(-0.357; 0.966)	
LS Mean (S.E.)		78.0 (62.21)	-2.0 (61.89)
95% C.I.		(-49.23; 205.25)	(-128.60; 124.56)
LS Mean Differences (S.E.)		80.0 (67.89)	
95% C.I.		(-58.82; 218.88)	
P-value		0.248	

S.D. = Standard Deviation; S.E. = Standard Error; AUC=Area Under the Curve; LS=Least Square
n is the number of patients with non-missing values, N1 is the total number of patients in the corresponding analysis set and subgroup regardless of missing value status, N is the total number of patients in the analysis set.
LS mean and LS mean difference is from an ANCOVA model with treatment, baseline score, Japanese/Non-Japanese and Standard Of Care(NSIDs/Non-NSIDs) as covariates. Interaction p-value is from the above ANCOVA model with additional factor/interaction of subgroup and subgroup by treatment.

Table 2.4.5.4: EQ-VAS: AUC between Baseline and Week 20 of Change From Baseline in EQ-VAS Score by Subgroup - ITT+

ANALYSIS SET: ITT+

	Interaction P-value	EFGARTIGIMOD (N=65)	PLACEBO (N=64)
BASELINE MG-ADL TOTAL SCORE	0.498		
MODERATE (8-9)			
n/N1 (%)		25/25 (100.0)	29/29 (100.0)
Mean (S.D.)		228.6 (266.91)	144.9 (217.89)
S.E.		53.38	40.46
95% C.I.		(118.41; 338.76)	(62.06; 227.82)
Median		154.0	145.0
Q1; Q3		(22.5; 379.0)	(2.5; 270.0)
Min; Max		(-169; 1002)	(-236; 813)
Hedge's G		0.34	
95% C.I.		(-0.190; 0.872)	
LS Mean (S.E.)		257.3 (84.70)	187.1 (81.13)
95% C.I.		(87.13; 427.54)	(24.07; 350.16)
LS Mean Differences (S.E.)		70.2 (57.79)	
95% C.I.		(-45.91; 186.35)	
P-value		0.230	

S.D. = Standard Deviation; S.E. = Standard Error; AUC=Area Under the Curve; LS=Least Square
n is the number of patients with non-missing values, N1 is the total number of patients in the corresponding analysis set and subgroup regardless of missing value status, N is the total number of patients in the analysis set.
LS mean and LS mean difference is from an ANCOVA model with treatment, baseline score, Japanese/Non-Japanese and Standard Of Care(NSIDs/Non-NSIDs) as covariates. Interaction p-value is from the above ANCOVA model with additional factor/interaction of subgroup and subgroup by treatment.

Table 2.4.5.4: EQ-VAS: AUC between Baseline and Week 20 of Change From Baseline in EQ-VAS Score by Subgroup - ITT+

ANALYSIS SET: ITT+

	Interaction P-value	EFGARTIGIMOD (N=65)	PLACEBO (N=64)
BASELINE MG-ADL TOTAL SCORE SEVERE (>=10)	0.498		
n/N1 (%)		24/24 (100.0)	17/17 (100.0)
Mean (S.D.)		183.0 (303.52)	31.6 (195.92)
S.E.		61.95	47.52
95% C.I.		(54.83; 311.16)	(-69.08; 132.38)
Median		150.0	25.0
Q1; Q3		(-7.0; 330.0)	(-55.0; 156.3)
Min; Max		(-445; 810)	(-405; 348)
Hedge's G		0.56	
95% C.I.		(-0.061; 1.182)	
LS Mean (S.E.)		165.7 (74.39)	-15.9 (85.67)
95% C.I.		(14.85; 316.57)	(-189.70; 157.80)
LS Mean Differences (S.E.)		181.7 (73.56)	
95% C.I.		(32.46; 330.85)	
P-value		0.018	

S.D. = Standard Deviation; S.E. = Standard Error; AUC=Area Under the Curve; LS=Least Square
n is the number of patients with non-missing values, N1 is the total number of patients in the corresponding analysis set and subgroup regardless of missing value status, N is the total number of patients in the analysis set.
LS mean and LS mean difference is from an ANCOVA model with treatment, baseline score, Japanese/Non-Japanese and Standard Of Care(NSIDs/Non-NSIDs) as covariates. Interaction p-value is from the above ANCOVA model with additional factor/interaction of subgroup and subgroup by treatment.

Table 2.4.5.4: EQ-VAS: AUC between Baseline and Week 20 of Change From Baseline in EQ-VAS Score by Subgroup - ITT+

ANALYSIS SET: ITT+

	Interaction P-value	EFGARTIGIMOD (N=65)	PLACEBO (N=64)
CONCIMATANT TREATMENT	0.392		
NSID			
n/N1 (%)		38/38 (100.0)	37/37 (100.0)
Mean (S.D.)		136.2 (279.85)	81.3 (208.90)
S.E.		45.40	34.34
95% C.I.		(44.23; 228.20)	(11.63; 150.93)
Median		102.8	75.0
Q1; Q3		(-32.0; 261.0)	(2.5; 163.0)
Min; Max		(-445; 1002)	(-405; 813)
Hedge's G		0.22	
95% C.I.		(-0.230; 0.669)	
LS Mean (S.E.)		116.4 (47.57)	32.7 (49.72)
95% C.I.		(21.51; 211.22)	(-66.47; 131.82)
LS Mean Differences (S.E.)		83.7 (48.99)	
95% C.I.		(-14.00; 181.38)	
P-value		0.092	

S.D. = Standard Deviation; S.E. = Standard Error; AUC=Area Under the Curve; LS=Least Square
n is the number of patients with non-missing values, N1 is the total number of patients in the corresponding analysis set and subgroup regardless of missing value status, N is the total number of patients in the analysis set.
LS mean and LS mean difference is from an ANCOVA model with treatment, baseline score, Japanese/Non-Japanese and Standard Of Care(NSIDs/Non-NSIDs) as covariates. Interaction p-value is from the above ANCOVA model with additional factor/interaction of subgroup and subgroup by treatment.

Table 2.4.5.4: EQ-VAS: AUC between Baseline and Week 20 of Change From Baseline in EQ-VAS Score by Subgroup - ITT+

ANALYSIS SET: ITT+

	Interaction P-value	EFGARTIGIMOD (N=65)	PLACEBO (N=64)
CONCIMATANT TREATMENT	0.392		
NON-NSID			
n/N1 (%)		27/27 (100.0)	27/27 (100.0)
Mean (S.D.)		249.6 (260.29)	96.3 (198.79)
S.E.		50.09	38.26
95% C.I.		(146.59; 352.52)	(17.65; 174.92)
Median		207.5	70.0
Q1; Q3		(60.0; 460.0)	(-13.5; 270.0)
Min; Max		(-241; 810)	(-493; 443)
Hedge's G		0.65	
95% C.I.		(0.112; 1.192)	
LS Mean (S.E.)		215.4 (82.51)	69.0 (82.64)
95% C.I.		(49.69; 381.14)	(-97.02; 234.96)
LS Mean Differences (S.E.)		146.4 (58.27)	
95% C.I.		(29.40; 263.49)	
P-value		0.015	

S.D. = Standard Deviation; S.E. = Standard Error; AUC=Area Under the Curve; LS=Least Square
n is the number of patients with non-missing values, N1 is the total number of patients in the corresponding analysis set and subgroup regardless of missing value status, N is the total number of patients in the analysis set.
LS mean and LS mean difference is from an ANCOVA model with treatment, baseline score, Japanese/Non-Japanese and Standard Of Care(NSIDs/Non-NSIDs) as covariates. Interaction p-value is from the above ANCOVA model with additional factor/interaction of subgroup and subgroup by treatment.

Table 2.4.5.4: EQ-VAS: AUC between Baseline and Week 20 of Change From Baseline in EQ-VAS Score by Subgroup - ITT+

ANALYSIS SET: ITT+

	Interaction P-value	EFGARTIGIMOD (N=65)	PLACEBO (N=64)
THYMECTOMY PERFORMED FOR MG	0.121		
YES			
n/N1 (%)		45/45 (100.0)	30/30 (100.0)
Mean (S.D.)		148.4 (268.44)	118.6 (209.31)
S.E.		40.02	38.21
95% C.I.		(67.80; 229.10)	(40.41; 196.73)
Median		118.0	107.0
Q1; Q3		(-30.6; 279.0)	(6.5; 188.9)
Min; Max		(-445; 1002)	(-405; 813)
Hedge's G		0.12	
95% C.I.		(-0.338; 0.578)	
LS Mean (S.E.)		165.9 (52.20)	107.4 (62.19)
95% C.I.		(61.77; 270.00)	(-16.67; 231.41)
LS Mean Differences (S.E.)		58.5 (50.29)	
95% C.I.		(-41.78; 158.81)	
P-value		0.249	

S.D. = Standard Deviation; S.E. = Standard Error; AUC=Area Under the Curve; LS=Least Square
n is the number of patients with non-missing values, N1 is the total number of patients in the corresponding analysis set and subgroup regardless of missing value status, N is the total number of patients in the analysis set.
LS mean and LS mean difference is from an ANCOVA model with treatment, baseline score, Japanese/Non-Japanese and Standard Of Care(NSIDs/Non-NSIDs) as covariates. Interaction p-value is from the above ANCOVA model with additional factor/interaction of subgroup and subgroup by treatment.

Table 2.4.5.4: EQ-VAS: AUC between Baseline and Week 20 of Change From Baseline in EQ-VAS Score by Subgroup - ITT+

ANALYSIS SET: ITT+

	Interaction P-value	EFGARTIGIMOD (N=65)	PLACEBO (N=64)
THYMECTOMY PERFORMED FOR MG	0.121		
NO			
n/N1 (%)		20/20 (100.0)	34/34 (100.0)
Mean (S.D.)		261.7 (282.27)	60.3 (196.74)
S.E.		63.12	33.74
95% C.I.		(129.58; 393.80)	(-8.35; 128.94)
Median		229.1	45.5
Q1; Q3		(62.5; 488.5)	(-28.3; 200.0)
Min; Max		(-241; 810)	(-493; 443)
Hedge's G		0.86	
95% C.I.		(0.289; 1.424)	
LS Mean (S.E.)		209.2 (71.30)	25.6 (59.59)
95% C.I.		(65.93; 352.49)	(-94.15; 145.34)
LS Mean Differences (S.E.)		183.6 (61.20)	
95% C.I.		(60.63; 306.61)	
P-value		0.004	

S.D. = Standard Deviation; S.E. = Standard Error; AUC=Area Under the Curve; LS=Least Square
n is the number of patients with non-missing values, N1 is the total number of patients in the corresponding analysis set and subgroup regardless of missing value status, N is the total number of patients in the analysis set.
LS mean and LS mean difference is from an ANCOVA model with treatment, baseline score, Japanese/Non-Japanese and Standard Of Care(NSIDs/Non-NSIDs) as covariates. Interaction p-value is from the above ANCOVA model with additional factor/interaction of subgroup and subgroup by treatment.

Table 2.5.1.5: MG-QoL15r: Responders of 5-Point Reduction During First Cycle by Subgroup - ITT+

ANALYSIS SET: ITT+

	COCHRANE'S Q P-VALE	EFGARTIGIMOD (N=65) n (%)	PLACEBO (N=64) n (%)	ODDS RATIO (95% C.I.)	RELATIVE RISK (95% C.I.)	ARR (%) (95% C.I.)	P-VALUE*
REGION	0.144						
EU							
n/N1		25/25 (100.0)	27/27 (100.0)				
RESPONSE		13 (52.0)	11 (40.7)	1.576 (0.526; 4.723)	1.276 (0.707; 2.304)	11.3 (-14.9; 35.5)	0.578
NO RESPONSE		12 (48.0)	16 (59.3)				
NON-EU							
n/N1		40/40 (100.0)	36/37 (97.3)				
RESPONSE		30 (75.0)	14 (38.9)	4.714 (1.769; 12.566)	1.929 (1.234; 3.015)	36.1 (13.9; 53.9)	0.002
NO RESPONSE		10 (25.0)	22 (61.1)				

ARR=Absolute Risk Reduction
n is the number of patients with non-missing values, N1 is the total number of patients in the corresponding analysis set, subgroup and cycle regardless of missing value status, N is the total number of patients in the analysis set.
0.5 is added if any cell count is zero for odds ratio and relative risk calculation
* P-value is from Fisher's exact test.
Program: /clinical/argx-113/mg/argx-113-1704/biostat/staging/gba/programs/t_responder_sub.sas, Version: 1.2

Table 2.5.1.5: MG-QoL15r: Responders of 5-Point Reduction During First Cycle by Subgroup - ITT+

ANALYSIS SET: ITT+

	COCHRANE'S Q P-VALE	EFGARTIGIMOD (N=65) n (%)	PLACEBO (N=64) n (%)	ODDS RATIO (95% C.I.)	RELATIVE RISK (95% C.I.)	ARR (%) (95% C.I.)	P-VALUE*
AGE CATEGORY	0.112						
18 - <65 years							
n/N1		57/57 (100.0)	51/51 (100.0)				
RESPONSE		37 (64.9)	23 (45.1)	2.252 (1.038; 4.887)	1.439 (1.006; 2.059)	19.8 (1.1; 36.8)	0.052
NO RESPONSE		20 (35.1)	28 (54.9)				
>= 65 years							
n/N1		8/8 (100.0)	12/13 (92.3)				
RESPONSE		6 (75.0)	2 (16.7)	15.000 (1.652; 136.172)	4.500 (1.194; 16.962)	58.3 (14.1; 79.8)	0.019
NO RESPONSE		2 (25.0)	10 (83.3)				

ARR=Absolute Risk Reduction
n is the number of patients with non-missing values, N1 is the total number of patients in the corresponding analysis set, subgroup and cycle regardless of missing value status, N is the total number of patients in the analysis set.
0.5 is added if any cell count is zero for odds ratio and relative risk calculation
* P-value is from Fisher's exact test.
Program: /clinical/argx-113/mg/argx-113-1704/biostat/staging/gba/programs/t_responder_sub.sas, Version: 1.2

Table 2.5.1.5: MG-QoL15r: Responders of 5-Point Reduction During First Cycle by Subgroup - ITT+

ANALYSIS SET: ITT+

	COCHRANE'S Q P-VALE	EFGARTIGIMOD (N=65) n (%)	PLACEBO (N=64) n (%)	ODDS RATIO (95% C.I.)	RELATIVE RISK (95% C.I.)	ARR (%) (95% C.I.)	P-VALUE*
SEX	0.859						
Female							
n/N1		46/46 (100.0)	40/40 (100.0)				
RESPONSE		31 (67.4)	17 (42.5)	2.796 (1.161; 6.736)	1.586 (1.049; 2.396)	24.9 (3.9; 43.2)	0.029
NO RESPONSE		15 (32.6)	23 (57.5)				
Male							
n/N1		19/19 (100.0)	23/24 (95.8)				
RESPONSE		12 (63.2)	8 (34.8)	3.214 (0.905; 11.411)	1.816 (0.942; 3.501)	28.4 (-1.7; 52.2)	0.120
NO RESPONSE		7 (36.8)	15 (65.2)				

ARR=Absolute Risk Reduction
n is the number of patients with non-missing values, N1 is the total number of patients in the corresponding analysis set, subgroup and cycle regardless of missing value status, N is the total number of patients in the analysis set.
0.5 is added if any cell count is zero for odds ratio and relative risk calculation
* P-value is from Fisher's exact test.
Program: /clinical/argx-113/mg/argx-113-1704/biostat/staging/gba/programs/t_responder_sub.sas, Version: 1.2

Table 2.5.1.5: MG-QoL15r: Responders of 5-Point Reduction During First Cycle by Subgroup - ITT+

ANALYSIS SET: ITT+

	COCHRANE'S Q P-VALE	EFGARTIGIMOD (N=65) n (%)	PLACEBO (N=64) n (%)	ODDS RATIO (95% C.I.)	RELATIVE RISK (95% C.I.)	ARR (%) (95% C.I.)	P-VALUE*
RACE	0.978						
WHITE							
n/N1		54/54 (100.0)	55/56 (98.2)				
RESPONSE		36 (66.7)	22 (40.0)	3.000 (1.373; 6.556)	1.667 (1.146; 2.424)	26.7 (7.9; 42.9)	0.007
NO RESPONSE		18 (33.3)	33 (60.0)				
NON-WHITE							
n/N1		11/11 (100.0)	8/8 (100.0)				
RESPONSE		7 (63.6)	3 (37.5)	2.917 (0.442; 19.234)	1.697 (0.624; 4.613)	26.1 (-16.5; 58.0)	0.370
NO RESPONSE		4 (36.4)	5 (62.5)				

ARR=Absolute Risk Reduction
n is the number of patients with non-missing values, N1 is the total number of patients in the corresponding analysis set, subgroup and cycle regardless of missing value status, N is the total number of patients in the analysis set.
0.5 is added if any cell count is zero for odds ratio and relative risk calculation
* P-value is from Fisher's exact test.
Program: /clinical/argx-113/mg/argx-113-1704/biostat/staging/gba/programs/t_responder_sub.sas, Version: 1.2

Table 2.5.1.5: MG-QoL15r: Responders of 5-Point Reduction During First Cycle by Subgroup - ITT+

ANALYSIS SET: ITT+

	COCHRANE'S Q P-VALE	EFGARTIGIMOD (N=65) n (%)	PLACEBO (N=64) n (%)	ODDS RATIO (95% C.I.)	RELATIVE RISK (95% C.I.)	ARR (%) (95% C.I.)	P-VALUE*
BASELINE MG-ADL TOTAL SCORE	0.265						
MILD (5-7)							
n/N1		16/16 (100.0)	18/18 (100.0)				
RESPONSE		6 (37.5)	6 (33.3)	1.200 (0.293; 4.909)	1.125 (0.453; 2.793)	4.2 (-25.6; 33.5)	1.000
NO RESPONSE		10 (62.5)	12 (66.7)				
MODERATE (8-9)							
n/N1		25/25 (100.0)	29/29 (100.0)				
RESPONSE		20 (80.0)	12 (41.4)	5.667 (1.661; 19.336)	1.933 (1.202; 3.110)	38.6 (12.4; 58.0)	0.006
NO RESPONSE		5 (20.0)	17 (58.6)				
SEVERE (>=10)							
n/N1		24/24 (100.0)	16/17 (94.1)				
RESPONSE		17 (70.8)	7 (43.8)	3.122 (0.832; 11.724)	1.619 (0.878; 2.986)	27.1 (-3.5; 52.2)	0.110
NO RESPONSE		7 (29.2)	9 (56.3)				

ARR=Absolute Risk Reduction
n is the number of patients with non-missing values, N1 is the total number of patients in the corresponding analysis set, subgroup and cycle regardless of missing value status, N is the total number of patients in the analysis set.
0.5 is added if any cell count is zero for odds ratio and relative risk calculation
* P-value is from Fisher's exact test.
Program: /clinical/argx-113/mg/argx-113-1704/biostat/staging/gba/programs/t_responder_sub.sas, Version: 1.2

Table 2.5.1.5: MG-QoL15r: Responders of 5-Point Reduction During First Cycle by Subgroup - ITT+

ANALYSIS SET: ITT+

	COCHRANE'S Q P-VALE	EFGARTIGIMOD (N=65) n (%)	PLACEBO (N=64) n (%)	ODDS RATIO (95% C.I.)	RELATIVE RISK (95% C.I.)	ARR (%) (95% C.I.)	P-VALUE*
CONCIMATANT TREATMENT	0.859						
NSID							
n/N1		38/38 (100.0)	37/37 (100.0)				
RESPONSE		24 (63.2)	13 (35.1)	3.165 (1.232; 8.130)	1.798 (1.090; 2.966)	28.0 (5.4; 47.0)	0.021
NO RESPONSE		14 (36.8)	24 (64.9)				
NON-NSID							
n/N1		27/27 (100.0)	26/27 (96.3)				
RESPONSE		19 (70.4)	12 (46.2)	2.771 (0.895; 8.577)	1.525 (0.942; 2.469)	24.2 (-2.1; 46.4)	0.098
NO RESPONSE		8 (29.6)	14 (53.8)				

ARR=Absolute Risk Reduction
n is the number of patients with non-missing values, N1 is the total number of patients in the corresponding analysis set, subgroup and cycle regardless of missing value status, N is the total number of patients in the analysis set.
0.5 is added if any cell count is zero for odds ratio and relative risk calculation
* P-value is from Fisher's exact test.
Program: /clinical/argx-113/mg/argx-113-1704/biostat/staging/gba/programs/t_responder_sub.sas, Version: 1.2

Table 2.5.1.5: MG-QoL15r: Responders of 5-Point Reduction During First Cycle by Subgroup - ITT+

ANALYSIS SET: ITT+

	COCHRANE'S Q P-VALE	EFGARTIGIMOD (N=65) n (%)	PLACEBO (N=64) n (%)	ODDS RATIO (95% C.I.)	RELATIVE RISK (95% C.I.)	ARR (%) (95% C.I.)	P-VALUE*
THYMECTOMY PERFORMED FOR MG	0.681						
YES							
n/N1		45/45 (100.0)	30/30 (100.0)				
RESPONSE		30 (66.7)	11 (36.7)	3.455 (1.313; 9.088)	1.818 (1.088; 3.039)	30.0 (7.0; 49.0)	0.017
NO RESPONSE		15 (33.3)	19 (63.3)				
NO							
n/N1		20/20 (100.0)	33/34 (97.1)				
RESPONSE		13 (65.0)	14 (42.4)	2.520 (0.799; 7.954)	1.532 (0.919; 2.555)	22.6 (-4.9; 45.3)	0.158
NO RESPONSE		7 (35.0)	19 (57.6)				

ARR=Absolute Risk Reduction
n is the number of patients with non-missing values, N1 is the total number of patients in the corresponding analysis set, subgroup and cycle regardless of missing value status, N is the total number of patients in the analysis set.
0.5 is added if any cell count is zero for odds ratio and relative risk calculation
* P-value is from Fisher's exact test.
Program: /clinical/argx-113/mg/argx-113-1704/biostat/staging/gba/programs/t_responder_sub.sas, Version: 1.2

Table 2.5.5.4: MG-QoL15r: AUC between Baseline and Week 20 of Change From Baseline in Total MG-QoL15r Score by Subgroup - ITT+

ANALYSIS SET: ITT+

	Interaction P-value	EFGARTIGIMOD (N=65)	PLACEBO (N=64)
REGION	0.556		
EU			
n/N1 (%)		25/25 (100.0)	27/27 (100.0)
Mean (S.D.)		-86.2 (97.74)	-27.5 (69.41)
S.E.		19.55	13.36
95% C.I.		(-126.55; -45.86)	(-55.00; -0.09)
Median		-85.0	-26.5
Q1; Q3		(-166.0; -17.5)	(-73.0; 20.0)
Min; Max		(-241; 83)	(-165; 113)
Hedge's G		-0.69	
95% C.I.		(-1.238; -0.134)	
LS Mean (S.E.)		-84.8 (15.30)	-28.1 (14.85)
95% C.I.		(-115.61; -54.09)	(-57.90; 1.79)
LS Mean Differences (S.E.)		-56.8 (21.28)	
95% C.I.		(-99.58; -14.01)	
P-value		0.010	

S.D. = Standard Deviation; S.E. = Standard Error; AUC=Area Under the Curve; LS=Least Square
n is the number of patients with non-missing values, N1 is the total number of patients in the corresponding analysis set and subgroup regardless of missing value status, N is the total number of patients in the analysis set.
LS mean and LS mean difference is from an ANCOVA model with treatment, baseline score, Japanese/Non-Japanese and Standard Of Care(NSIDs/Non-NSIDs) as covariates. Interaction p-value is from the above ANCOVA model with additional factor/interaction of subgroup and subgroup by treatment.

Table 2.5.5.4: MG-QoL15r: AUC between Baseline and Week 20 of Change From Baseline in Total MG-QoL15r Score by Subgroup - ITT+

ANALYSIS SET: ITT+

	Interaction P-value	EFGARTIGIMOD (N=65)	PLACEBO (N=64)
REGION	0.556		
NON-EU			
n/N1 (%)		40/40 (100.0)	37/37 (100.0)
Mean (S.D.)		-120.9 (89.44)	-58.9 (76.93)
S.E.		14.14	12.65
95% C.I.		(-149.47; -92.26)	(-84.57; -33.27)
Median		-114.8	-36.0
Q1; Q3		(-178.5; -53.3)	(-99.5; -3.5)
Min; Max		(-340; 27)	(-308; 63)
Hedge's G		-0.73	
95% C.I.		(-1.190; -0.276)	
LS Mean (S.E.)		-103.5 (16.37)	-31.4 (16.72)
95% C.I.		(-136.09; -70.83)	(-64.72; 1.93)
LS Mean Differences (S.E.)		-72.1 (17.70)	
95% C.I.		(-107.36; -36.77)	
P-value		<.001	

S.D. = Standard Deviation; S.E. = Standard Error; AUC=Area Under the Curve; LS=Least Square
n is the number of patients with non-missing values, N1 is the total number of patients in the corresponding analysis set and subgroup regardless of missing value status, N is the total number of patients in the analysis set.
LS mean and LS mean difference is from an ANCOVA model with treatment, baseline score, Japanese/Non-Japanese and Standard Of Care(NSIDs/Non-NSIDs) as covariates. Interaction p-value is from the above ANCOVA model with additional factor/interaction of subgroup and subgroup by treatment.

Table 2.5.5.4: MG-QoL15r: AUC between Baseline and Week 20 of Change From Baseline in Total MG-QoL15r Score by Subgroup - ITT+

ANALYSIS SET: ITT+

	Interaction P-value	EFGARTIGIMOD (N=65)	PLACEBO (N=64)
AGE CATEGORY	0.061		
18 - <65 years			
n/N1 (%)		57/57 (100.0)	51/51 (100.0)
Mean (S.D.)		-104.4 (93.07)	-56.1 (72.18)
S.E.		12.33	10.11
95% C.I.		(-129.05; -79.66)	(-76.42; -35.81)
Median		-109.0	-36.0
Q1; Q3		(-171.5; -31.5)	(-103.0; -2.5)
Min; Max		(-340; 83)	(-308; 63)
Hedge's G		-0.57	
95% C.I.		(-0.954; -0.188)	
LS Mean (S.E.)		-88.8 (16.59)	-33.2 (17.19)
95% C.I.		(-121.66; -55.85)	(-67.30; 0.87)
LS Mean Differences (S.E.)		-55.5 (14.82)	
95% C.I.		(-84.92; -26.15)	
P-value		<.001	

S.D. = Standard Deviation; S.E. = Standard Error; AUC=Area Under the Curve; LS=Least Square
n is the number of patients with non-missing values, N1 is the total number of patients in the corresponding analysis set and subgroup regardless of missing value status, N is the total number of patients in the analysis set.
LS mean and LS mean difference is from an ANCOVA model with treatment, baseline score, Japanese/Non-Japanese and Standard Of Care(NSIDs/Non-NSIDs) as covariates. Interaction p-value is from the above ANCOVA model with additional factor/interaction of subgroup and subgroup by treatment.

Table 2.5.5.4: MG-QoL15r: AUC between Baseline and Week 20 of Change From Baseline in Total MG-QoL15r Score by Subgroup - ITT+

ANALYSIS SET: ITT+

	Interaction P-value	EFGARTIGIMOD (N=65)	PLACEBO (N=64)
AGE CATEGORY	0.061		
>= 65 years			
n/N1 (%)		8/8 (100.0)	13/13 (100.0)
Mean (S.D.)		-130.2 (99.97)	-4.8 (74.06)
S.E.		35.35	20.54
95% C.I.		(-213.78; -46.62)	(-49.51; 40.00)
Median		-110.8	14.4
Q1; Q3		(-206.0; -56.1)	(-79.0; 27.0)
Min; Max		(-298; 3)	(-100; 113)
Hedge's G		-1.42	
95% C.I.		(-2.374; -0.476)	
LS Mean (S.E.)		-113.8 (38.36)	12.6 (36.11)
95% C.I.		(-195.17; -32.52)	(-63.94; 89.15)
LS Mean Differences (S.E.)		-126.4 (37.98)	
95% C.I.		(-206.97; -45.92)	
P-value		0.004	

S.D. = Standard Deviation; S.E. = Standard Error; AUC=Area Under the Curve; LS=Least Square
n is the number of patients with non-missing values, N1 is the total number of patients in the corresponding analysis set and subgroup regardless of missing value status, N is the total number of patients in the analysis set.
LS mean and LS mean difference is from an ANCOVA model with treatment, baseline score, Japanese/Non-Japanese and Standard Of Care(NSIDs/Non-NSIDs) as covariates. Interaction p-value is from the above ANCOVA model with additional factor/interaction of subgroup and subgroup by treatment.

Table 2.5.5.4: MG-QoL15r: AUC between Baseline and Week 20 of Change From Baseline in Total MG-QoL15r Score by Subgroup - ITT+

ANALYSIS SET: ITT+

	Interaction P-value	EFGARTIGIMOD (N=65)	PLACEBO (N=64)
SEX	0.837		
Female			
n/N1 (%)		46/46 (100.0)	40/40 (100.0)
Mean (S.D.)		-104.6 (84.54)	-47.4 (66.05)
S.E.		12.46	10.44
95% C.I.		(-129.69; -79.48)	(-68.56; -26.31)
Median		-110.0	-30.3
Q1; Q3		(-169.0; -32.0)	(-97.3; -1.5)
Min; Max		(-285; 54)	(-219; 63)
Hedge's G		-0.74	
95% C.I.		(-1.174; -0.306)	
LS Mean (S.E.)		-89.2 (17.26)	-26.3 (18.46)
95% C.I.		(-123.50; -54.80)	(-63.06; 10.38)
LS Mean Differences (S.E.)		-62.8 (16.15)	
95% C.I.		(-94.94; -30.68)	
P-value		<.001	

S.D. = Standard Deviation; S.E. = Standard Error; AUC=Area Under the Curve; LS=Least Square
n is the number of patients with non-missing values, N1 is the total number of patients in the corresponding analysis set and subgroup regardless of missing value status, N is the total number of patients in the analysis set.
LS mean and LS mean difference is from an ANCOVA model with treatment, baseline score, Japanese/Non-Japanese and Standard Of Care(NSIDs/Non-NSIDs) as covariates. Interaction p-value is from the above ANCOVA model with additional factor/interaction of subgroup and subgroup by treatment.

Table 2.5.5.4: MG-QoL15r: AUC between Baseline and Week 20 of Change From Baseline in Total MG-QoL15r Score by Subgroup - ITT+

ANALYSIS SET: ITT+

	Interaction P-value	EFGARTIGIMOD (N=65)	PLACEBO (N=64)
SEX	0.837		
Male			
n/N1 (%)		19/19 (100.0)	24/24 (100.0)
Mean (S.D.)		-114.7 (114.69)	-42.8 (89.25)
S.E.		26.31	18.22
95% C.I.		(-169.97; -59.41)	(-80.45; -5.08)
Median		-101.0	-43.0
Q1; Q3		(-198.5; -3.0)	(-92.3; 12.3)
Min; Max		(-340; 83)	(-308; 113)
Hedge's G		-0.70	
95% C.I.		(-1.307; -0.089)	
LS Mean (S.E.)		-83.6 (29.52)	-12.0 (27.40)
95% C.I.		(-143.39; -23.85)	(-67.51; 43.42)
LS Mean Differences (S.E.)		-71.6 (24.93)	
95% C.I.		(-122.05; -21.10)	
P-value		0.007	

S.D. = Standard Deviation; S.E. = Standard Error; AUC=Area Under the Curve; LS=Least Square
n is the number of patients with non-missing values, N1 is the total number of patients in the corresponding analysis set and subgroup regardless of missing value status, N is the total number of patients in the analysis set.
LS mean and LS mean difference is from an ANCOVA model with treatment, baseline score, Japanese/Non-Japanese and Standard Of Care(NSIDs/Non-NSIDs) as covariates. Interaction p-value is from the above ANCOVA model with additional factor/interaction of subgroup and subgroup by treatment.

Table 2.5.5.4: MG-QoL15r: AUC between Baseline and Week 20 of Change From Baseline in Total MG-QoL15r Score by Subgroup - ITT+

ANALYSIS SET: ITT+

	Interaction P-value	EFGARTIGIMOD (N=65)	PLACEBO (N=64)
RACE	0.714		
WHITE			
n/N1 (%)		54/54 (100.0)	56/56 (100.0)
Mean (S.D.)		-108.0 (90.97)	-41.7 (66.40)
S.E.		12.38	8.87
95% C.I.		(-132.83; -83.17)	(-59.52; -23.96)
Median		-110.0	-36.0
Q1; Q3		(-177.5; -32.0)	(-95.3; 5.0)
Min; Max		(-298; 83)	(-188; 113)
Hedge's G		-0.83	
95% C.I.		(-1.216; -0.442)	
LS Mean (S.E.)		-108.8 (10.14)	-40.5 (9.94)
95% C.I.		(-128.87; -88.66)	(-60.19; -20.80)
LS Mean Differences (S.E.)		-68.3 (14.14)	
95% C.I.		(-96.31; -40.23)	
P-value		<.001	

S.D. = Standard Deviation; S.E. = Standard Error; AUC=Area Under the Curve; LS=Least Square
n is the number of patients with non-missing values, N1 is the total number of patients in the corresponding analysis set and subgroup regardless of missing value status, N is the total number of patients in the analysis set.
LS mean and LS mean difference is from an ANCOVA model with treatment, baseline score, Japanese/Non-Japanese and Standard Of Care(NSIDs/Non-NSIDs) as covariates. Interaction p-value is from the above ANCOVA model with additional factor/interaction of subgroup and subgroup by treatment.

Table 2.5.5.4: MG-QoL15r: AUC between Baseline and Week 20 of Change From Baseline in Total MG-QoL15r Score by Subgroup - ITT+

ANALYSIS SET: ITT+

	Interaction P-value	EFGARTIGIMOD (N=65)	PLACEBO (N=64)
RACE	0.714		
NON-WHITE			
n/N1 (%)		11/11 (100.0)	8/8 (100.0)
Mean (S.D.)		-105.3 (110.03)	-73.3 (121.99)
S.E.		33.17	43.13
95% C.I.		(-179.20; -31.36)	(-175.28; 28.70)
Median		-102.8	-14.8
Q1; Q3		(-153.0; 5.5)	(-137.0; -1.8)
Min; Max		(-340; 27)	(-308; 29)
Hedge's G		-0.27	
95% C.I.		(-1.139; 0.609)	
LS Mean (S.E.)		-125.1 (33.85)	-49.9 (39.78)
95% C.I.		(-197.72; -52.53)	(-135.20; 35.43)
LS Mean Differences (S.E.)		-75.2 (53.90)	
95% C.I.		(-190.84; 40.36)	
P-value		0.184	

S.D. = Standard Deviation; S.E. = Standard Error; AUC=Area Under the Curve; LS=Least Square
n is the number of patients with non-missing values, N1 is the total number of patients in the corresponding analysis set and subgroup regardless of missing value status, N is the total number of patients in the analysis set.
LS mean and LS mean difference is from an ANCOVA model with treatment, baseline score, Japanese/Non-Japanese and Standard Of Care(NSIDs/Non-NSIDs) as covariates. Interaction p-value is from the above ANCOVA model with additional factor/interaction of subgroup and subgroup by treatment.

Table 2.5.5.4: MG-QoL15r: AUC between Baseline and Week 20 of Change From Baseline in Total MG-QoL15r Score by Subgroup - ITT+

ANALYSIS SET: ITT+

	Interaction P-value	EFGARTIGIMOD (N=65)	PLACEBO (N=64)
BASELINE MG-ADL TOTAL SCORE	0.198		
MILD (5-7)			
n/N1 (%)		16/16 (100.0)	18/18 (100.0)
Mean (S.D.)		-61.4 (83.55)	-49.1 (68.06)
S.E.		20.89	16.04
95% C.I.		(-105.93; -16.88)	(-82.91; -15.22)
Median		-47.5	-36.1
Q1; Q3		(-124.3; -0.3)	(-79.0; -2.0)
Min; Max		(-221; 83)	(-219; 34)
Hedge's G		-0.16	
95% C.I.		(-0.818; 0.499)	
LS Mean (S.E.)		-67.9 (22.93)	-44.3 (22.97)
95% C.I.		(-114.78; -20.98)	(-91.29; 2.66)
LS Mean Differences (S.E.)		-23.6 (25.34)	
95% C.I.		(-75.38; 28.25)	
P-value		0.360	

S.D. = Standard Deviation; S.E. = Standard Error; AUC=Area Under the Curve; LS=Least Square
n is the number of patients with non-missing values, N1 is the total number of patients in the corresponding analysis set and subgroup regardless of missing value status, N is the total number of patients in the analysis set.
LS mean and LS mean difference is from an ANCOVA model with treatment, baseline score, Japanese/Non-Japanese and Standard Of Care(NSIDs/Non-NSIDs) as covariates. Interaction p-value is from the above ANCOVA model with additional factor/interaction of subgroup and subgroup by treatment.

Table 2.5.5.4: MG-QoL15r: AUC between Baseline and Week 20 of Change From Baseline in Total MG-QoL15r Score by Subgroup - ITT+

ANALYSIS SET: ITT+

	Interaction P-value	EFGARTIGIMOD (N=65)	PLACEBO (N=64)
BASELINE MG-ADL TOTAL SCORE	0.198		
MODERATE (8-9)			
n/N1 (%)		25/25 (100.0)	29/29 (100.0)
Mean (S.D.)		-129.4 (93.23)	-36.3 (89.50)
S.E.		18.65	16.62
95% C.I.		(-167.85; -90.88)	(-70.33; -2.24)
Median		-125.0	-26.5
Q1; Q3		(-184.0; -67.2)	(-89.0; 18.5)
Min; Max		(-340; 22)	(-308; 113)
Hedge's G		-1.01	
95% C.I.		(-1.566; -0.445)	
LS Mean (S.E.)		-91.4 (35.11)	-8.8 (33.64)
95% C.I.		(-162.00; -20.88)	(-76.41; 58.79)
LS Mean Differences (S.E.)		-82.6 (24.05)	
95% C.I.		(-130.95; -34.31)	
P-value		0.001	

S.D. = Standard Deviation; S.E. = Standard Error; AUC=Area Under the Curve; LS=Least Square
n is the number of patients with non-missing values, N1 is the total number of patients in the corresponding analysis set and subgroup regardless of missing value status, N is the total number of patients in the analysis set.
LS mean and LS mean difference is from an ANCOVA model with treatment, baseline score, Japanese/Non-Japanese and Standard Of Care(NSIDs/Non-NSIDs) as covariates. Interaction p-value is from the above ANCOVA model with additional factor/interaction of subgroup and subgroup by treatment.

Table 2.5.5.4: MG-QoL15r: AUC between Baseline and Week 20 of Change From Baseline in Total MG-QoL15r Score by Subgroup - ITT+

ANALYSIS SET: ITT+

	Interaction P-value	EFGARTIGIMOD (N=65)	PLACEBO (N=64)
BASELINE MG-ADL TOTAL SCORE SEVERE (>=10)	0.198		
n/N1 (%)		24/24 (100.0)	17/17 (100.0)
Mean (S.D.)		-115.6 (93.00)	-58.1 (53.15)
S.E.		18.98	12.89
95% C.I.		(-154.82; -76.29)	(-85.46; -30.80)
Median		-118.3	-55.0
Q1; Q3		(-184.5; -46.0)	(-96.0; -10.0)
Min; Max		(-298; 54)	(-151; 23)
Hedge's G		-0.71	
95% C.I.		(-1.340; -0.083)	
LS Mean (S.E.)		-85.3 (24.18)	-6.0 (26.51)
95% C.I.		(-134.32; -36.23)	(-59.75; 47.79)
LS Mean Differences (S.E.)		-79.3 (24.03)	
95% C.I.		(-128.02; -30.57)	
P-value		0.002	

S.D. = Standard Deviation; S.E. = Standard Error; AUC=Area Under the Curve; LS=Least Square
n is the number of patients with non-missing values, N1 is the total number of patients in the corresponding analysis set and subgroup regardless of missing value status, N is the total number of patients in the analysis set.
LS mean and LS mean difference is from an ANCOVA model with treatment, baseline score, Japanese/Non-Japanese and Standard Of Care(NSIDs/Non-NSIDs) as covariates. Interaction p-value is from the above ANCOVA model with additional factor/interaction of subgroup and subgroup by treatment.

Table 2.5.5.4: MG-QoL15r: AUC between Baseline and Week 20 of Change From Baseline in Total MG-QoL15r Score by Subgroup - ITT+

ANALYSIS SET: ITT+

	Interaction P-value	EFGARTIGIMOD (N=65)	PLACEBO (N=64)
CONCIMATANT TREATMENT	0.840		
NSID			
n/N1 (%)		38/38 (100.0)	37/37 (100.0)
Mean (S.D.)		-105.6 (97.95)	-45.8 (77.24)
S.E.		15.89	12.70
95% C.I.		(-137.81; -73.42)	(-71.60; -20.09)
Median		-98.9	-25.5
Q1; Q3		(-177.5; -29.0)	(-89.0; -2.0)
Min; Max		(-340; 83)	(-308; 88)
Hedge's G		-0.67	
95% C.I.		(-1.130; -0.209)	
LS Mean (S.E.)		-86.2 (18.03)	-15.8 (18.58)
95% C.I.		(-122.17; -50.27)	(-52.83; 21.25)
LS Mean Differences (S.E.)		-70.4 (18.50)	
95% C.I.		(-107.32; -33.53)	
P-value		<.001	

S.D. = Standard Deviation; S.E. = Standard Error; AUC=Area Under the Curve; LS=Least Square
n is the number of patients with non-missing values, N1 is the total number of patients in the corresponding analysis set and subgroup regardless of missing value status, N is the total number of patients in the analysis set.
LS mean and LS mean difference is from an ANCOVA model with treatment, baseline score, Japanese/Non-Japanese and Standard Of Care(NSIDs/Non-NSIDs) as covariates. Interaction p-value is from the above ANCOVA model with additional factor/interaction of subgroup and subgroup by treatment.

Table 2.5.5.4: MG-QoL15r: AUC between Baseline and Week 20 of Change From Baseline in Total MG-QoL15r Score by Subgroup - ITT+

ANALYSIS SET: ITT+

	Interaction P-value	EFGARTIGIMOD (N=65)	PLACEBO (N=64)
CONCIMATANT TREATMENT	0.840		
NON-NSID			
n/N1 (%)		27/27 (100.0)	27/27 (100.0)
Mean (S.D.)		-110.2 (88.67)	-45.5 (73.09)
S.E.		17.06	14.07
95% C.I.		(-145.31; -75.16)	(-74.38; -16.55)
Median		-120.6	-36.0
Q1; Q3		(-177.0; -42.0)	(-99.5; 14.4)
Min; Max		(-298; 54)	(-219; 113)
Hedge's G		-0.79	
95% C.I.		(-1.332; -0.239)	
LS Mean (S.E.)		-115.9 (29.07)	-51.3 (29.07)
95% C.I.		(-174.28; -57.50)	(-109.72; 7.05)
LS Mean Differences (S.E.)		-64.6 (20.53)	
95% C.I.		(-105.80; -23.31)	
P-value		0.003	

S.D. = Standard Deviation; S.E. = Standard Error; AUC=Area Under the Curve; LS=Least Square
n is the number of patients with non-missing values, N1 is the total number of patients in the corresponding analysis set and subgroup regardless of missing value status, N is the total number of patients in the analysis set.
LS mean and LS mean difference is from an ANCOVA model with treatment, baseline score, Japanese/Non-Japanese and Standard Of Care(NSIDs/Non-NSIDs) as covariates. Interaction p-value is from the above ANCOVA model with additional factor/interaction of subgroup and subgroup by treatment.

Table 2.5.5.4: MG-QoL15r: AUC between Baseline and Week 20 of Change From Baseline in Total MG-QoL15r Score by Subgroup - ITT+

ANALYSIS SET: ITT+

	Interaction P-value	EFGARTIGIMOD (N=65)	PLACEBO (N=64)
THYMECTOMY PERFORMED FOR MG	0.682		
YES			
n/N1 (%)		45/45 (100.0)	30/30 (100.0)
Mean (S.D.)		-107.3 (93.97)	-53.5 (75.74)
S.E.		14.01	13.83
95% C.I.		(-135.50; -79.04)	(-81.79; -25.23)
Median		-102.8	-36.4
Q1; Q3		(-169.0; -42.5)	(-99.5; -2.5)
Min; Max		(-340; 83)	(-308; 63)
Hedge's G		-0.61	
95% C.I.		(-1.078; -0.143)	
LS Mean (S.E.)		-81.8 (19.41)	-20.6 (23.16)
95% C.I.		(-120.52; -43.11)	(-66.76; 25.61)
LS Mean Differences (S.E.)		-61.2 (18.55)	
95% C.I.		(-98.24; -24.24)	
P-value		0.002	

S.D. = Standard Deviation; S.E. = Standard Error; AUC=Area Under the Curve; LS=Least Square
n is the number of patients with non-missing values, N1 is the total number of patients in the corresponding analysis set and subgroup regardless of missing value status, N is the total number of patients in the analysis set.
LS mean and LS mean difference is from an ANCOVA model with treatment, baseline score, Japanese/Non-Japanese and Standard Of Care(NSIDs/Non-NSIDs) as covariates. Interaction p-value is from the above ANCOVA model with additional factor/interaction of subgroup and subgroup by treatment.

Table 2.5.5.4: MG-QoL15r: AUC between Baseline and Week 20 of Change From Baseline in Total MG-QoL15r Score by Subgroup - ITT+

ANALYSIS SET: ITT+

	Interaction P-value	EFGARTIGIMOD (N=65)	PLACEBO (N=64)
THYMECTOMY PERFORMED FOR MG	0.682		
NO			
n/N1 (%)		20/20 (100.0)	34/34 (100.0)
Mean (S.D.)		-108.1 (94.92)	-38.8 (74.64)
S.E.		21.22	12.80
95% C.I.		(-152.56; -63.71)	(-64.82; -12.74)
Median		-110.0	-33.0
Q1; Q3		(-185.5; -31.8)	(-90.0; 14.4)
Min; Max		(-298; 33)	(-219; 113)
Hedge's G		-0.83	
95% C.I.		(-1.393; -0.261)	
LS Mean (S.E.)		-106.0 (25.48)	-34.2 (21.62)
95% C.I.		(-157.18; -54.76)	(-77.67; 9.24)
LS Mean Differences (S.E.)		-71.8 (22.17)	
95% C.I.		(-116.32; -27.19)	
P-value		0.002	

S.D. = Standard Deviation; S.E. = Standard Error; AUC=Area Under the Curve; LS=Least Square
n is the number of patients with non-missing values, N1 is the total number of patients in the corresponding analysis set and subgroup regardless of missing value status, N is the total number of patients in the analysis set.
LS mean and LS mean difference is from an ANCOVA model with treatment, baseline score, Japanese/Non-Japanese and Standard Of Care(NSIDs/Non-NSIDs) as covariates. Interaction p-value is from the above ANCOVA model with additional factor/interaction of subgroup and subgroup by treatment.

Table 3.1.1.13: Overview of Treatment-Emergent Adverse Events up to Study Day 140 by Subgroup - Safety+

ANALYSIS SET: SAF+

	EFGARTIGIMOD (N=65) n/N1 (%)	PLACEBO (N=64) n/N1 (%)	ODDS RATIO (95% C.I.)	RELATIVE RISK (95% C.I.)	ARR (%) (95% C.I.)	P-VALUE*
REGION						
EU						
ALL TEAE	20 /25 (80.0)	23 /27 (85.2)	0.696 (0.164; 2.951)	0.939 (0.730; 1.207)	-5.2 (-26.3; 15.7)	0.722
MILD TEAE	14 /25 (56.0)	19 /27 (70.4)	0.536 (0.171; 1.680)	0.796 (0.520; 1.217)	-14.4 (-37.8; 11.2)	0.389
MODERATE TEAE	13 /25 (52.0)	10 /27 (37.0)	1.842 (0.609; 5.572)	1.404 (0.756; 2.608)	15.0 (-11.4; 38.7)	0.402
SEVERE TEAE	2 /25 (8.0)	3 /27 (11.1)	0.696 (0.106; 4.552)	0.720 (0.131; 3.959)	-3.1 (-21.0; 15.3)	1.000
SERIOUS TEAE	1 /25 (4.0)	3 /27 (11.1)	0.333 (0.032; 3.436)	0.360 (0.040; 3.239)	-7.1 (-24.4; 10.0)	0.611
ALL TEAESI	8 /25 (32.0)	5 /27 (18.5)	2.071 (0.573; 7.478)	1.728 (0.651; 4.586)	13.5 (-10.0; 35.6)	0.343
MILD TEAESI	4 /25 (16.0)	4 /27 (14.8)	1.095 (0.243; 4.942)	1.080 (0.302; 3.864)	1.2 (-18.9; 21.9)	1.000
MODERATE TEAESI	4 /25 (16.0)	2 /27 (7.4)	2.381 (0.396; 14.315)	2.160 (0.433; 10.783)	8.6 (-10.0; 28.0)	0.411
SEVERE TEAESI	0 /25	0 /27				
SERIOUS TEAESI	0 /25	0 /27				
TEAE LEADING TO TRT DISCONTINUATION	1 /25 (4.0)	1 /27 (3.7)	1.083 (0.064; 18.299)	1.080 (0.071; 16.360)	0.3 (-14.7; 16.1)	1.000
NON-EU						
ALL TEAE	29 /40 (72.5)	31 /37 (83.8)	0.510 (0.167; 1.558)	0.865 (0.682; 1.098)	-11.3 (-28.8; 7.5)	0.279
MILD TEAE	27 /40 (67.5)	26 /37 (70.3)	0.879 (0.334; 2.311)	0.961 (0.711; 1.297)	-2.8 (-22.5; 17.5)	0.811
MODERATE TEAE	16 /40 (40.0)	17 /37 (45.9)	0.784 (0.317; 1.938)	0.871 (0.520; 1.458)	-5.9 (-26.7; 15.5)	0.650
SEVERE TEAE	3 /40 (7.5)	4 /37 (10.8)	0.669 (0.139; 3.211)	0.694 (0.166; 2.895)	-3.3 (-18.1; 10.7)	0.705
SERIOUS TEAE	1 /40 (2.5)	3 /37 (8.1)	0.291 (0.029; 2.926)	0.308 (0.034; 2.835)	-5.6 (-19.0; 6.1)	0.346
ALL TEAESI	21 /40 (52.5)	16 /37 (43.2)	1.451 (0.590; 3.564)	1.214 (0.757; 1.947)	9.3 (-12.6; 29.9)	0.496
MILD TEAESI	14 /40 (35.0)	7 /37 (18.9)	2.308 (0.809; 6.583)	1.850 (0.840; 4.074)	16.1 (-3.9; 34.2)	0.132
MODERATE TEAESI	10 /40 (25.0)	10 /37 (27.0)	0.900 (0.325; 2.494)	0.925 (0.435; 1.966)	-2.0 (-21.3; 17.1)	1.000
SEVERE TEAESI	1 /40 (2.5)	1 /37 (2.7)	0.923 (0.056; 15.310)	0.925 (0.060; 14.261)	-0.2 (-11.5; 10.4)	1.000
SERIOUS TEAESI	0 /40 (0.0)	1 /37 (2.7)	0.300 (0.012; 7.607)	0.309 (0.013; 7.355)	-2.7 (-13.8; 6.3)	0.481
TEAE LEADING TO TRT DISCONTINUATION	1 /40 (2.5)	2 /37 (5.4)	0.449 (0.039; 5.166)	0.463 (0.044; 4.891)	-2.9 (-15.4; 8.2)	0.605

TEAE=Treatment-Emergent Adverse Event; TEAESI= Treatment-Emergent Adverse Event of Special Interest; TRT=Treatment;
ARR=Absolute Risk Reduction.
n is the number of patients with at least one adverse event, N1 is the total number of patients in the subgroup and analysis set,
N is the total number of patients in the analysis set. The denominator for the percentage calculations is N1.
0.5 is added if any cell count is zero for odds ratio and relative risk calculation.
* P-value is from Fisher's exact test.
Program: /clinical/argx-113/mg/argx-113-1704/biostat/staging/gba/programs/t_ae_by_subgroup.sas, Version: 0.6

Table 3.1.1.13: Overview of Treatment-Emergent Adverse Events up to Study Day 140 by Subgroup - Safety+

ANALYSIS SET: SAF+

	EFGARTIGIMOD (N=65) n/N1 (%)	PLACEBO (N=64) n/N1 (%)	ODDS RATIO (95% C.I.)	RELATIVE RISK (95% C.I.)	ARR (%) (95% C.I.)	P-VALUE*
AGE CATEGORY						
18 - <65 years						
ALL TEAE	43 /57 (75.4)	43 /51 (84.3)	0.571 (0.217; 1.501)	0.895 (0.740; 1.082)	-8.9 (-23.5; 6.6)	0.340
MILD TEAE	36 /57 (63.2)	36 /51 (70.6)	0.714 (0.318; 1.602)	0.895 (0.686; 1.167)	-7.4 (-24.3; 10.3)	0.540
MODERATE TEAE	25 /57 (43.9)	18 /51 (35.3)	1.432 (0.659; 3.115)	1.243 (0.774; 1.996)	8.6 (-9.7; 25.9)	0.433
SEVERE TEAE	5 /57 (8.8)	6 /51 (11.8)	0.721 (0.206; 2.522)	0.746 (0.242; 2.297)	-3.0 (-15.6; 9.0)	0.753
SERIOUS TEAE	2 /57 (3.5)	5 /51 (9.8)	0.335 (0.062; 1.806)	0.358 (0.073; 1.765)	-6.3 (-17.8; 3.8)	0.251
ALL TEAESI	25 /57 (43.9)	15 /51 (29.4)	1.875 (0.844; 4.164)	1.491 (0.889; 2.500)	14.4 (-3.7; 31.2)	0.162
MILD TEAESI	16 /57 (28.1)	8 /51 (15.7)	2.098 (0.811; 5.426)	1.789 (0.837; 3.826)	12.4 (-3.5; 27.2)	0.165
MODERATE TEAESI	12 /57 (21.1)	7 /51 (13.7)	1.676 (0.604; 4.651)	1.534 (0.654; 3.596)	7.3 (-7.4; 21.4)	0.448
SEVERE TEAESI	1 /57 (1.8)	1 /51 (2.0)	0.893 (0.054; 14.652)	0.895 (0.057; 13.939)	-0.2 (-8.7; 7.5)	1.000
SERIOUS TEAESI	0 /57 (0.0)	1 /51 (2.0)	0.293 (0.012; 7.348)	0.299 (0.012; 7.177)	-2.0 (-10.3; 4.6)	0.472
TEAE LEADING TO TRT DISCONTINUATION	2 /57 (3.5)	2 /51 (3.9)	0.891 (0.121; 6.566)	0.895 (0.131; 6.123)	-0.4 (-10.0; 8.5)	1.000
>= 65 years						
ALL TEAE	6 /8 (75.0)	11 /13 (84.6)	0.545 (0.061; 4.913)	0.886 (0.558; 1.407)	-9.6 (-45.4; 22.6)	0.618
MILD TEAE	5 /8 (62.5)	9 /13 (69.2)	0.741 (0.116; 4.728)	0.903 (0.472; 1.725)	-6.7 (-43.4; 29.2)	1.000
MODERATE TEAE	4 /8 (50.0)	9 /13 (69.2)	0.444 (0.072; 2.740)	0.722 (0.330; 1.579)	-19.2 (-53.0; 19.9)	0.646
SEVERE TEAE	0 /8 (0.0)	1 /13 (7.7)	0.490 (0.018; 13.520)	0.519 (0.024; 11.386)	-7.7 (-33.3; 25.4)	1.000
SERIOUS TEAE	0 /8 (0.0)	1 /13 (7.7)	0.490 (0.018; 13.520)	0.519 (0.024; 11.386)	-7.7 (-33.3; 25.4)	1.000
ALL TEAESI	4 /8 (50.0)	6 /13 (46.2)	1.167 (0.200; 6.805)	1.083 (0.437; 2.687)	3.8 (-33.9; 40.4)	1.000
MILD TEAESI	2 /8 (25.0)	3 /13 (23.1)	1.111 (0.142; 8.680)	1.083 (0.228; 5.142)	1.9 (-30.6; 39.1)	1.000
MODERATE TEAESI	2 /8 (25.0)	5 /13 (38.5)	0.533 (0.076; 3.755)	0.650 (0.163; 2.592)	-13.5 (-45.0; 26.4)	0.656
SEVERE TEAESI	0 /8	0 /13				
SERIOUS TEAESI	0 /8	0 /13				
TEAE LEADING TO TRT DISCONTINUATION	0 /8 (0.0)	1 /13 (7.7)	0.490 (0.018; 13.520)	0.519 (0.024; 11.386)	-7.7 (-33.3; 25.4)	1.000

TEAE=Treatment-Emergent Adverse Event; TEAESI= Treatment-Emergent Adverse Event of Special Interest; TRT=Treatment;
ARR=Absolute Risk Reduction.
n is the number of patients with at least one adverse event, N1 is the total number of patients in the subgroup and analysis set,
N is the total number of patients in the analysis set. The denominator for the percentage calculations is N1.
0.5 is added if any cell count is zero for odds ratio and relative risk calculation.
* P-value is from Fisher's exact test.
Program: /clinical/argx-113/mg/argx-113-1704/biostat/staging/gba/programs/t_ae_by_subgroup.sas, Version: 0.6

Table 3.1.1.13: Overview of Treatment-Emergent Adverse Events up to Study Day 140 by Subgroup - Safety+

ANALYSIS SET: SAF+

	EFGARTIGIMOD (N=65) n/N1 (%)	PLACEBO (N=64) n/N1 (%)	ODDS RATIO (95% C.I.)	RELATIVE RISK (95% C.I.)	ARR (%) (95% C.I.)	P-VALUE*
SEX						
FEMALE						
ALL TEAE	34 /46 (73.9)	33 /40 (82.5)	0.601 (0.211; 1.714)	0.896 (0.717; 1.120)	-8.6 (-25.2; 9.3)	0.437
MILD TEAE	28 /46 (60.9)	28 /40 (70.0)	0.667 (0.271; 1.638)	0.870 (0.639; 1.183)	-9.1 (-27.8; 10.9)	0.497
MODERATE TEAE	22 /46 (47.8)	18 /40 (45.0)	1.120 (0.479; 2.622)	1.063 (0.673; 1.678)	2.8 (-17.6; 22.9)	0.831
SEVERE TEAE	5 /46 (10.9)	2 /40 (5.0)	2.317 (0.424; 12.660)	2.174 (0.446; 10.598)	5.9 (-7.2; 18.6)	0.442
SERIOUS TEAE	2 /46 (4.3)	1 /40 (2.5)	1.773 (0.155; 20.315)	1.739 (0.164; 18.470)	1.8 (-9.0; 12.2)	1.000
ALL TEAESI	21 /46 (45.7)	15 /40 (37.5)	1.400 (0.590; 3.321)	1.217 (0.731; 2.026)	8.2 (-12.4; 27.6)	0.514
MILD TEAESI	10 /46 (21.7)	8 /40 (20.0)	1.111 (0.391; 3.158)	1.087 (0.475; 2.487)	1.7 (-15.8; 18.5)	1.000
MODERATE TEAESI	14 /46 (30.4)	8 /40 (20.0)	1.750 (0.646; 4.744)	1.522 (0.713; 3.248)	10.4 (-8.2; 27.7)	0.326
SEVERE TEAESI	1 /46 (2.2)	1 /40 (2.5)	0.867 (0.052; 14.320)	0.870 (0.056; 13.457)	-0.3 (-10.9; 9.1)	1.000
SERIOUS TEAESI	0 /46 (0.0)	1 /40 (2.5)	0.283 (0.011; 7.148)	0.291 (0.012; 6.944)	-2.5 (-12.9; 5.5)	0.465
TEAE LEADING TO TRT DISCONTINUATION	2 /46 (4.3)	0 /40 (0.0)	4.551 (0.212; 97.642)	4.362 (0.216; 88.252)	4.3 (-5.0; 14.5)	0.497
MALE						
ALL TEAE	15 /19 (78.9)	21 /24 (87.5)	0.536 (0.104; 2.754)	0.902 (0.684; 1.190)	-8.6 (-32.3; 13.8)	0.680
MILD TEAE	13 /19 (68.4)	17 /24 (70.8)	0.892 (0.241; 3.299)	0.966 (0.648; 1.440)	-2.4 (-29.0; 23.3)	1.000
MODERATE TEAE	7 /19 (36.8)	9 /24 (37.5)	0.972 (0.280; 3.379)	0.982 (0.449; 2.150)	-0.7 (-27.2; 26.8)	1.000
SEVERE TEAE	0 /19 (0.0)	5 /24 (20.8)	0.091 (0.005; 1.758)	0.114 (0.007; 1.935)	-20.8 (-40.5; -0.4)	0.056
SERIOUS TEAE	0 /19 (0.0)	5 /24 (20.8)	0.091 (0.005; 1.758)	0.114 (0.007; 1.935)	-20.8 (-40.5; -0.4)	0.056
ALL TEAESI	8 /19 (42.1)	6 /24 (25.0)	2.182 (0.596; 7.984)	1.684 (0.705; 4.023)	17.1 (-10.4; 42.3)	0.329
MILD TEAESI	8 /19 (42.1)	3 /24 (12.5)	5.091 (1.120; 23.142)	3.368 (1.032; 10.990)	29.6 (3.1; 52.7)	0.038
MODERATE TEAESI	0 /19 (0.0)	4 /24 (16.7)	0.117 (0.006; 2.315)	0.139 (0.008; 2.430)	-16.7 (-35.9; 2.9)	0.118
SEVERE TEAESI	0 /19	0 /24				
SERIOUS TEAESI	0 /19	0 /24				
TEAE LEADING TO TRT DISCONTINUATION	0 /19 (0.0)	3 /24 (12.5)	0.158 (0.008; 3.247)	0.179 (0.010; 3.259)	-12.5 (-31.0; 6.2)	0.243

TEAE=Treatment-Emergent Adverse Event; TEAESI= Treatment-Emergent Adverse Event of Special Interest; TRT=Treatment;
ARR=Absolute Risk Reduction.
n is the number of patients with at least one adverse event, N1 is the total number of patients in the subgroup and analysis set,
N is the total number of patients in the analysis set. The denominator for the percentage calculations is N1.
0.5 is added if any cell count is zero for odds ratio and relative risk calculation.
* P-value is from Fisher's exact test.
Program: /clinical/argx-113/mg/argx-113-1704/biostat/staging/gba/programs/t_ae_by_subgroup.sas, Version: 0.6

Table 3.1.1.13: Overview of Treatment-Emergent Adverse Events up to Study Day 140 by Subgroup - Safety+

ANALYSIS SET: SAF+

	EFGARTIGIMOD (N=65) n/N1 (%)	PLACEBO (N=64) n/N1 (%)	ODDS RATIO (95% C.I.)	RELATIVE RISK (95% C.I.)	ARR (%) (95% C.I.)	P-VALUE*
RACE						
WHITE						
ALL TEAE	39 /54 (72.2)	46 /56 (82.1)	0.565 (0.228; 1.400)	0.879 (0.716; 1.080)	-9.9 (-25.2; 5.8)	0.259
MILD TEAE	31 /54 (57.4)	40 /56 (71.4)	0.539 (0.244; 1.190)	0.804 (0.605; 1.067)	-14.0 (-30.7; 3.8)	0.163
MODERATE TEAE	25 /54 (46.3)	22 /56 (39.3)	1.332 (0.625; 2.842)	1.178 (0.763; 1.819)	7.0 (-11.2; 24.6)	0.563
SEVERE TEAE	5 /54 (9.3)	4 /56 (7.1)	1.327 (0.337; 5.228)	1.296 (0.368; 4.572)	2.1 (-9.0; 13.6)	0.740
SERIOUS TEAE	2 /54 (3.7)	4 /56 (7.1)	0.500 (0.088; 2.850)	0.519 (0.099; 2.715)	-3.4 (-13.6; 6.4)	0.679
ALL TEAESI	25 /54 (46.3)	16 /56 (28.6)	2.155 (0.979; 4.743)	1.620 (0.979; 2.682)	17.7 (-0.3; 34.3)	0.076
MILD TEAESI	15 /54 (27.8)	11 /56 (19.6)	1.573 (0.647; 3.825)	1.414 (0.715; 2.798)	8.1 (-7.7; 23.7)	0.373
MODERATE TEAESI	12 /54 (22.2)	7 /56 (12.5)	2.000 (0.722; 5.542)	1.778 (0.757; 4.176)	9.7 (-4.6; 23.9)	0.213
SEVERE TEAESI	1 /54 (1.9)	1 /56 (1.8)	1.038 (0.063; 17.020)	1.037 (0.067; 16.165)	0.1 (-7.7; 8.1)	1.000
SERIOUS TEAESI	0 /54 (0.0)	1 /56 (1.8)	0.339 (0.014; 8.516)	0.345 (0.014; 8.300)	-1.8 (-9.4; 5.0)	1.000
TEAE LEADING TO TRT DISCONTINUATION	2 /54 (3.7)	2 /56 (3.6)	1.038 (0.141; 7.647)	1.037 (0.151; 7.102)	0.1 (-8.8; 9.3)	1.000
NON-WHITE						
ALL TEAE	10 /11 (90.9)	8 /8 (100.0)	0.412 (0.015; 11.457)	0.926 (0.710; 1.209)	-9.1 (-37.7; 24.2)	1.000
MILD TEAE	10 /11 (90.9)	5 /8 (62.5)	6.000 (0.490; 73.452)	1.455 (0.824; 2.568)	28.4 (-8.8; 61.2)	0.262
MODERATE TEAE	4 /11 (36.4)	5 /8 (62.5)	0.343 (0.052; 2.261)	0.582 (0.225; 1.502)	-26.1 (-58.0; 16.5)	0.370
SEVERE TEAE	0 /11 (0.0)	3 /8 (37.5)	0.068 (0.003; 1.567)	0.107 (0.006; 1.823)	-37.5 (-69.4; -2.3)	0.058
SERIOUS TEAE	0 /11 (0.0)	2 /8 (25.0)	0.113 (0.005; 2.732)	0.150 (0.008; 2.756)	-25.0 (-59.1; 6.4)	0.164
ALL TEAESI	4 /11 (36.4)	5 /8 (62.5)	0.343 (0.052; 2.261)	0.582 (0.225; 1.502)	-26.1 (-58.0; 16.5)	0.370
MILD TEAESI	3 /11 (27.3)	0 /8 (0.0)	7.000 (0.312; 157.26)	5.250 (0.308; 89.351)	27.3 (-9.6; 56.6)	0.228
MODERATE TEAESI	2 /11 (18.2)	5 /8 (62.5)	0.133 (0.016; 1.085)	0.291 (0.074; 1.138)	-44.3 (-71.5; -0.8)	0.074
SEVERE TEAESI	0 /11	0 /8				
SERIOUS TEAESI	0 /11	0 /8				
TEAE LEADING TO TRT DISCONTINUATION	0 /11 (0.0)	1 /8 (12.5)	0.217 (0.008; 6.075)	0.250 (0.011; 5.449)	-12.5 (-47.1; 15.3)	0.421

TEAE=Treatment-Emergent Adverse Event; TEAESI= Treatment-Emergent Adverse Event of Special Interest; TRT=Treatment;
ARR=Absolute Risk Reduction.
n is the number of patients with at least one adverse event, N1 is the total number of patients in the subgroup and analysis set,
N is the total number of patients in the analysis set. The denominator for the percentage calculations is N1.
0.5 is added if any cell count is zero for odds ratio and relative risk calculation.
* P-value is from Fisher's exact test.
Program: /clinical/argx-113/mg/argx-113-1704/biostat/staging/gba/programs/t_ae_by_subgroup.sas, Version: 0.6

Table 3.1.1.13: Overview of Treatment-Emergent Adverse Events up to Study Day 140 by Subgroup - Safety+

ANALYSIS SET: SAF+

	EFGARTIGIMOD (N=65) n/N1 (%)	PLACEBO (N=64) n/N1 (%)	ODDS RATIO (95% C.I.)	RELATIVE RISK (95% C.I.)	ARR (%) (95% C.I.)	P-VALUE*
BASELEINE MG-ADL TOTAL SCORE						
MILD (5-7)						
ALL TEAE	11 /16 (68.8)	16 /18 (88.9)	0.275 (0.045; 1.681)	0.773 (0.535; 1.118)	-20.1 (-45.8; 7.5)	0.214
MILD TEAE	8 /16 (50.0)	11 /18 (61.1)	0.636 (0.163; 2.487)	0.818 (0.443; 1.510)	-11.1 (-39.9; 20.4)	0.730
MODERATE TEAE	6 /16 (37.5)	12 /18 (66.7)	0.300 (0.073; 1.227)	0.563 (0.276; 1.146)	-29.2 (-54.7; 3.9)	0.168
SEVERE TEAE	0 /16 (0.0)	1 /18 (5.6)	0.354 (0.013; 9.307)	0.373 (0.016; 8.547)	-5.6 (-25.8; 14.3)	1.000
SERIOUS TEAE	0 /16	0 /18				
ALL TEAESI	8 /16 (50.0)	7 /18 (38.9)	1.571 (0.402; 6.142)	1.286 (0.602; 2.745)	11.1 (-20.4; 39.9)	0.730
MILD TEAESI	4 /16 (25.0)	4 /18 (22.2)	1.167 (0.239; 5.698)	1.125 (0.335; 3.778)	2.8 (-24.6; 30.6)	1.000
MODERATE TEAESI	4 /16 (25.0)	5 /18 (27.8)	0.867 (0.187; 4.007)	0.900 (0.291; 2.784)	-2.8 (-30.2; 26.1)	1.000
SEVERE TEAESI	0 /16	0 /18				
SERIOUS TEAESI	0 /16	0 /18				
TEAE LEADING TO TRT DISCONTINUATION	0 /16	0 /18				
MODERATE (8-9)						
ALL TEAE	20 /25 (80.0)	24 /29 (82.8)	0.833 (0.211; 3.294)	0.967 (0.748; 1.250)	-2.8 (-24.2; 17.8)	1.000
MILD TEAE	17 /25 (68.0)	20 /29 (69.0)	0.956 (0.302; 3.023)	0.986 (0.686; 1.418)	-1.0 (-24.9; 22.5)	1.000
MODERATE TEAE	12 /25 (48.0)	10 /29 (34.5)	1.754 (0.586; 5.250)	1.392 (0.729; 2.657)	13.5 (-12.0; 37.0)	0.407
SEVERE TEAE	2 /25 (8.0)	4 /29 (13.8)	0.543 (0.091; 3.253)	0.580 (0.116; 2.904)	-5.8 (-23.5; 13.1)	0.675
SERIOUS TEAE	1 /25 (4.0)	3 /29 (10.3)	0.361 (0.035; 3.712)	0.387 (0.043; 3.486)	-6.3 (-22.7; 10.6)	0.615
ALL TEAESI	9 /25 (36.0)	10 /29 (34.5)	1.069 (0.349; 3.274)	1.044 (0.506; 2.154)	1.5 (-22.5; 25.8)	1.000
MILD TEAESI	4 /25 (16.0)	4 /29 (13.8)	1.190 (0.265; 5.348)	1.160 (0.323; 4.166)	2.2 (-17.1; 22.6)	1.000
MODERATE TEAESI	5 /25 (20.0)	6 /29 (20.7)	0.958 (0.254; 3.622)	0.967 (0.335; 2.789)	-0.7 (-21.6; 21.3)	1.000
SEVERE TEAESI	1 /25 (4.0)	1 /29 (3.4)	1.167 (0.069; 19.670)	1.160 (0.076; 17.604)	0.6 (-13.6; 16.4)	1.000
SERIOUS TEAESI	0 /25 (0.0)	1 /29 (3.4)	0.373 (0.015; 9.559)	0.385 (0.016; 9.041)	-3.4 (-17.2; 10.2)	1.000
TEAE LEADING TO TRT DISCONTINUATION	1 /25 (4.0)	1 /29 (3.4)	1.167 (0.069; 19.670)	1.160 (0.076; 17.604)	0.6 (-13.6; 16.4)	1.000

TEAE=Treatment-Emergent Adverse Event; TEAESI= Treatment-Emergent Adverse Event of Special Interest; TRT=Treatment;
ARR=Absolute Risk Reduction.
n is the number of patients with at least one adverse event, N1 is the total number of patients in the subgroup and analysis set,
N is the total number of patients in the analysis set. The denominator for the percentage calculations is N1.
0.5 is added if any cell count is zero for odds ratio and relative risk calculation.
* P-value is from Fisher's exact test.
Program: /clinical/argx-113/mg/argx-113-1704/biostat/staging/gba/programs/t_ae_by_subgroup.sas, Version: 0.6

Table 3.1.1.13: Overview of Treatment-Emergent Adverse Events up to Study Day 140 by Subgroup - Safety+

ANALYSIS SET: SAF+

	EFGARTIGIMOD (N=65) n/N1 (%)	PLACEBO (N=64) n/N1 (%)	ODDS RATIO (95% C.I.)	RELATIVE RISK (95% C.I.)	ARR (%) (95% C.I.)	P-VALUE*
BASELEINE MG-ADL TOTAL SCORE SEVERE (>=10)						
ALL TEAE	18 /24 (75.0)	14 /17 (82.4)	0.643 (0.136; 3.035)	0.911 (0.662; 1.253)	-7.4 (-30.3; 19.4)	0.711
MILD TEAE	16 /24 (66.7)	14 /17 (82.4)	0.429 (0.095; 1.937)	0.810 (0.566; 1.158)	-15.7 (-38.7; 12.3)	0.309
MODERATE TEAE	11 /24 (45.8)	5 /17 (29.4)	2.031 (0.544; 7.575)	1.558 (0.663; 3.665)	16.4 (-13.3; 41.4)	0.344
SEVERE TEAE	3 /24 (12.5)	2 /17 (11.8)	1.071 (0.159; 7.221)	1.063 (0.198; 5.689)	0.7 (-23.3; 21.1)	1.000
SERIOUS TEAE	1 /24 (4.2)	3 /17 (17.6)	0.203 (0.019; 2.146)	0.236 (0.027; 2.081)	-13.5 (-37.1; 6.3)	0.290
ALL TEAESI	12 /24 (50.0)	4 /17 (23.5)	3.250 (0.820; 12.880)	2.125 (0.825; 5.471)	26.5 (-3.7; 49.7)	0.113
MILD TEAESI	10 /24 (41.7)	3 /17 (17.6)	3.333 (0.753; 14.757)	2.361 (0.762; 7.315)	24.0 (-5.0; 46.6)	0.173
MODERATE TEAESI	5 /24 (20.8)	1 /17 (5.9)	4.211 (0.445; 39.855)	3.542 (0.454; 27.654)	15.0 (-9.1; 35.2)	0.373
SEVERE TEAESI	0 /24	0 /17				
SERIOUS TEAESI	0 /24	0 /17				
TEAE LEADING TO TRT DISCONTINUATION	1 /24 (4.2)	2 /17 (11.8)	0.326 (0.027; 3.921)	0.354 (0.035; 3.599)	-7.6 (-30.4; 10.6)	0.560

TEAE=Treatment-Emergent Adverse Event; TEAESI= Treatment-Emergent Adverse Event of Special Interest; TRT=Treatment;
ARR=Absolute Risk Reduction.
n is the number of patients with at least one adverse event, N1 is the total number of patients in the subgroup and analysis set,
N is the total number of patients in the analysis set. The denominator for the percentage calculations is N1.
0.5 is added if any cell count is zero for odds ratio and relative risk calculation.
* P-value is from Fisher's exact test.
Program: /clinical/argx-113/mg/argx-113-1704/biostat/staging/gba/programs/t_ae_by_subgroup.sas, Version: 0.6

Table 3.1.1.13: Overview of Treatment-Emergent Adverse Events up to Study Day 140 by Subgroup - Safety+

ANALYSIS SET: SAF+

	EFGARTIGIMOD (N=65) n/N1 (%)	PLACEBO (N=64) n/N1 (%)	ODDS RATIO (95% C.I.)	RELATIVE RISK (95% C.I.)	ARR (%) (95% C.I.)	P-VALUE*
CONCOMITANT TREATMENT						
NSID						
ALL TEAE	28 /38 (73.7)	30 /37 (81.1)	0.653 (0.219; 1.952)	0.909 (0.711; 1.162)	-7.4 (-25.7; 11.6)	0.583
MILD TEAE	25 /38 (65.8)	24 /37 (64.9)	1.042 (0.402; 2.697)	1.014 (0.729; 1.411)	0.9 (-19.8; 21.6)	1.000
MODERATE TEAE	15 /38 (39.5)	10 /37 (27.0)	1.761 (0.665; 4.666)	1.461 (0.755; 2.825)	12.4 (-8.7; 32.1)	0.329
SEVERE TEAE	3 /38 (7.9)	4 /37 (10.8)	0.707 (0.147; 3.401)	0.730 (0.175; 3.042)	-2.9 (-17.7; 11.5)	0.711
SERIOUS TEAE	1 /38 (2.6)	4 /37 (10.8)	0.223 (0.024; 2.097)	0.243 (0.029; 2.077)	-8.2 (-22.2; 4.5)	0.200
ALL TEAESI	18 /38 (47.4)	11 /37 (29.7)	2.127 (0.823; 5.500)	1.593 (0.876; 2.898)	17.6 (-4.3; 37.3)	0.156
MILD TEAESI	12 /38 (31.6)	6 /37 (16.2)	2.385 (0.786; 7.236)	1.947 (0.817; 4.644)	15.4 (-4.1; 33.4)	0.176
MODERATE TEAESI	7 /38 (18.4)	5 /37 (13.5)	1.445 (0.414; 5.041)	1.363 (0.475; 3.913)	4.9 (-12.2; 21.7)	0.754
SEVERE TEAESI	1 /38 (2.6)	0 /37 (0.0)	3.000 (0.118; 76.025)	2.923 (0.123; 69.541)	2.6 (-7.0; 13.5)	1.000
SERIOUS TEAESI	0 /38	0 /37				
TEAE LEADING TO TRT DISCONTINUATION	1 /38 (2.6)	2 /37 (5.4)	0.473 (0.041; 5.451)	0.487 (0.046; 5.143)	-2.8 (-15.3; 8.8)	0.615
NON-NSID						
ALL TEAE	21 /27 (77.8)	24 /27 (88.9)	0.438 (0.097; 1.970)	0.875 (0.687; 1.114)	-11.1 (-31.0; 9.4)	0.467
MILD TEAE	16 /27 (59.3)	21 /27 (77.8)	0.416 (0.127; 1.364)	0.762 (0.525; 1.105)	-18.5 (-40.4; 6.1)	0.241
MODERATE TEAE	14 /27 (51.9)	17 /27 (63.0)	0.633 (0.214; 1.877)	0.824 (0.518; 1.310)	-11.1 (-34.8; 14.5)	0.583
SEVERE TEAE	2 /27 (7.4)	3 /27 (11.1)	0.640 (0.098; 4.173)	0.667 (0.121; 3.678)	-3.7 (-21.5; 13.8)	1.000
SERIOUS TEAE	1 /27 (3.7)	2 /27 (7.4)	0.481 (0.041; 5.641)	0.500 (0.048; 5.193)	-3.7 (-20.0; 11.8)	1.000
ALL TEAESI	11 /27 (40.7)	10 /27 (37.0)	1.169 (0.391; 3.494)	1.100 (0.563; 2.150)	3.7 (-21.1; 27.9)	1.000
MILD TEAESI	6 /27 (22.2)	5 /27 (18.5)	1.257 (0.333; 4.748)	1.200 (0.416; 3.464)	3.7 (-17.9; 24.9)	1.000
MODERATE TEAESI	7 /27 (25.9)	7 /27 (25.9)	1.000 (0.296; 3.378)	1.000 (0.406; 2.464)	0.0 (-22.7; 22.7)	1.000
SEVERE TEAESI	0 /27 (0.0)	1 /27 (3.7)	0.321 (0.013; 8.241)	0.333 (0.014; 7.837)	-3.7 (-18.3; 9.1)	1.000
SERIOUS TEAESI	0 /27 (0.0)	1 /27 (3.7)	0.321 (0.013; 8.241)	0.333 (0.014; 7.837)	-3.7 (-18.3; 9.1)	1.000
TEAE LEADING TO TRT DISCONTINUATION	1 /27 (3.7)	1 /27 (3.7)	1.000 (0.059; 16.854)	1.000 (0.066; 15.180)	0.0 (-14.9; 14.9)	1.000

TEAE=Treatment-Emergent Adverse Event; TEAESI= Treatment-Emergent Adverse Event of Special Interest; TRT=Treatment;
ARR=Absolute Risk Reduction.
n is the number of patients with at least one adverse event, N1 is the total number of patients in the subgroup and analysis set,
N is the total number of patients in the analysis set. The denominator for the percentage calculations is N1.
0.5 is added if any cell count is zero for odds ratio and relative risk calculation.
* P-value is from Fisher's exact test.
Program: /clinical/argx-113/mg/argx-113-1704/biostat/staging/gba/programs/t_ae_by_subgroup.sas, Version: 0.6

Table 3.1.1.13: Overview of Treatment-Emergent Adverse Events up to Study Day 140 by Subgroup - Safety+

ANALYSIS SET: SAF+

	EFGARTIGIMOD (N=65) n/N1 (%)	PLACEBO (N=64) n/N1 (%)	ODDS RATIO (95% C.I.)	RELATIVE RISK (95% C.I.)	ARR (%) (95% C.I.)	P-VALUE*
THYMECTOMY PERFORMED FOR MG						
YES						
ALL TEAE	36 /45 (80.0)	25 /30 (83.3)	0.800 (0.239; 2.673)	0.960 (0.773; 1.192)	-3.3 (-20.0; 15.9)	0.772
MILD TEAE	31 /45 (68.9)	20 /30 (66.7)	1.107 (0.413; 2.971)	1.033 (0.750; 1.423)	2.2 (-18.0; 23.5)	1.000
MODERATE TEAE	21 /45 (46.7)	8 /30 (26.7)	2.406 (0.886; 6.534)	1.750 (0.895; 3.422)	20.0 (-2.5; 38.9)	0.095
SEVERE TEAE	4 /45 (8.9)	2 /30 (6.7)	1.366 (0.234; 7.971)	1.333 (0.260; 6.828)	2.2 (-13.4; 15.0)	1.000
SERIOUS TEAE	1 /45 (2.2)	2 /30 (6.7)	0.318 (0.028; 3.675)	0.333 (0.032; 3.515)	-4.4 (-19.2; 6.1)	0.560
ALL TEAESI	21 /45 (46.7)	8 /30 (26.7)	2.406 (0.886; 6.534)	1.750 (0.895; 3.422)	20.0 (-2.5; 38.9)	0.095
MILD TEAESI	12 /45 (26.7)	6 /30 (20.0)	1.455 (0.478; 4.423)	1.333 (0.562; 3.164)	6.7 (-13.7; 24.5)	0.589
MODERATE TEAESI	12 /45 (26.7)	2 /30 (6.7)	5.091 (1.049; 24.701)	4.000 (0.963; 16.613)	20.0 (1.9; 35.2)	0.036
SEVERE TEAESI	1 /45 (2.2)	0 /30 (0.0)	2.056 (0.081; 52.167)	2.022 (0.085; 48.038)	2.2 (-9.3; 11.6)	1.000
SERIOUS TEAESI	0 /45	0 /30				
TEAE LEADING TO TRT DISCONTINUATION	1 /45 (2.2)	1 /30 (3.3)	0.659 (0.040; 10.960)	0.667 (0.043; 10.253)	-1.1 (-14.6; 8.6)	1.000
NO						
ALL TEAE	13 /20 (65.0)	29 /34 (85.3)	0.320 (0.085; 1.200)	0.762 (0.537; 1.082)	-20.3 (-43.5; 2.6)	0.101
MILD TEAE	10 /20 (50.0)	25 /34 (73.5)	0.360 (0.113; 1.150)	0.680 (0.420; 1.102)	-23.5 (-46.8; 2.5)	0.139
MODERATE TEAE	8 /20 (40.0)	19 /34 (55.9)	0.526 (0.171; 1.616)	0.716 (0.387; 1.323)	-15.9 (-39.6; 11.1)	0.398
SEVERE TEAE	1 /20 (5.0)	5 /34 (14.7)	0.305 (0.033; 2.821)	0.340 (0.043; 2.707)	-9.7 (-25.7; 10.7)	0.395
SERIOUS TEAE	1 /20 (5.0)	4 /34 (11.8)	0.395 (0.041; 3.803)	0.425 (0.051; 3.543)	-6.8 (-22.2; 13.2)	0.640
ALL TEAESI	8 /20 (40.0)	13 /34 (38.2)	1.077 (0.348; 3.336)	1.046 (0.527; 2.077)	1.8 (-22.9; 27.5)	1.000
MILD TEAESI	6 /20 (30.0)	5 /34 (14.7)	2.486 (0.646; 9.563)	2.040 (0.714; 5.832)	15.3 (-6.5; 38.7)	0.294
MODERATE TEAESI	2 /20 (10.0)	10 /34 (29.4)	0.267 (0.052; 1.370)	0.340 (0.083; 1.398)	-19.4 (-37.7; 4.3)	0.174
SEVERE TEAESI	0 /20 (0.0)	1 /34 (2.9)	0.545 (0.021; 14.013)	0.556 (0.024; 13.024)	-2.9 (-14.9; 13.4)	1.000
SERIOUS TEAESI	0 /20 (0.0)	1 /34 (2.9)	0.545 (0.021; 14.013)	0.556 (0.024; 13.024)	-2.9 (-14.9; 13.4)	1.000
TEAE LEADING TO TRT DISCONTINUATION	1 /20 (5.0)	2 /34 (5.9)	0.842 (0.071; 9.923)	0.850 (0.082; 8.789)	-0.9 (-14.7; 18.2)	1.000

TEAE=Treatment-Emergent Adverse Event; TEAESI= Treatment-Emergent Adverse Event of Special Interest; TRT=Treatment;
ARR=Absolute Risk Reduction.
n is the number of patients with at least one adverse event, N1 is the total number of patients in the subgroup and analysis set,
N is the total number of patients in the analysis set. The denominator for the percentage calculations is N1.
0.5 is added if any cell count is zero for odds ratio and relative risk calculation.
* P-value is from Fisher's exact test.
Program: /clinical/argx-113/mg/argx-113-1704/biostat/staging/gba/programs/t_ae_by_subgroup.sas, Version: 0.6

Table 3.1.1.14: Test of Subgroup Homogeneity of Treatment-Emergent Adverse Events up to Study Day 140 - Safety+

ANALYSIS SET: SAF+

	COCHRANE'S Q P-VALUE
REGION	
ALL TEAE	0.739
MILD TEAE	0.517
MODERATE TEAE	0.242
SEVERE TEAE	0.975
SERIOUS TEAE	0.935
ALL TEAESI	0.656
MILD TEAESI	0.426
MODERATE TEAESI	0.355
SEVERE TEAESI	0.950
SERIOUS TEAESI	0.624
TEAE LEADING TO TRT DISCONTINUATION	0.644
AGE CATEGORY	
ALL TEAE	0.970
MILD TEAE	0.972
MODERATE TEAE	0.246
SEVERE TEAE	0.831
SERIOUS TEAE	0.841
ALL TEAESI	0.631
MILD TEAESI	0.582
MODERATE TEAESI	0.308
SEVERE TEAESI	0.818
SERIOUS TEAESI	0.520
TEAE LEADING TO TRT DISCONTINUATION	0.762

TEAE=Treatment-Emergent Adverse Event; TEAESI= Treatment-Emergent Adverse Event of Special Interest; TRT=Treatment;
0.5 is added if any cell count is zero for odds ratio.
Program: /clinical/argx-113/mg/argx-113-1704/biostat/staging/gba/programs/t_ae_by_subgroup_q_test.sas, Version: 0.4

Table 3.1.1.14: Test of Subgroup Homogeneity of Treatment-Emergent Adverse Events up to Study Day 140 - Safety+

ANALYSIS SET: SAF+

	COCHRANE'S Q P-VALUE
SEX	
ALL TEAE	0.908
MILD TEAE	0.719
MODERATE TEAE	0.854
SEVERE TEAE	0.063
SERIOUS TEAE	0.129
ALL TEAESI	0.577
MILD TEAESI	0.105
MODERATE TEAESI	0.092
SEVERE TEAESI	0.881
SERIOUS TEAESI	0.568
TEAE LEADING TO TRT DISCONTINUATION	0.126
RACE	
ALL TEAE	0.857
MILD TEAE	0.072
MODERATE TEAE	0.191
SEVERE TEAE	0.089
SERIOUS TEAE	0.422
ALL TEAESI	0.078
MILD TEAESI	0.366
MODERATE TEAESI	0.023
SEVERE TEAESI	0.892
SERIOUS TEAESI	0.767
TEAE LEADING TO TRT DISCONTINUATION	0.430

TEAE=Treatment-Emergent Adverse Event; TEAESI= Treatment-Emergent Adverse Event of Special Interest; TRT=Treatment;
0.5 is added if any cell count is zero for odds ratio.
Program: /clinical/argx-113/mg/argx-113-1704/biostat/staging/gba/programs/t_ae_by_subgroup_q_test.sas, Version: 0.4

Table 3.1.1.14: Test of Subgroup Homogeneity of Treatment-Emergent Adverse Events up to Study Day 140 - Safety+

ANALYSIS SET: SAF+

	COCHRANE'S Q P-VALUE
BASELEINE MG-ADL TOTAL SCORE	
ALL TEAE	0.626
MILD TEAE	0.703
MODERATE TEAE	0.092
SEVERE TEAE	0.806
SERIOUS TEAE	0.766
ALL TEAESI	0.469
MILD TEAESI	0.544
MODERATE TEAESI	0.477
SEVERE TEAESI	0.979
SERIOUS TEAESI	0.912
TEAE LEADING TO TRT DISCONTINUATION	0.766
CONCOMITANT TREATMENT	
ALL TEAE	0.673
MILD TEAE	0.237
MODERATE TEAE	0.170
SEVERE TEAE	0.936
SERIOUS TEAE	0.651
ALL TEAESI	0.418
MILD TEAESI	0.469
MODERATE TEAESI	0.679
SEVERE TEAESI	0.339
SERIOUS TEAESI	0.670
TEAE LEADING TO TRT DISCONTINUATION	0.694

TEAE=Treatment-Emergent Adverse Event; TEAESI= Treatment-Emergent Adverse Event of Special Interest; TRT=Treatment;
0.5 is added if any cell count is zero for odds ratio.
Program: /clinical/argx-113/mg/argx-113-1704/biostat/staging/gba/programs/t_ae_by_subgroup_q_test.sas, Version: 0.4

Table 3.1.1.14: Test of Subgroup Homogeneity of Treatment-Emergent Adverse Events up to Study Day 140 - Safety+

ANALYSIS SET: SAF+

	COCHRANE'S Q P-VALUE
THYMECTOMY PERFORMED FOR MG	
ALL TEAE	0.316
MILD TEAE	0.149
MODERATE TEAE	0.047
SEVERE TEAE	0.301
SERIOUS TEAE	0.899
ALL TEAESI	0.296
MILD TEAESI	0.548
MODERATE TEAESI	0.011
SEVERE TEAESI	0.570
SERIOUS TEAESI	0.937
TEAE LEADING TO TRT DISCONTINUATION	0.898

TEAE=Treatment-Emergent Adverse Event; TEAESI= Treatment-Emergent Adverse Event of Special Interest; TRT=Treatment;
0.5 is added if any cell count is zero for odds ratio.
Program: /clinical/argx-113/mg/argx-113-1704/biostat/staging/gba/programs/t_ae_by_subgroup_q_test.sas, Version: 0.4