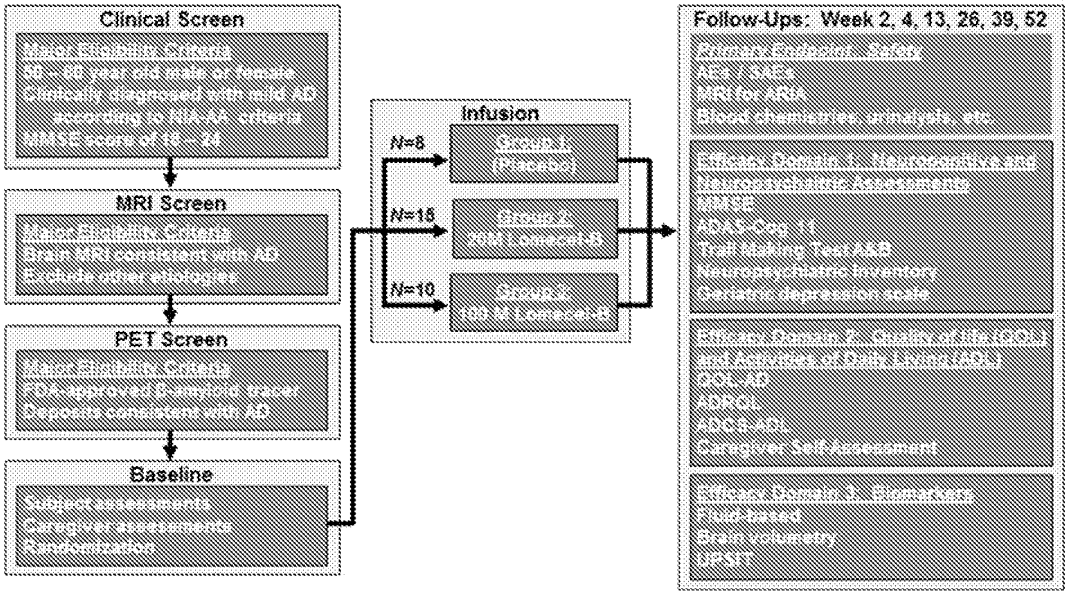

Clinical Screen
Major Eligibility Criteria
50 – 80 year old male or female
Clinically diagnosed with mild AD according to NIA-AA criteria
MMSE score of 18 – 24
MRI Screen
Major Eligibility Criteria
Brain MRI consistent with AD
Exclude other etiologies
PET Screen
Major Eligibility Criteria
FDA-approved β-amyloid tracer
Deposits consistent with AD
Baseline
Subject assessments
Caregiver assessments
Randomization
Infusion
N=8
Group 1: (Placebo)
N=15
Group 2: 20M Lomecel-B
N=10
Group 3: 100 M Lomecel-B
Follow-Ups: Week 2, 4, 13, 26, 39, 52
Primary Endpoint: Safety
AEs / SAEs
MRI for ARIA
Blood chemistries, urinalysis, etc.
Efficacy Domain 1: Neuropsychiatric and Neuropsychiatric Assessments
MMSE
ADAS-Cog 11
Trail Making Test A&B
Neuropsychiatric Inventory
Geriatric depression scale
Efficacy Domain 2: Quality of life (QOL) and Activities of Daily Living (ADL)
QOL-AD
ADRQL
ADCS-ADL
Caregiver Self-Assessment
Efficacy Domain 3: Biomarkers
Fluid-based
Brain volumetry
UPSIT

FIG. 1

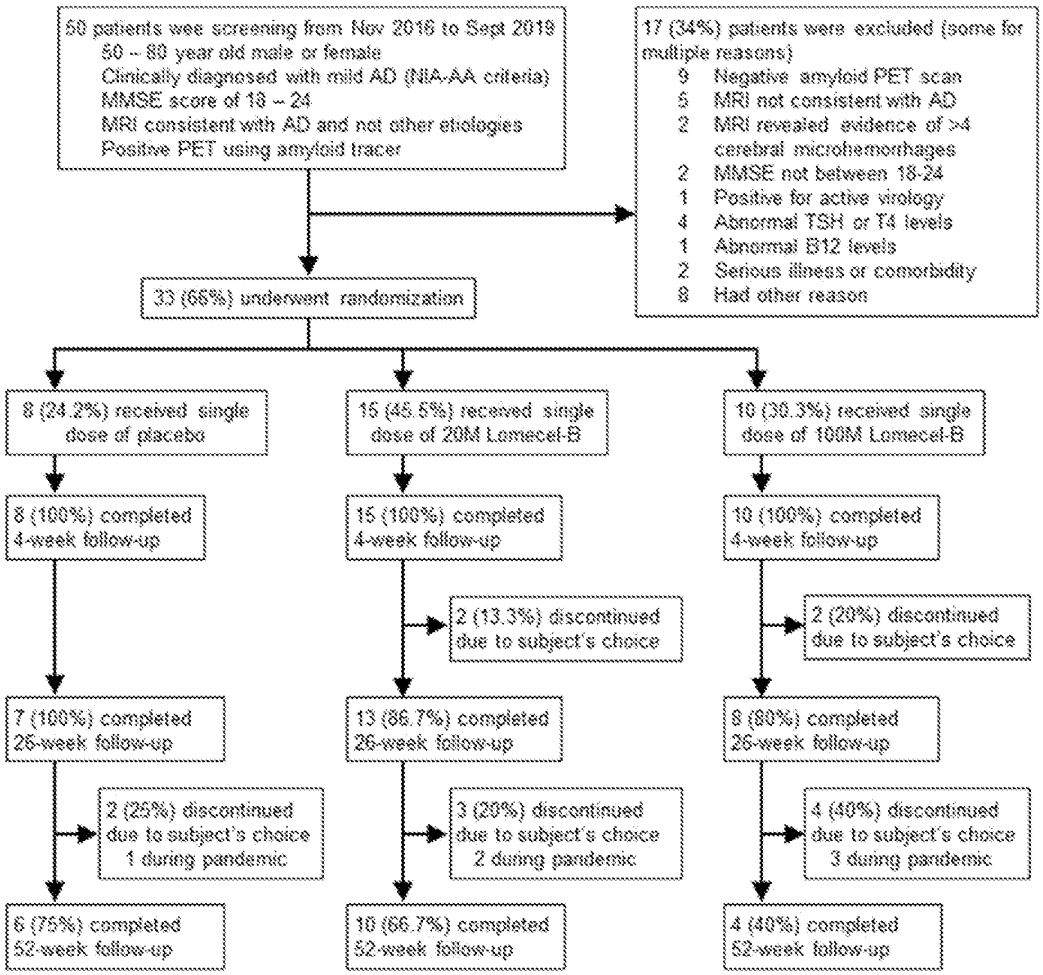

50 patients wee screening from Nov 2016 to Sept 2019
50 – 80 year old male or female
Clinically diagnosed with mild AD (NIA-AA criteria)
MMSE score of 18 – 24
MRI consistent with AD and not other etiologies
Positive PET using amyloid tracer
17 (34%) patients were excluded (some for multiple reasons)
9 Negative amyloid PET scan
5 MRI not consistent with AD
2 MRI revealed evidence of >4 cerebral microhemorrhages
2 MMSE not between 18-24
1 Positive for active virology
4 Abnormal TSH or T4 levels
1 Abnormal B12 levels
2 Serious illness or comorbidity
8 Had other reason
33 (66%) underwent randomization
8 (24.2%) received single dose of placebo
15 (45.5%) received single dose of 20M Lomecel-B
10 (30.3%) received single dose of 100M Lomecel-B
8 (100%) completed 4-week follow-up
15 (100%) completed 4-week follow-up
10 (100%) completed 4-week follow-up
2 (13.3%) discontinued due to subject's choice
2 (20%) discontinued due to subject's choice
7 (100%) completed 26-week follow-up
13 (86.7%) completed 26-week follow-up
8 (80%) completed 26-week follow-up
2 (25%) discontinued due to subject's choice 1 during pandemic
3 (20%) discontinued due to subject's choice 2 during pandemic
4 (40%) discontinued due to subject's choice 3 during pandemic
6 (75%) completed 52-week follow-up
10 (66.7%) completed 52-week follow-up
4 (40%) completed 52-week follow-up

FIG. 2

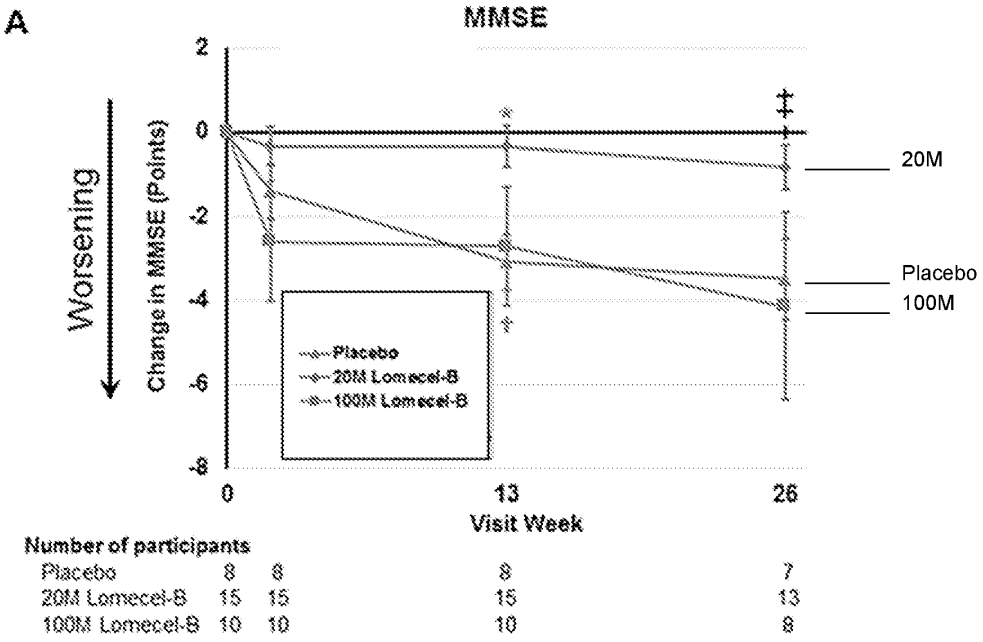

A
MMSE
Worsening
Change in MMSE (Points)
2
0
-2
-4
-6
-8
Placebo
20M Lomecel-B
100M Lomecel-B
20M
Placebo
100M
0
13
26
Visit Week
Number of participants
Placebo 8 8 8 7
20M Lomecel-B 15 15 15 13
100M Lomecel-B 10 10 10 8

FIG. 3A

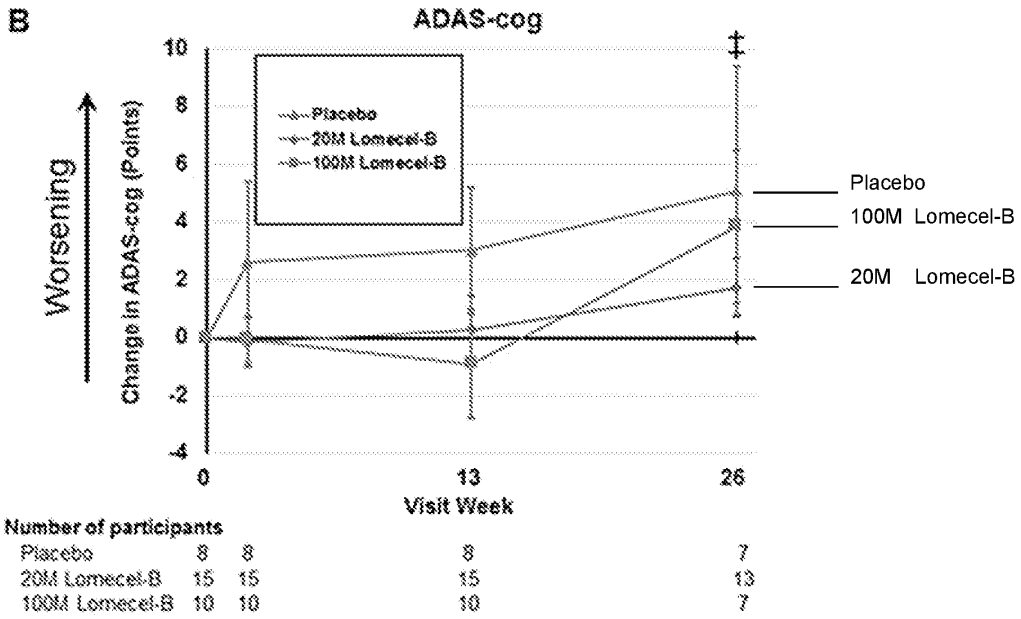

B
ADAS-cog
Worsening
Change in ADAS-cog (Points)
10
8
6
4
2
0
-2
-4
Placebo
20M Lomecel-B
100M Lomecel-B
0
13
26
Visit Week
Placebo
100M Lomecel-B
20M Lomecel-B
Number of participants
Placebo 8 8 8 7
20M Lomecel-B 15 15 15 13
100M Lomecel-B 10 10 10 7

FIG. 3B

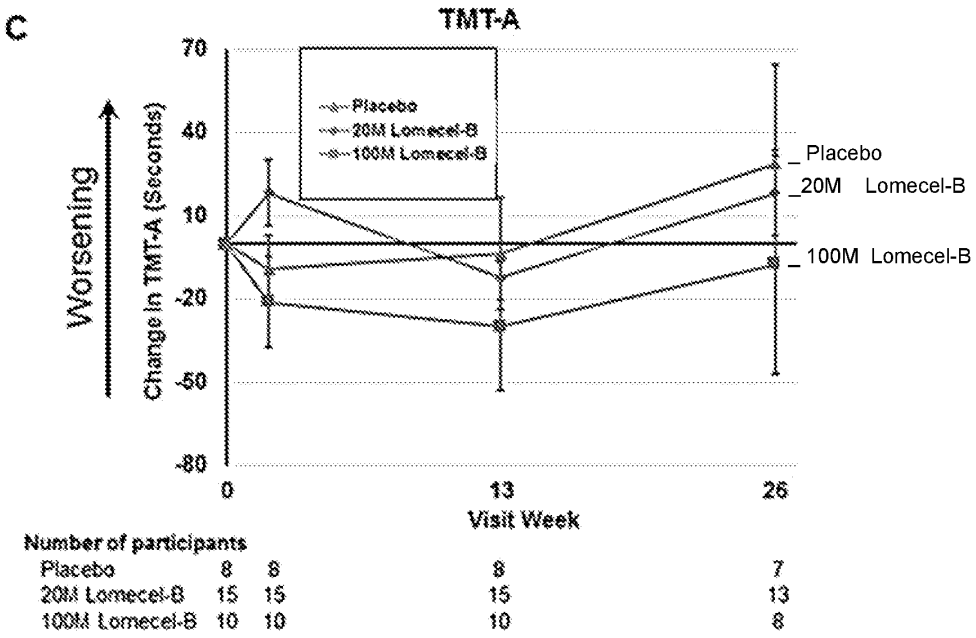

C
TMT-A
70
40
10
-20
-50
-80
Worsening
Change in TMT-A (Seconds)
Placebo
20M Lomecel-B
100M Lomecel-B
_ Placebo
_20M Lomecel-B
_ 100M Lomecel-B
0
13
26
Visit Week
Number of participants
Placebo 8 8 8 7
20M Lomecel-B 15 15 15 13
100M Lomecel-B 10 10 10 8

FIG. 3C

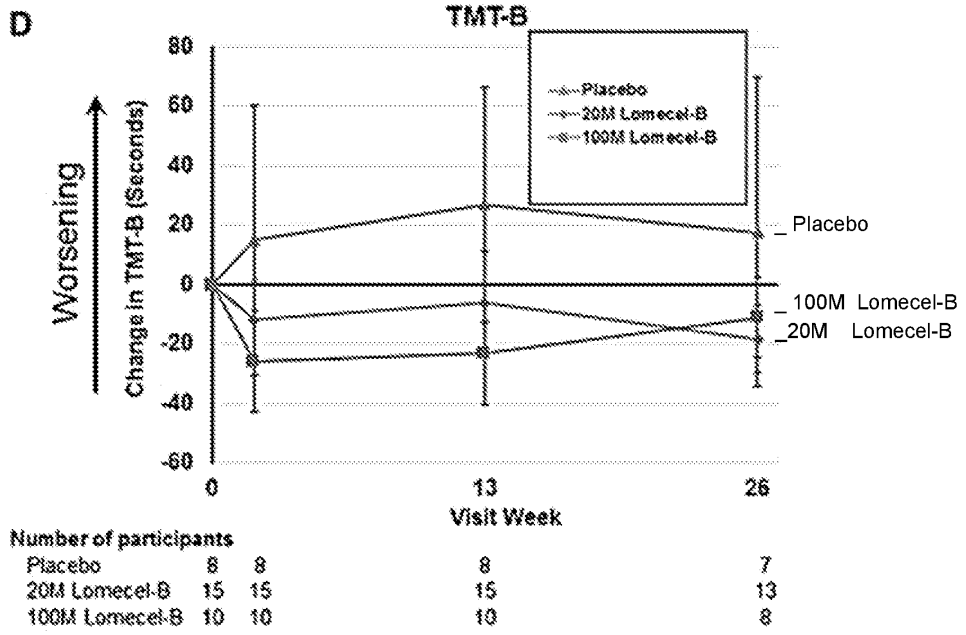

D
TMT-B
Placebo
20M Lomecel-B
100M Lomecel-B
Worsening
Change in TMT-B (Seconds)
80
60
40
20
0
-20
-40
-60
0
13
26
Visit Week
_ Placebo
_ 100M Lomecel-B
_20M Lomecel-B
Number of participants
Placebo 8 8 8 7
20M Lomecel-B 15 15 15 13
100M Lomecel-B 10 10 10 8

FIG. 3D

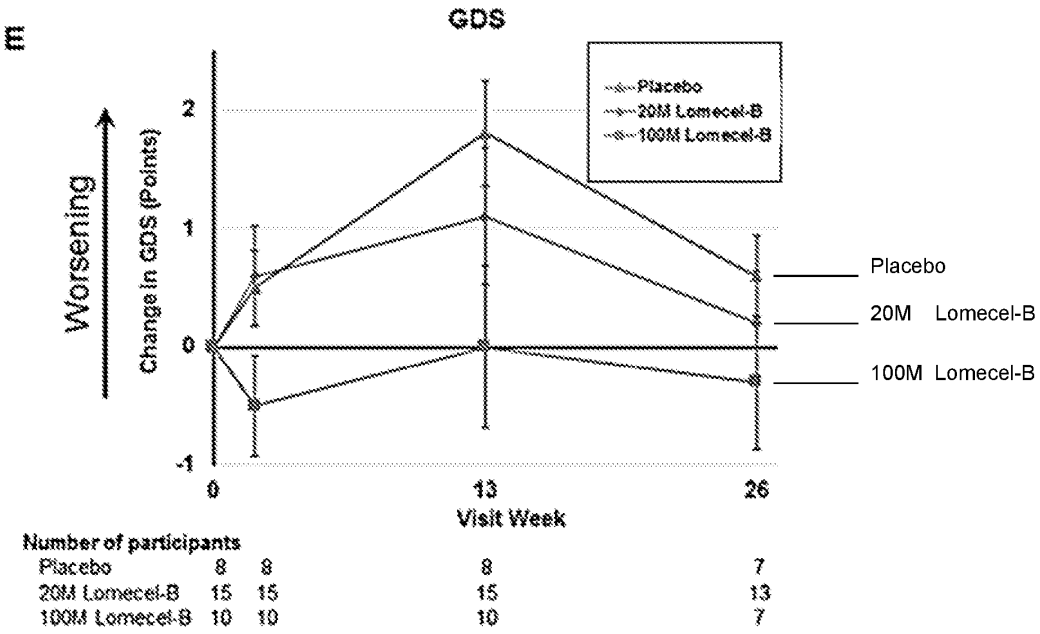
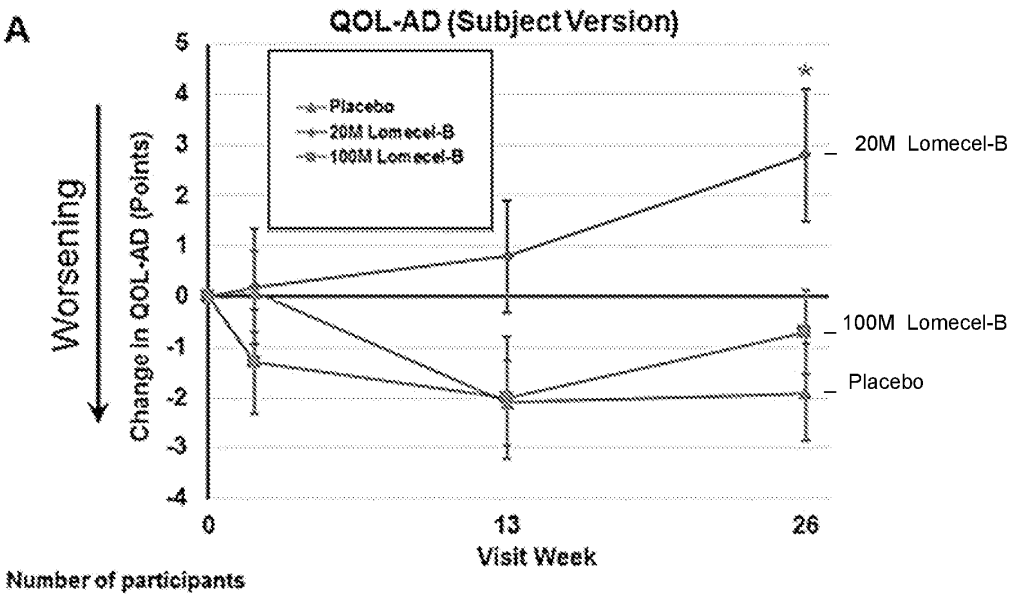

E
GDS
Placebo
20M Lomecel-B
100M Lomecel-B
Worsening
Change in GDS (Points)
2
1
0
-1
0
13
26
Visit Week
Placebo
20M Lomecel-B
100M Lomecel-B
Number of participants
Placebo 8 8 8 7
20M Lomecel-B 15 15 15 13
100M Lomecel-B 10 10 10 7

FIG. 3E



Number of participants				
Placebo	8	8	8	7
20M Lomecel-B	15	15	15	13
100M Lomecel-B	10	10	10	7

FIG. 4A

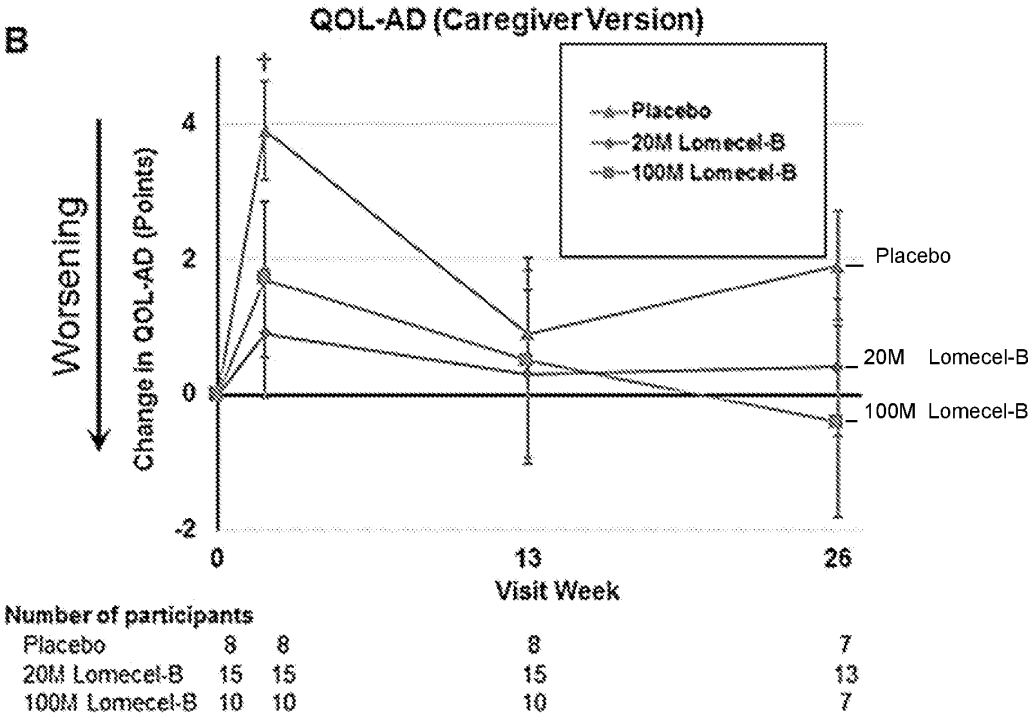

B
QOL-AD (Caregiver Version)
Placebo
20M Lomecel-B
100M Lomecel-B
Worsening
Change in QOL-AD (Points)
4
2
0
-2
Placebo
20M Lomecel-B
100M Lomecel-B
0
13
26
Visit Week
Number of participants
Placebo 8 8 8 7
20M Lomecel-B 15 15 15 13
100M Lomecel-B 10 10 10 7

FIG. 4B

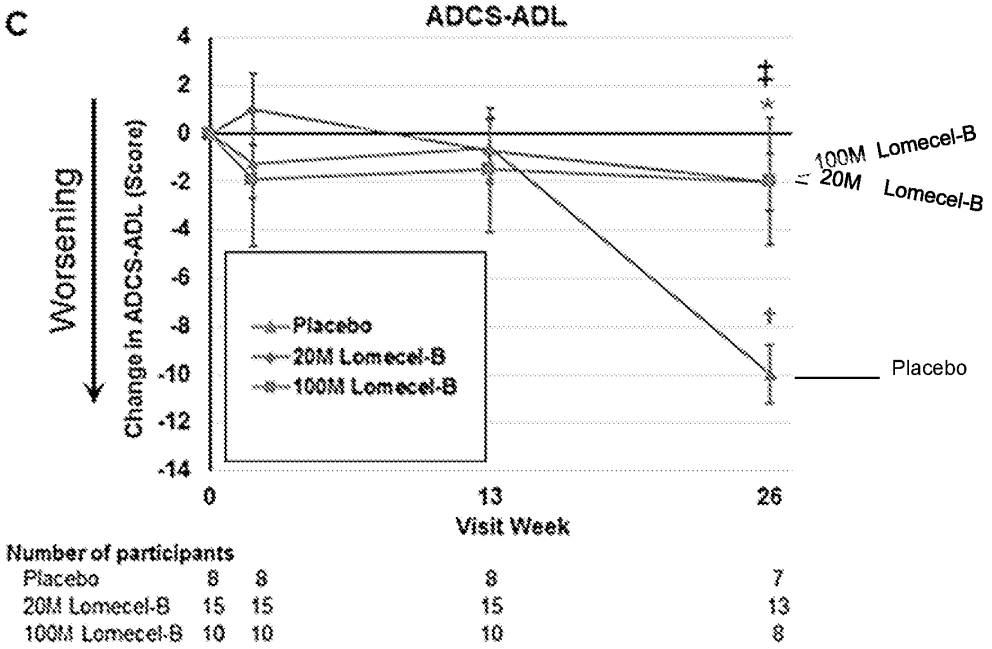
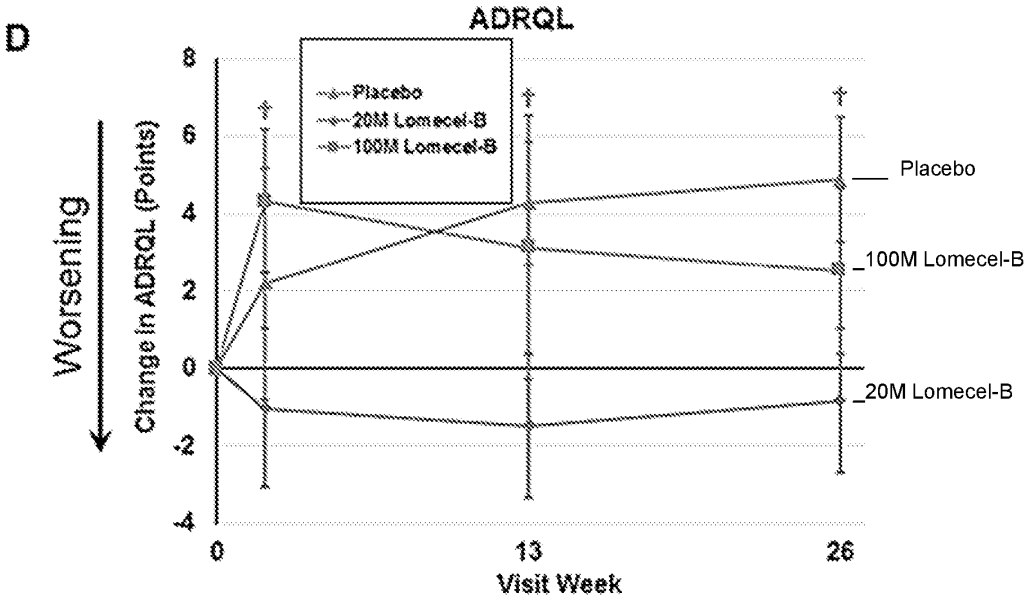

C
ADCS-ADL
Worsening
Change in ADCS-ADL (Score)
4
2
0
-2
-4
-6
-8
-10
-12
-14
Placebo
20M Lomecel-B
100M Lomecel-B
100M Lomecel-B
20M Lomecel-B
Placebo
0
13
26
Visit Week
Number of participants
Placebo 8 8 8 7
20M Lomecel-B 15 15 15 13
100M Lomecel-B 10 10 10 8

FIG. 4C



Number of participants				
Placebo	8	8	8	7
20M Lomecel-B	15	15	15	13
100M Lomecel-B	10	10	10	8

FIG. 4D

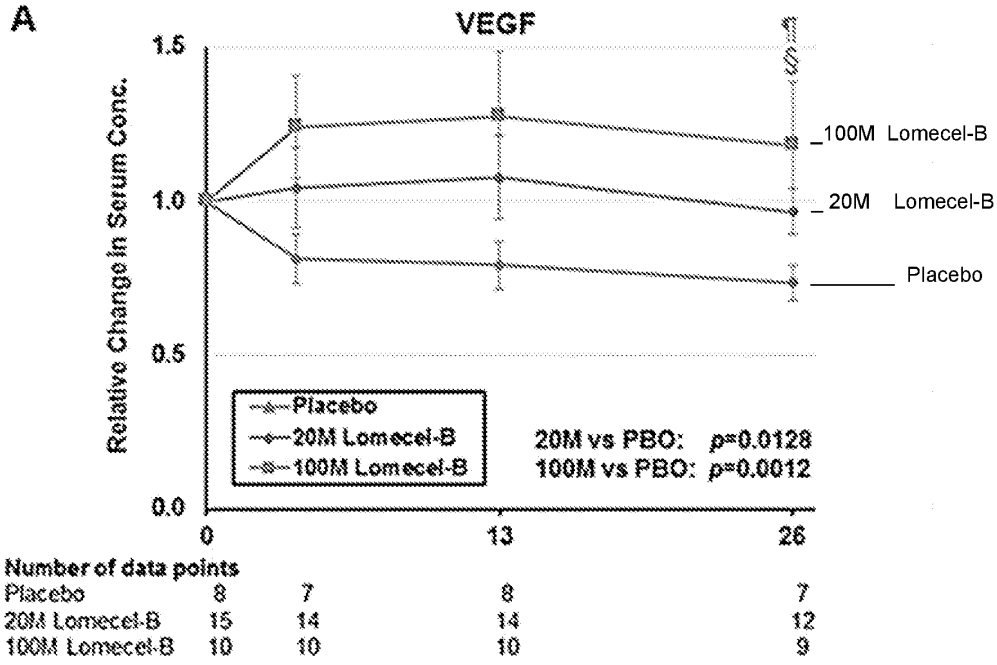

A
VEGF
Relative Change in Serum Conc.
1.5
1.0
0.5
0.0
0
13
26
100M Lomecel-B
20M Lomecel-B
Placebo
Placebo
20M Lomecel-B
100M Lomecel-B
20M vs PBO: p=0.0128
100M vs PBO: p=0.0012
Number of data points
Placebo 8 7 8 7
20M Lomecel-B 15 14 14 12
100M Lomecel-B 10 10 10 9

FIG. 5A

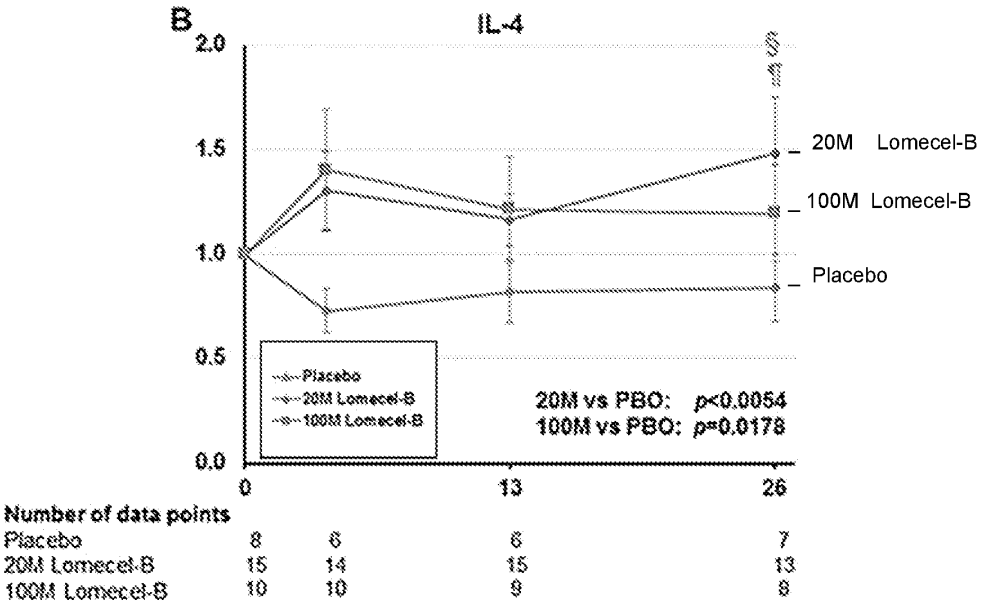

B
IL-4
2.0
1.5
1.0
0.5
0.0
0
13
26
20M Lomecel-B
100M Lomecel-B
Placebo
Placebo
20M Lomecel-B
100M Lomecel-B
20M vs PBO: p<0.0054
100M vs PBO: p=0.0178
Number of data points
Placebo 8 6 6 7
20M Lomecel-B 15 14 15 13
100M Lomecel-B 10 10 9 8

FIG. 5B

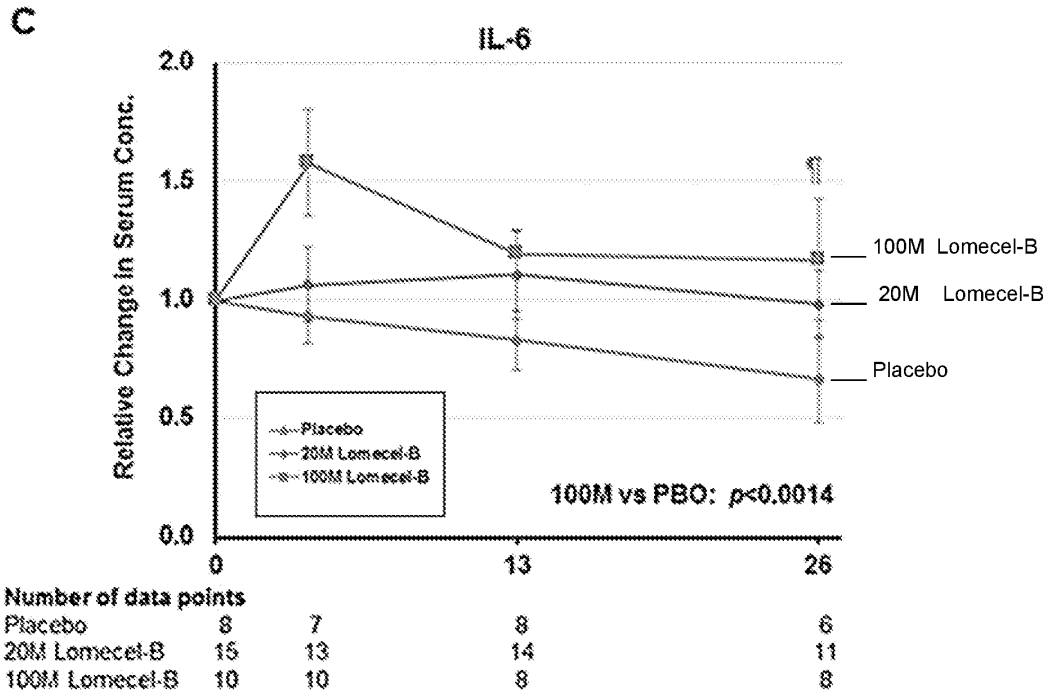

C
IL-6
Relative Change in Serum Conc.
2.0
1.5
1.0
0.5
0.0
0
13
26
100M Lomecel-B
20M Lomecel-B
Placebo
Placebo
20M Lomecel-B
100M Lomecel-B
100M vs PBO: p<0.0014
Number of data points
Placebo 8 7 8 6
20M Lomecel-B 15 13 14 11
100M Lomecel-B 10 10 8 8

FIG. 5C

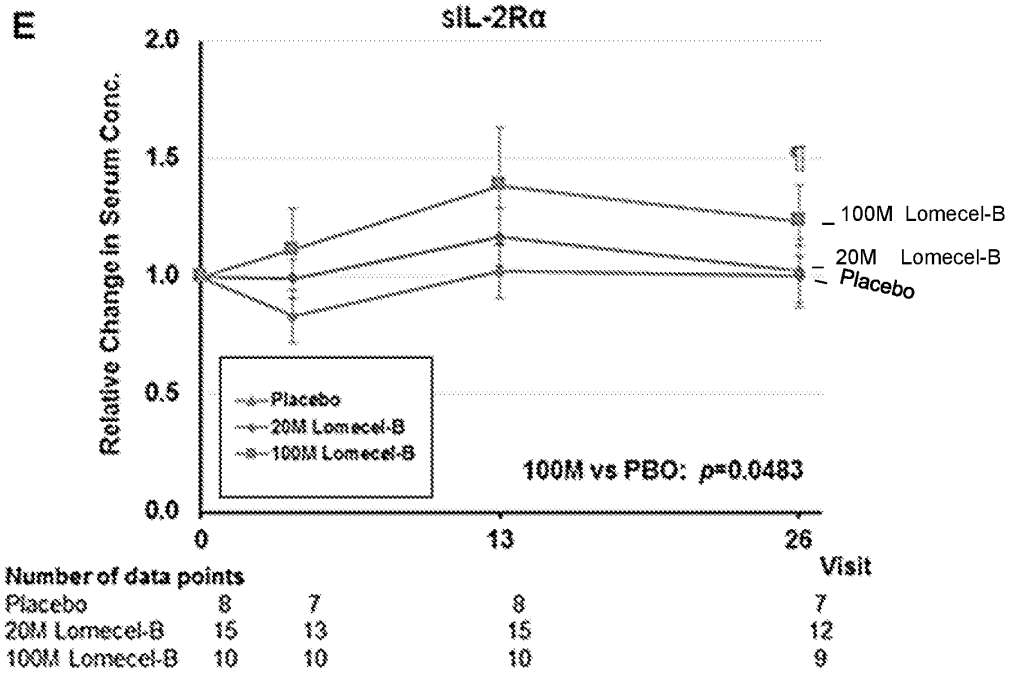

E
sIL-2Rα
Relative Change in Serum Conc.
2.0
1.5
1.0
0.5
0.0
0
13
26
Visit
100M Lomecel-B
20M Lomecel-B
Placebo
Placebo
20M Lomecel-B
100M Lomecel-B
100M vs PBO: p=0.0483
Number of data points
Placebo 8 7 8 7
20M Lomecel-B 15 13 15 12
100M Lomecel-B 10 10 10 9

FIG. 5D

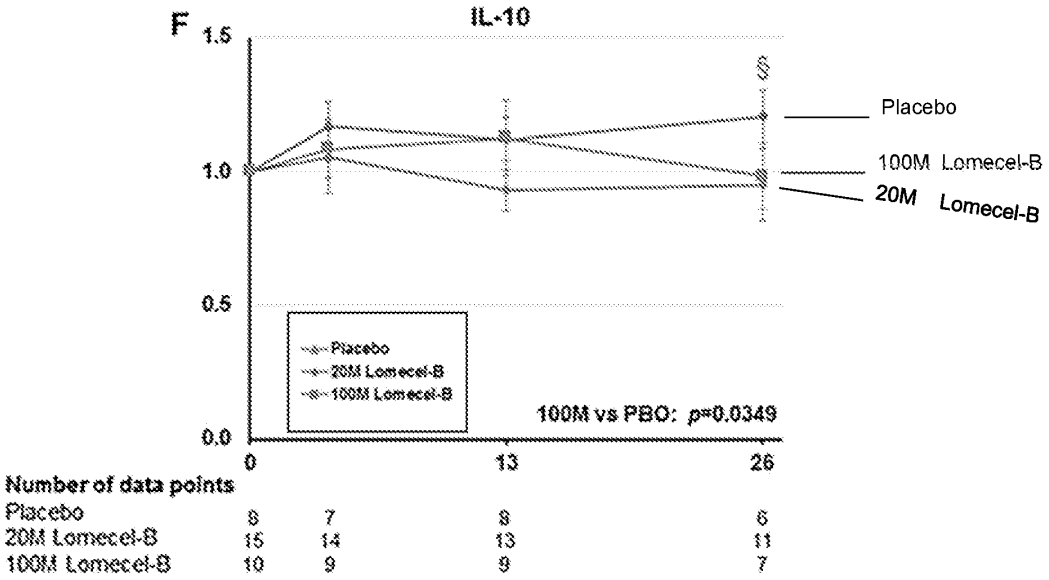

IL-10
F
1.5
1.0
0.5
0.0
§
Placebo
100M Lomecel-B
20M Lomecel-B
Placebo
20M Lomecel-B
100M Lomecel-B
100M vs PBO: p=0.0349
0
13
26
Number of data points
Placebo 8 7 8 6
20M Lomecel-B 15 14 13 11
100M Lomecel-B 10 9 9 7

FIG. 5E

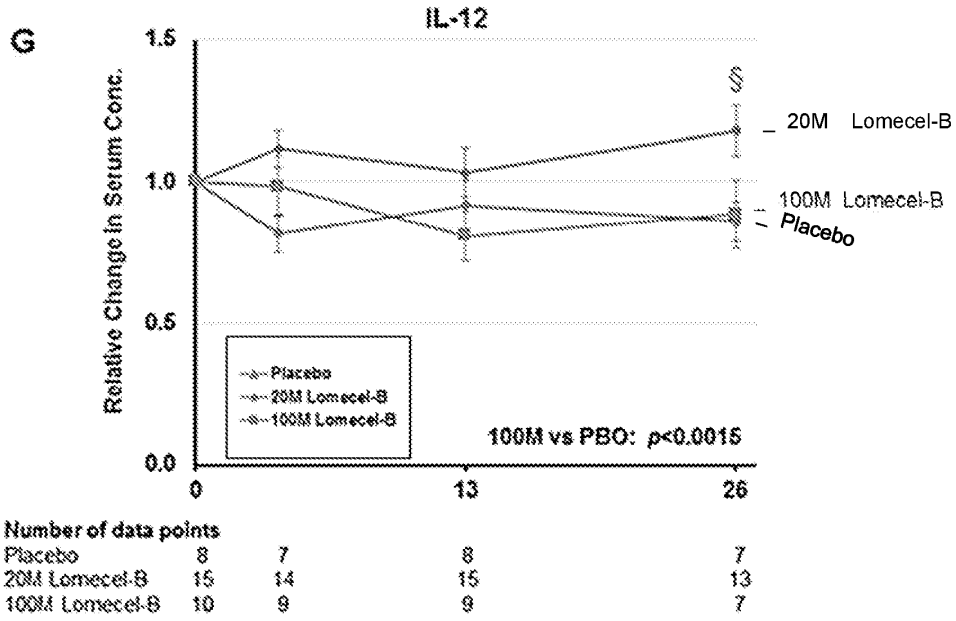

G
IL-12
Relative Change in Serum Conc.
1.5
1.0
0.5
0.0
§
20M Lomecel-B
100M Lomecel-B
Placebo
Placebo
20M Lomecel-B
100M Lomecel-B
100M vs PBO: p<0.0015
0
13
26
Number of data points
Placebo 8 7 8 7
20M Lomecel-B 15 14 15 13
100M Lomecel-B 10 9 9 7

FIG. 5F

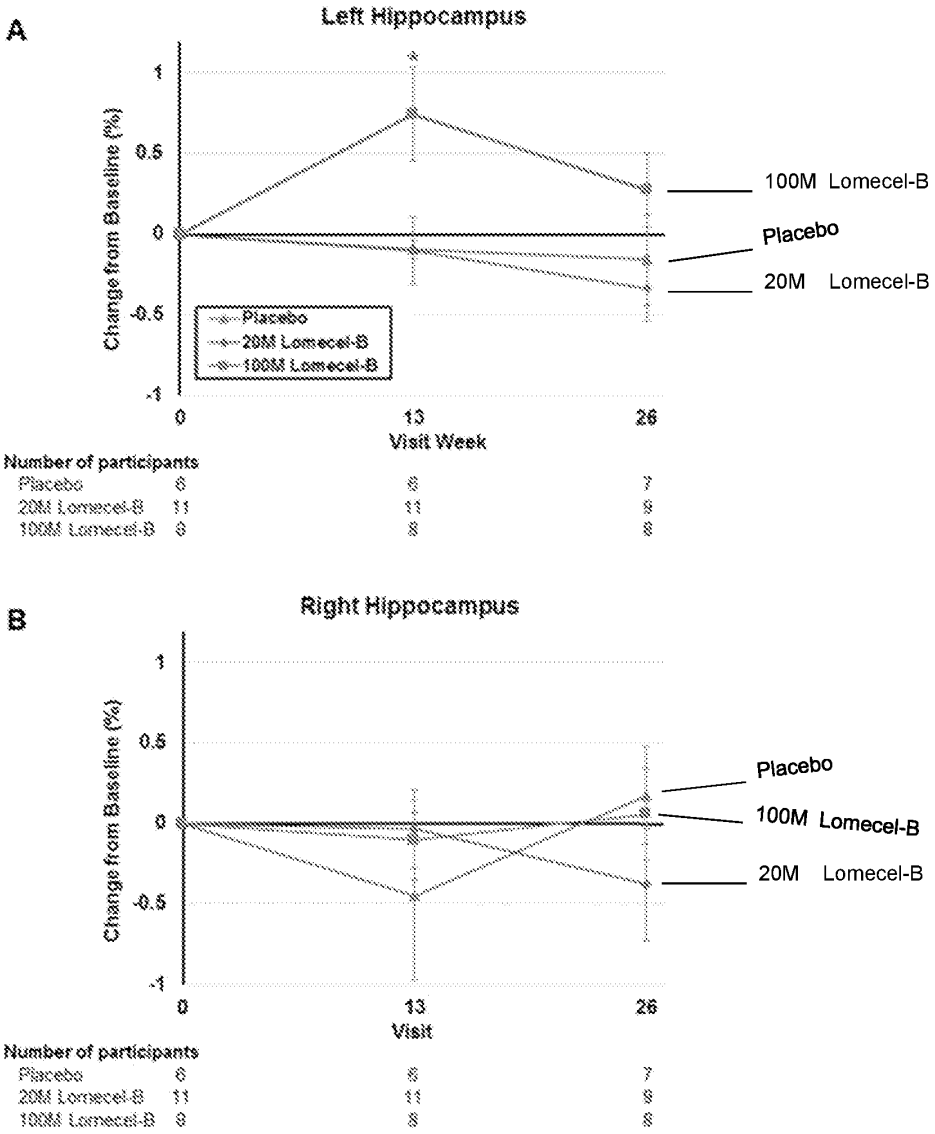


FIG. 6A and FIG. 6B