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O'Donnell Brain Institute

Updates in Myasthenia Gravis

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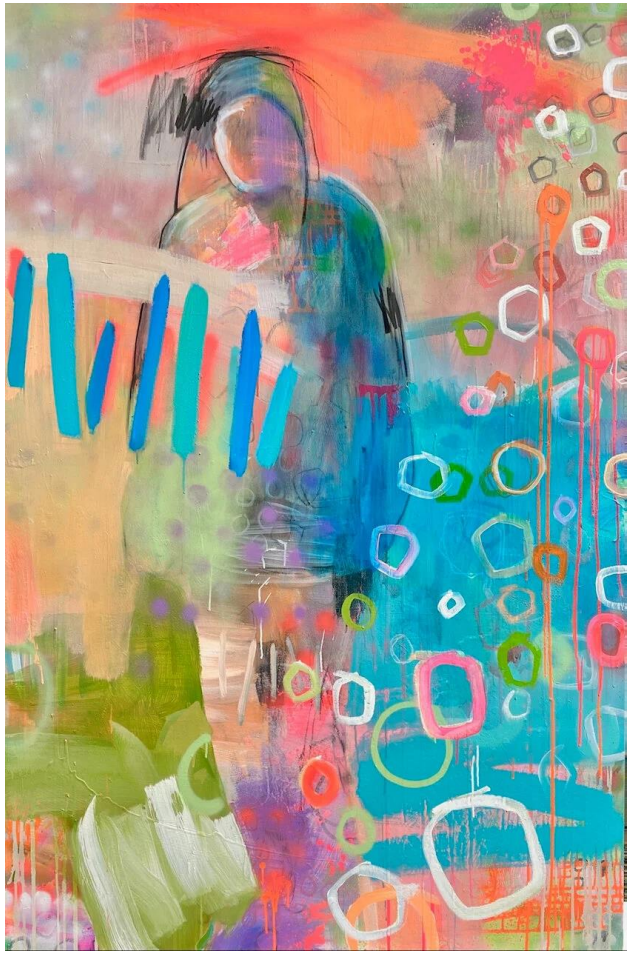
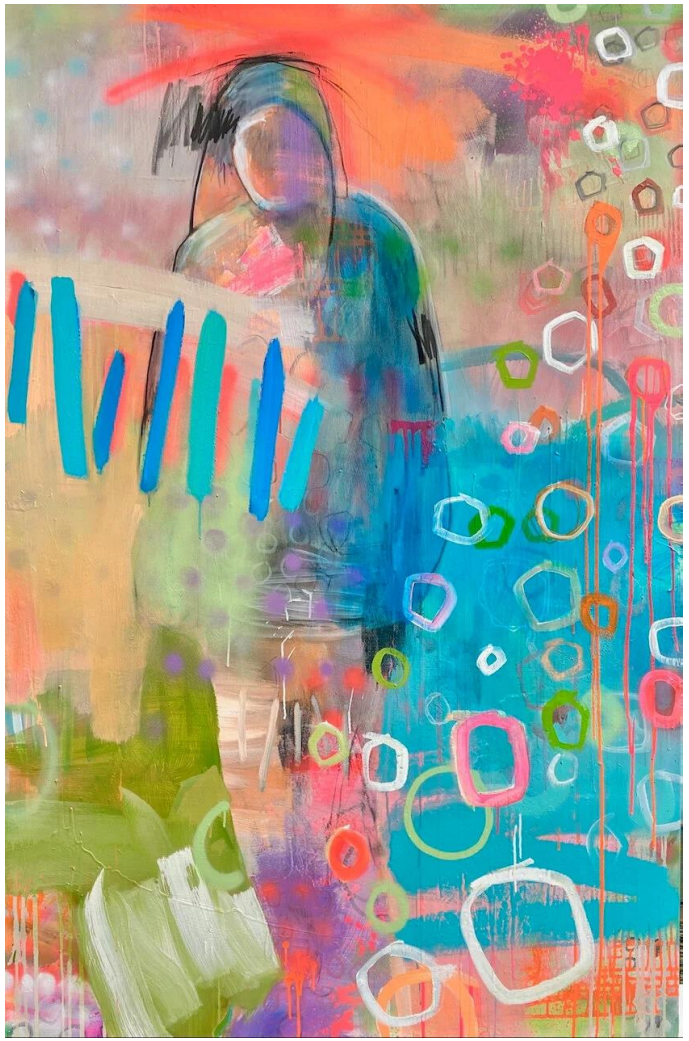


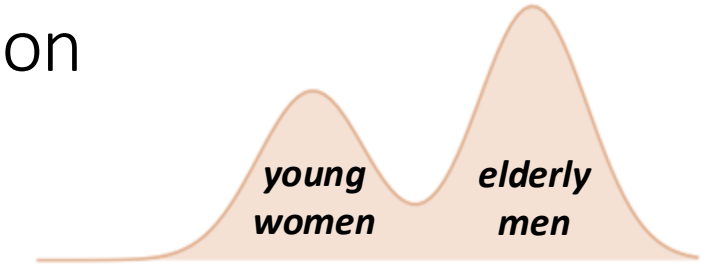
Disclosures

- UCB pharma - advisory board & consultant
- NIH DSMB
- Gather-ed

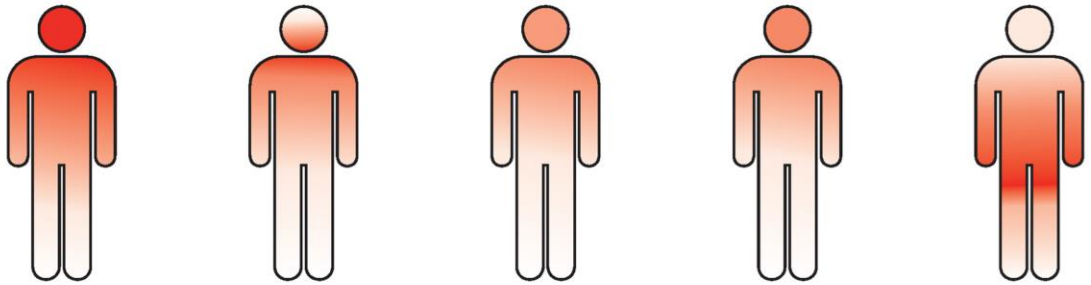
- Some medications discussed are off-label



Clinical presentation



Incidence: 14-40/100,000 in US

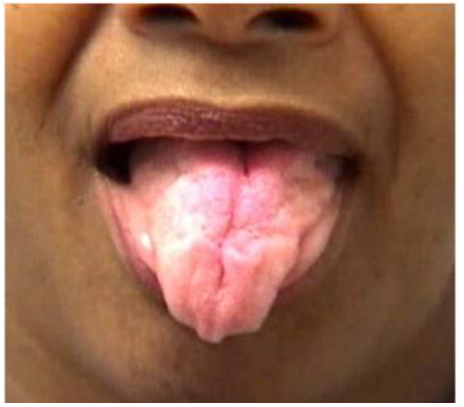
Subtype	AchR+	MuSK+	LRP4+	Seronegative	LEMS
					
Relative prevalence	80%	4%	2%	5%	4%

Gilhus, *Lancet Neurol*, Oct 2015

15% OMG, 85% generalized MG (gMG)

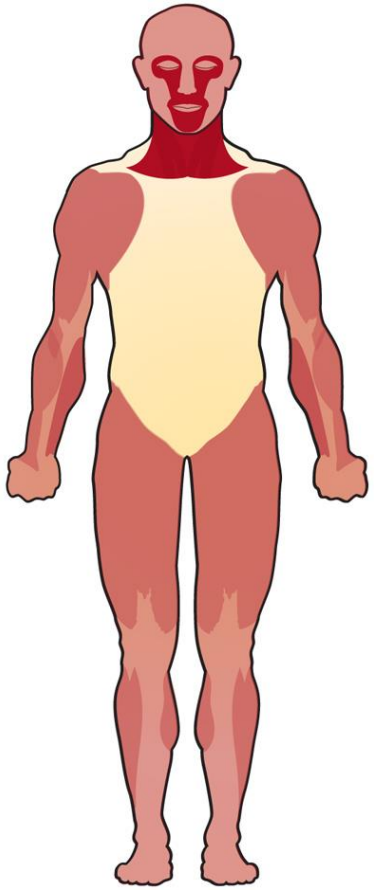
1st sx onset usually **ocular** (2/3 of pts)

- Pattern of ext weakness: proximal, extensors
- *Fluctuating, fatigable*
- Rarely distal weakness 1st sx – *foot drop, wrist drop*



Sanders D, Juel. V, *J of Neuroimm*, Sept 2008

Pt with **MuSK+** MG



https://www.mda.org/disease/myasthenia-gravis

Current MG immunotherapy treatments

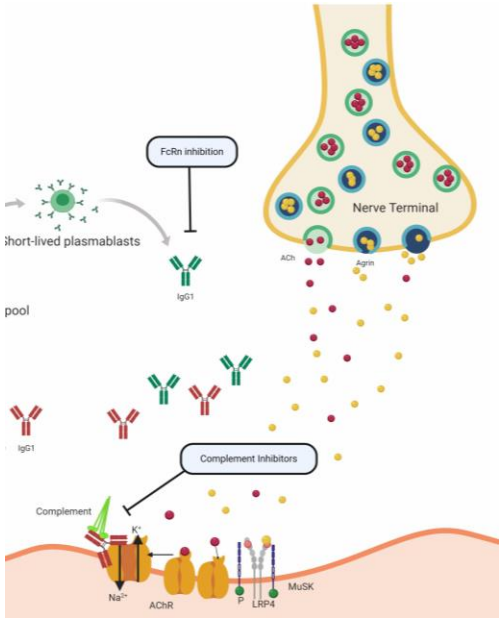
Traditional Therapies

Prednisone	Thymectomy
Azathioprine	• Expert consensus & multiple RCT support *as **1st line***
Mycophenolate Mofetil	• Not supported by RCT, **widely used**
Cyclosporine/ Tacrolimus	• Not widely used, works faster • ↑ monitoring/side effect profile
Rituximab	• Refractory dz, BEAT-MG trial – no sig steroid-sparing effect for AchR+, helpful for MuSK+
PLEX/IVIG	• Used for exacerbation/crisis • Used for bridge/maintenance

Newer Therapies

Complement inhibitors			
	Antibody status	*FDA approval*	*Maintenance schedule*
Eculizumab (IV)	AchR Ab (+)	2017	q 2 wks
Ravalizumab (IV)	AchR Ab (+)	2022	q 8 wks
Zilucoplan (SC)	AchR Ab (+)	**2023**	Daily
Neonatal Fc Receptor Antagonists			
Efgartigimod (IV)	AchR Ab (+), seronegative	2021	Cycle: weekly x 4
Efgartigimod alpha (SC)	AchR Ab (+), seronegative	**2023**	Cycle: weekly x 4
Rozanolixizumab (SC)	AchR Ab (+), **MuSK Ab (+)**, seronegative	**2023**	Cycle: weekly x 6
Nipocalimab (IV)	AchR Ab (+), **MuSK Ab (+)**	**2025 (12 yrs+)**	Every other week

Cemdisiran: *SC every 3 mon*, U.S. regulatory submission planned for 1st quarter of 2026, pending discussions with FDA



Fichtner et al, *Front. Immunol*, May 2020

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MG drug pipeline

Agent / Therapy	Mechanism or Modality	Trial Phase & Details	Antibody / Pt Population	Estimated Timeline / Status
Cemdisiran	**siRNA targeting complement factor C5** → reducing C5 / complement pathway activity	**Phase 3 trial ("NIMBLE") in gMG**	gMG (AChR+, general population)	Completed primary + key secondary endpoints; regulatory submission planned Q1 2026
Cemdisiran + Pozelimab	**Dual complement inhibition** (siRNA + antibody)	Part of same Phase 3 trial as above; combination arm	Same as above	Also met endpoints, nearly 99% inhibition of complement activity; comparative data vs monotherapy show monotherapy numerically better across endpoints
Iptacopan	Inhibitor of the **alternative complement pathway** via factor B inhibition	Phase 3 in AChR+ gMG on stable standard-of-care	AChR antibody+ gMG	Active/recruiting
Efgartigimod IV	FcRn blocker (antibody recycling dump)	"ADAPT SERON" - Phase 3	***Seronegative gMG***	Active & recruiting
Descartes-08	**CAR T-cell therapy** (engineered)	Phase 2b (Phase Ib/IIa) trial in gMG	gMG, heavily pretreated symptomatic patients	Reported sustained benefits through 12 mon post single 6-wk course; active & recruiting
Telitacicept	Dual targeting of BLyS/APRIL pathways → **B cell / plasma cell modulation**	Phase 3 trial in gMG	gMG (likely AChR+ or general)	Results shared in 2025; promising safety & efficacy
Uplizna (inebilizumab)	**Anti-CD19 B cell depleter**	Phase 3 ("MINT") trial in MG (AChR or MuSK Ab positive)	AChR+ or MuSK+ generalized MG	Active; looking at MG-ADL over 26/52 weeks
NMD670	Small molecule or novel immunomodulator (details less fully public)	Phase 2, dose-finding / proof-of-concept, multiple doses vs placebo	Adults with MG (AChR or MuSK positive)	Active & recruiting
MyClad (Oral Cladribine)	Immunosuppressant, **lymphocyte depletion** (a purine-analog)	Phase 3, randomized, placebo-controlled in gMG	gMG	Global trial; started dosing
RESET-MG (CABA-201)	**Cell therapy** (CABA-201) in gMG	Phase 1/2 open label; safety & efficacy evaluation	gMG, likely with standard criteria	Active & recruiting
MuSK-CAART	**CAAR T therapy targeting MuSK autoantibody-producing B cells** (Chimeric AutoAntigen Receptor T cells)	Phase 1 study (safety & dosing)	MuSK antibody-positive MG	Recruiting
CNP-106	Antigen-based / autoantigen encapsulated therapy. Possibly tolerization/resetting immune response rather than depletion	Phase 1b/2a (First-in-Human) study	gMG (adult 18-75)	Active & recruiting; safety, PD/efficacy endpoints

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MG goals of treatment

- ***Individualized***
- Good (consistent) disease control, minimal/no medication side effects
- Return to normal/near normal daily activities, work, social engagements

MGFA-Post Intervention Status (PIS)

- **Minimal manifestation status (MMS)** = no sx or functional limitation
  - Allows *mild* weakness on exam, can be on meds
- **Remission (pharmacologic, complete stable)**: same, only allows eyelid closure weakness but *no use of pyridostigmine*

MG-ADL

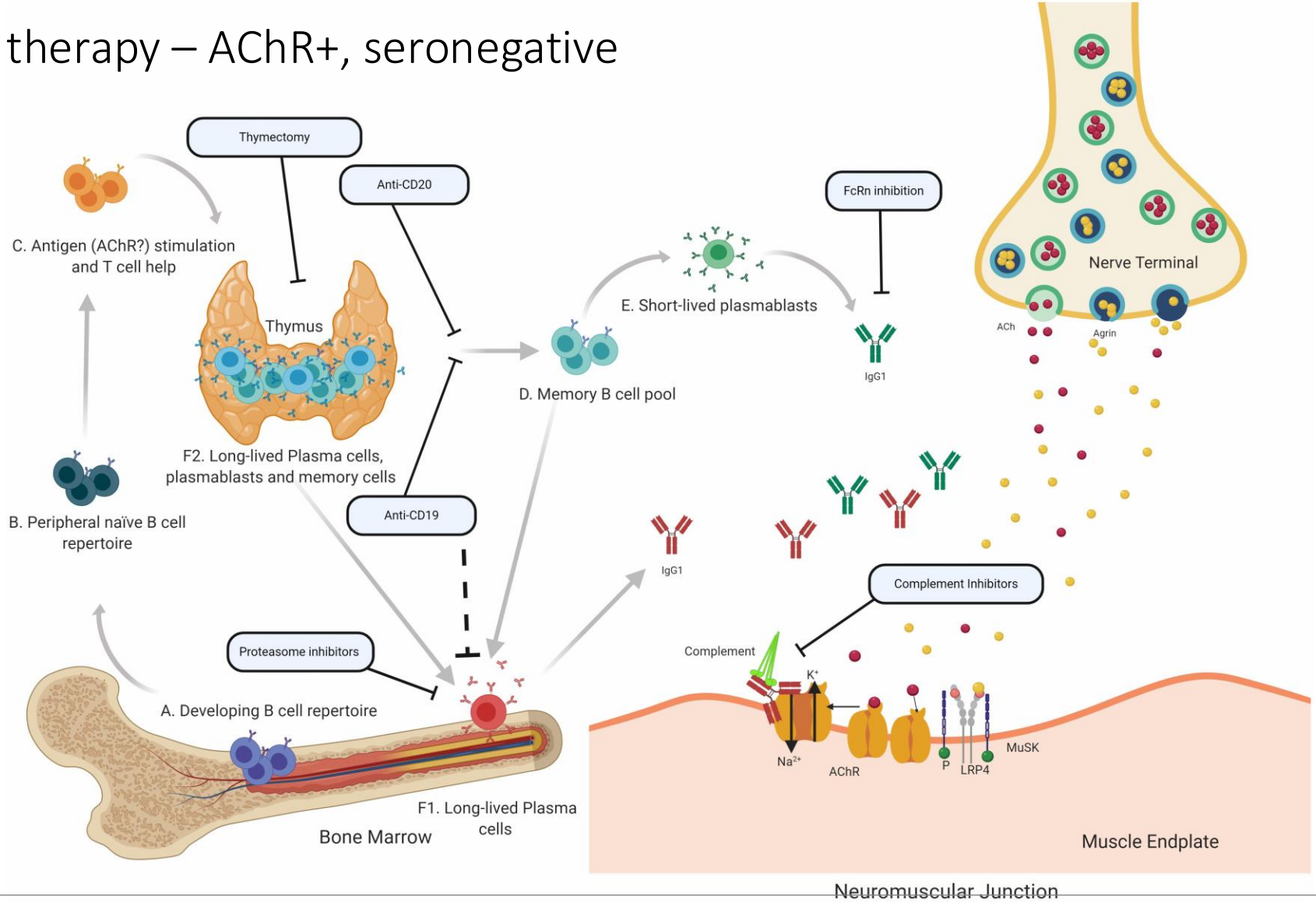
Grade	0	1	2	3	Score
Talking	Normal	Intermittent slurring or nasal speech	Constant slurring or nasal, but can be understood	Difficult to understand speech	
Chewing	Normal	Fatigue with solid food	Fatigue with soft food	Gastric tube	
Swallowing	Normal	Rare episode of choking	Frequent choking necessitating changes in diet	Gastric tube	
Breathing	Normal	Shortness of breath with exertion	Shortness of breath at rest	Ventilator dependence	
Impairment of ability to brush teeth or comb hair	None	Extra effort, but no rest periods needed	Rest periods needed	Cannot do one of these functions	
Impairment of ability to arise from a chair	None	Mild, sometimes uses arms	Moderate, always uses arms	Severe, requires assistance	
Double vision	None	Occurs, but not daily	Daily, but not constant	Constant	
Eyelid droop	None	Occurs, but not daily	Daily, but not constant	Constant	
				Total Score:	

Initial presentation → Tx with Pyrido + IST → Improved → MMS, remission → *De-escalation trial*

Sustain for >1 year

https://myasthenia.org/Portals/0/MGFA%20-%20PIS.pdf

Targets of therapy – AChR+, seronegative



Fichtner et al, *Front. Immunol*, May 2020

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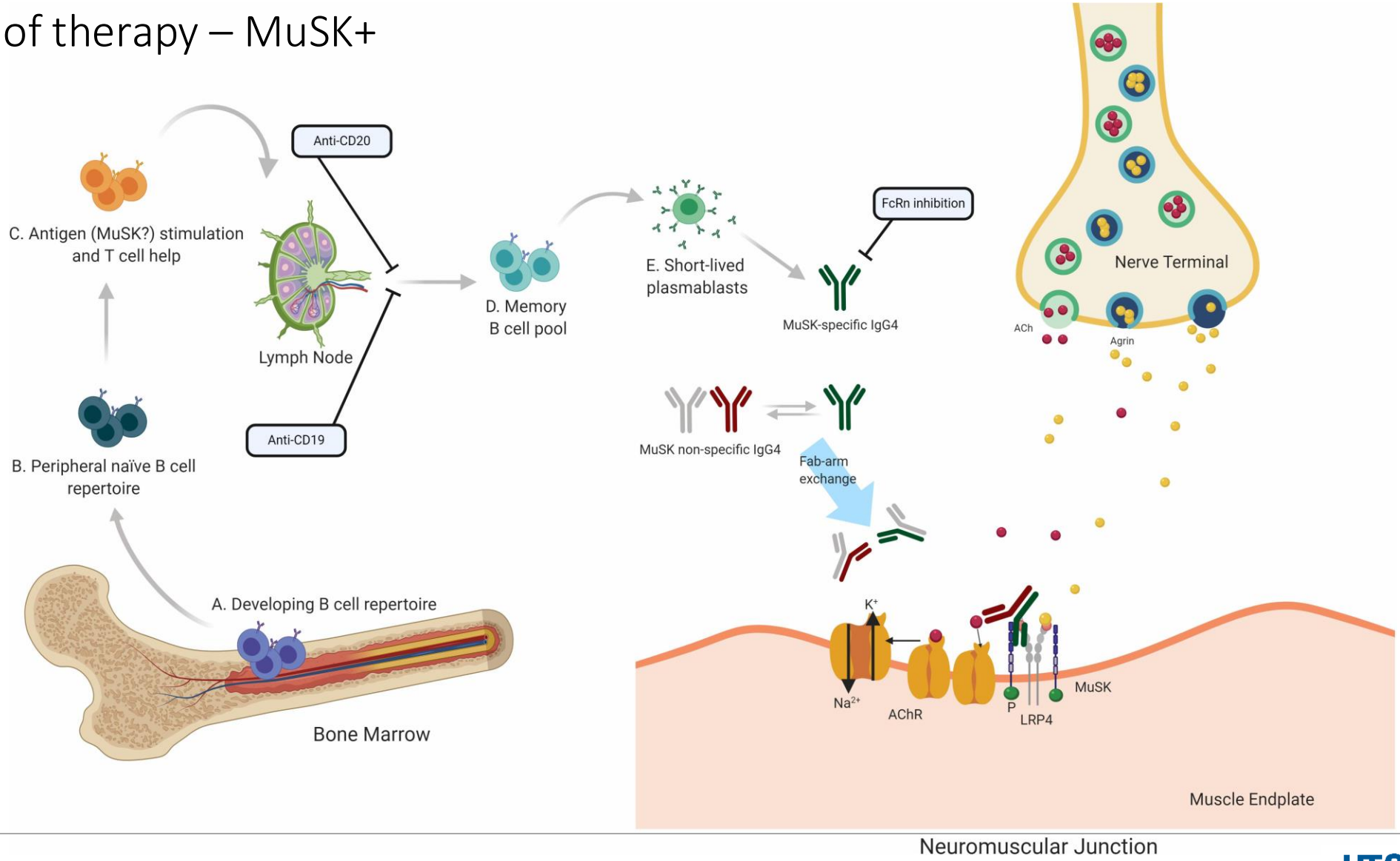
Targets of therapy – MuSK+



Fichtner et al, *Front. Immunol*, May 2020

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C5 inhibitors

Clinical Trial > Lancet Neurol. 2017 Dec;16(12):976-986.
doi: 10.1016/S1474-4422(17)30369-1. Epub 2017 Oct 20.

Safety and efficacy of eculizumab in anti-acetylcholine receptor antibody-positive refractory generalised myasthenia gravis (REGAIN): a phase 3, randomised, double-blind, placebo-controlled, multicentre study

James F Howard Jr [1], Kimiaki Utsugisawa [2], Michael Benatar [3], Hiroyuki Murai [4], Richard J Barohn [5], Isabel Illa [6], Saiju Jacob [7], John Vissing [8], Ted M Burns [9], John T Kissel [10], Srikanth Muppidi [11], Richard J Nowak [12], Fanny O'Brien [13], Jing-Jing Wang [13], Renato Mantegazza [14]; REGAIN Study Group

Eculizumab (Soliris)

- 26 wks, 125 pts
- IV Dosing – loading x 4 weeks, 5th week higher dose, then **q 2 weeks**
- **4.2-point improvement in mean MG-ADL score from baseline → wk 26** in Ecu group vs **2.3-pt** placebo (p=0.006)
- **4.6-point improvement in mean QMG score from baseline → wk 26** in Ecu group vs **1.6-pt** placebo (p=0.0006)
- Most common adverse events: HA, URI

Clinical Trial > J Neurol. 2023 Aug;270(8):3862-3875. doi: 10.1007/s00415-023-11699-x.
Epub 2023 Apr 27.

Long-term efficacy and safety of ravulizumab in adults with anti-acetylcholine receptor antibody-positive generalized myasthenia gravis: results from the phase 3 CHAMPION MG open-label extension

Andreas Meisel [1], Djillali Annane [2], Tuan Vu [3], Renato Mantegazza [4], Masahisa Katsuno [5], Rasha Aguzzi [6], Glen Frick [6], Laura Gault [6], James F Howard Jr [7]; CHAMPION MG Study Group

Affiliations + expand

PMID: 37103755 PMCID: PMC10134722 DOI: 10.1007/s00415-023-11699-x

Ravulizumab (Ultomiris)

- 26 weeks, 175 pts
- IV Dosing – loading, maintenance dose day 15, then **q 8 weeks**
- **Significantly improved score from baseline to wk 26 in both MG-ADL + QMG scores** in Rava group
  - MG-ADL [**–3.1** vs. –1.4; *p<0.001*]
  - QMG [**–2.8** vs. –0.8; *p<0.001*]
- Improvements in both measures MG-ADL + QMG, occurred within **1 wk** of initiation, sustained through wk 26

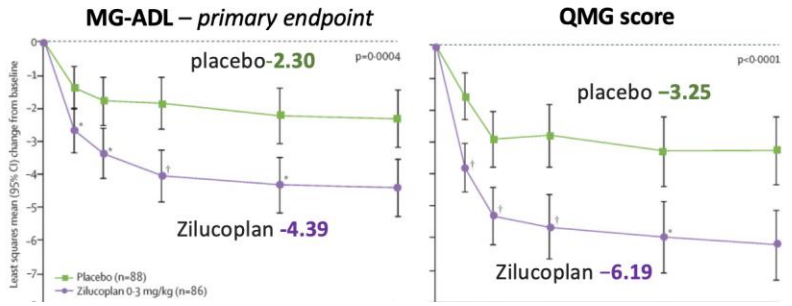
Clinical Trial > Lancet Neurol. 2023 May;22(5):395-406.
doi: 10.1016/S1474-4422(23)00080-7.

Safety and efficacy of zilucoplan in patients with generalised myasthenia gravis (RAISE): a randomised, double-blind, placebo-controlled, phase 3 study

James F Howard Jr [1], Saskia Bresch [2], Angela Genge [3], Channa Hewamadduma [4], John Hinton [5], Yessar Hussain [6], Raul Juntas-Morales [7], Henry J Kaminski [8], Angelina Maniaol [9], Renato Mantegazza [10], Masayuki Masuda [11], Kumaraswamy Sivakumar [12], Marek Śmiłowski [13], Kimiaki Utsugisawa [14], Tuan Vu [15], Michael D Weiss [16], Małgorzata Zajda [17], Babak Boroojerdi [18], Melissa Brock [19], Guillemette de la Borderie [20], Petra W Duda [21], Romana Lowcock [22], Mark Vanderkelen [23], M Isabel Leite [24]; RAISE Study Team

Zilucoplan (Zilbrysq)

- 12 wks, 174 pts
- SC Dosing: 0.3 mg/kg once **daily** self-injection. **Small molecule peptide** (**3.5 kDa**, 15–aa)**, 40x smaller than IgG**
- Achieves significant clinical improvements **within 1 wk →** *sustained 12 wks*



Humanized monoclonal Ab - molecular weight of ~**148 kDa**

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Can a pt switch from IV to SC? Is it safe?

› Ther Adv Neurol Disord. 2025 Jul 5:18:17562864251347283. doi: 10.1177/17562864251347283 eCollection 2025.

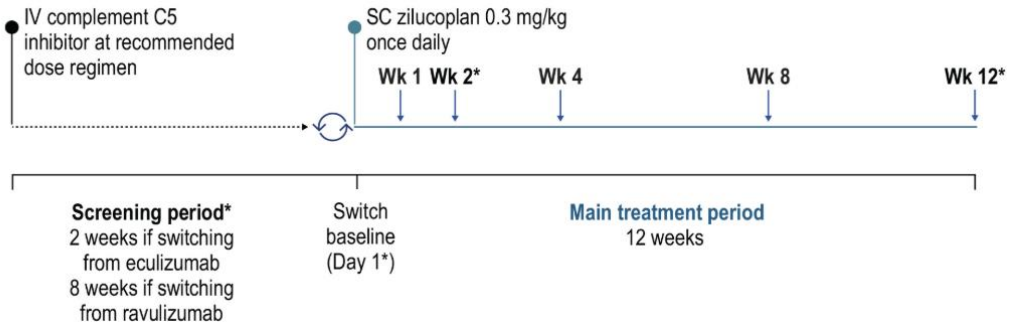
Switching to subcutaneous zilucoplan from intravenous complement component 5 inhibitors in generalised myasthenia gravis: a phase IIIb, open-label study

Miriam Freimer [1], Urvi Desai [2], Raghav Govindarajan [3], Min K Kang [4], Shaida Khan [5], Bhupendra Khatri [6], Todd Levine [7], Samir Macwan [8], Perry B Shieh [9], Michael D Weiss [10], Jos Bloemers [11], Babak Boroojerdi [12], Eumorphia Maria Delicha [13], Andreea Lavrov [12], Puneet Singh [14], James F Howard Jr [15]

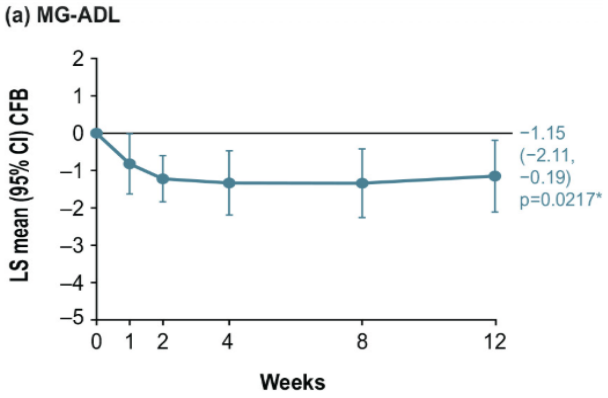
Affiliations + expand

PMID: 40620733 PMCID: PMC12228924 DOI: 10.1177/17562864251347283

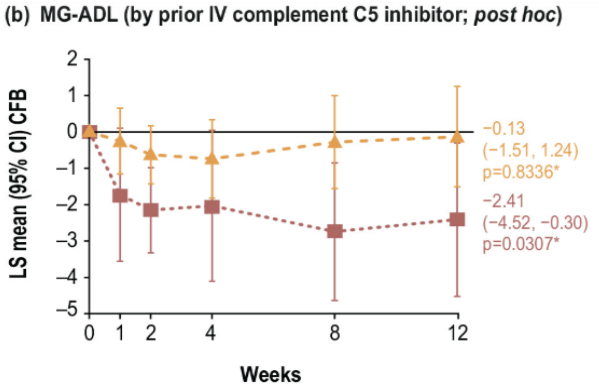
- 26 pts clinically stable pts with gMG on IV C5 inhibitor who **wanted to switch from IV to SC**
  - 16 switched from Ecu, 10 from Rava

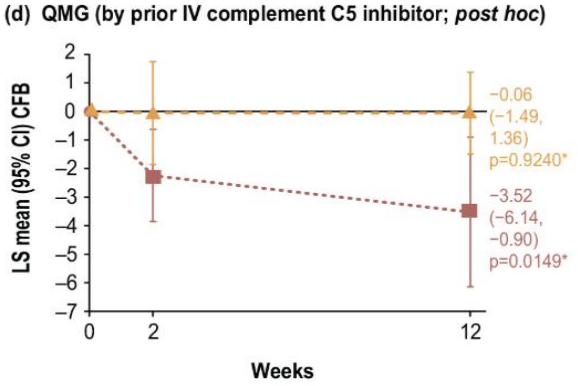


- TEAEs occurred in 19/26 (73%) pts, mostly mild in severity



- **At wk 12, MG-ADL & QMG scores improved from baseline (significant)**
- Clinically meaningful improvement in mean MG-ADL & QMG scores observed at wk 12 from baseline among pts who switched from Rava





At wk 12, **77%** (*n* = 20) **pts preferred SC injection** vs IV

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Meningococcal vaccines

Recommendation for meningococcal vaccine **at least 2 weeks prior** to treatment for those receiving C5 inhibitor

SAMPLE VACCINATION SCHEDULE*

VACCINE	PRIMARY VACCINATION	BOOSTER VACCINATION
MenACWY (Menveo, MenQuadfi)	2 doses at least 8 weeks apart	1 dose every 5 years if risk remains
+		
MenB-4C (Bexsero)	3 doses 0, 1-2, and 6 months apart	1 dose 1 year following completion of primary series and every 2 to 3 years if risk remains
OR		
MenB-FHbp (Trumenba)	3 doses 0, 1-2, and 6 months apart	1 dose 1 year following completion of primary series and every 2 to 3 years if risk remains

https://alexiononesource.com/

If drug must be started immediately, provide abx & administer vaccines as soon as possible

Nipocalimab

Clinical Trial > Lancet Neurol. 2025 Feb;24(2):105-116. doi: 10.1016/S1474-4422(24)00498-8.

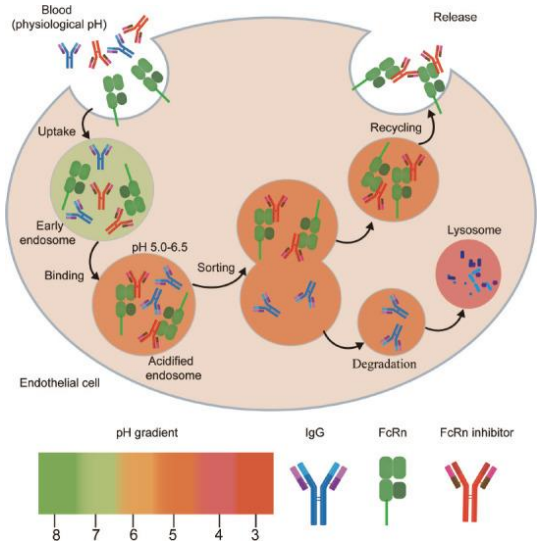
Safety and efficacy of nipocalimab in adults with generalised myasthenia gravis (Vivacity-MG3): a phase 3, randomised, double-blind, placebo-controlled study

Carlo Antozzi [1], Tuan Vu [2], Sindhu Ramchandren [3], Richard J Nowak [4], Constantine Farmakidis [5], Vera Bril [6], Jan De Bleecker [7], Huan Yang [8], Eduard Minks [9], Jin-Sung Park [10], Mariusz Grudniak [11], Marek Smilowski [12], Teresa Sevilla [13], Sarah Hoffmann [14], Kumaraswamy Sivakumar [15], Yasushi Suzuki [16], Eriene Youssef [17], Panna Sanga [17], Keith Karcher [18], Yaowei Zhu [17], John J Sheehan [19], Hong Sun [17]; Vivacity-MG3 Study Group

Affiliations + expand

PMID: 39862879 DOI: 10.1016/S1474-4422(24)00498-8

- MG-ADL score ≥6, Ab positive (AChR/MuSK/LRP4)
- Nipocalimab vs placebo IV infusions q 2 wks for 24 wks (added to standard-of-care therapy)
- **196 pts** (98 in Nipo group, 98 in placebo group)
  - 153 were **Ab+** (77 in Nipo group & 76 in placebo)



Designed to binds to FcRn, reducing circulating IgG Ab levels, **blocks IgG recycling**

- *Primary endpoint*: mean change in MG-ADL from baseline to wks 22, 23, & 24
- **-4.70** in the Nipo group vs **-3.25** in placebo (difference -1.45 [95% CI -2.38 to -0.52]; *p=0.0024*)
- Adverse events was similar btwn groups
- SAE reported for 9 (9%) of 98 pts in the nipocalimab group, 14% of pts in the placebo group, 3 had a fatal outcome
  - Nipocalimab: MG crisis; placebo: cardiac arrest & MI

Al-Samkari et al. Novel therapeutics and future directions for refractory immune thrombocytopenia. British Journal of Haematology. 2023. 203. 65-78.

FcRN inhibitors

Efgartigimod (Vyvgart)

- Human IgG1 ab Fc-fragment
- 167 pts
  - 129 (77%) AchR ab+, **6 MuSK ab+**
- 26 wks IV Dosing
  - 10 mg/kg weekly x 4 wks, repeated based on clinical response

68%

of AChR-Ab+ pts treated with efgart ***achieved primary endpoint*** compared w **29.7% on placebo** *(p<0.0001)*

14%

of AChR-Ab+ pts pts **responded to efgart on QMG score** compared w **14% on placebo** *(p<0.0001)*

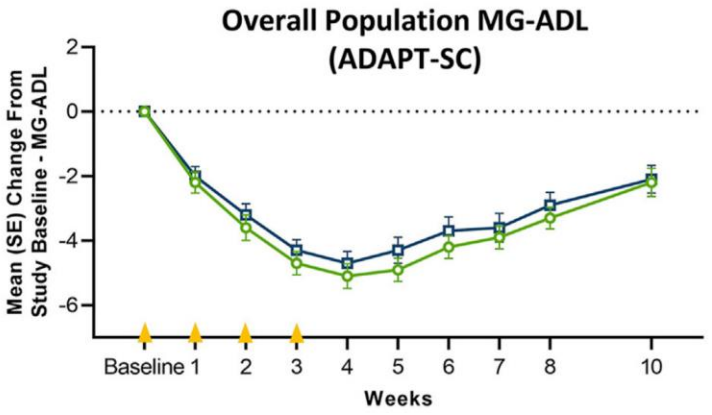
40%

of AChR-Ab+ pts treated with efgart **achieved minimal symptom expression (MG-ADL 0 or 1)**, vs **11% placebo**

Mean MG-ADL = **9**

Efgartigimod alpha (Vyvgart Hytrulo)

- 6 mL injection over **30 - 90 sec**
- Clinical trial bridging study: Efgart IV & Efgart alfa SC (non-inferiority study)
- Essentially, outcomes same btwn both studies (MG-ADL, QMG, MSE) as well as SE
  - Injection site reaction (38% in SC group vs 1.8% in IV group)

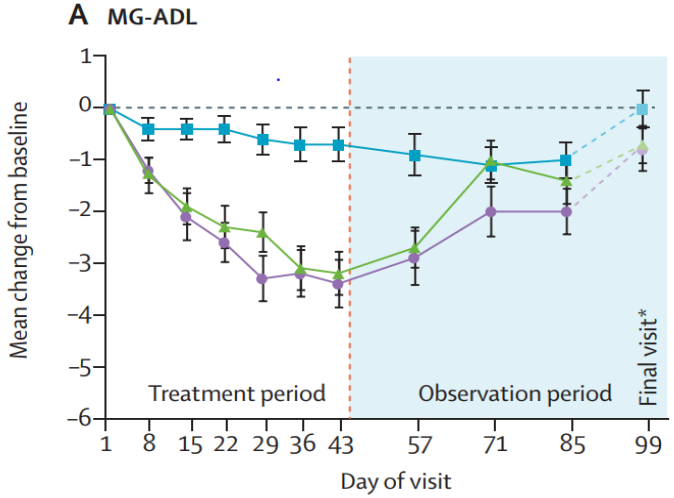


Adverse events: HA, nasopharyngitis

Rozanolixizumab (Rystiggo)

Humanized IgG4 ab Fc-fragment

- 200 pts
  - 179 (90%) AchR ab+, **21 (11%) MuSK ab+**
- SC infusions weekly x 6
  - Rozanolixizumab 7 mg/kg, Rozanolixizumab 10 mg/kg, or placebo

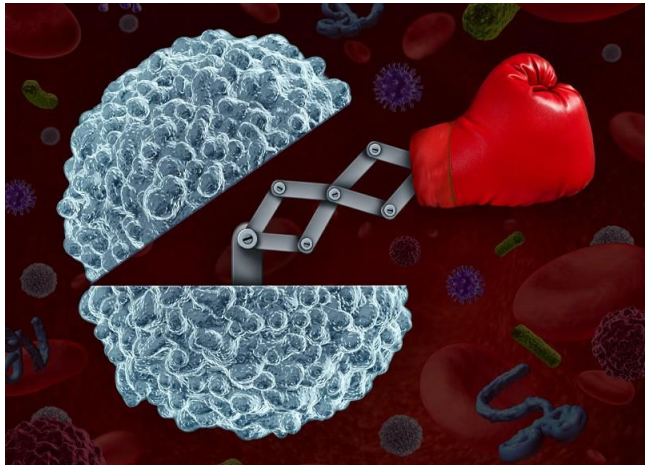


Adverse events: HA, diarrhea, fever

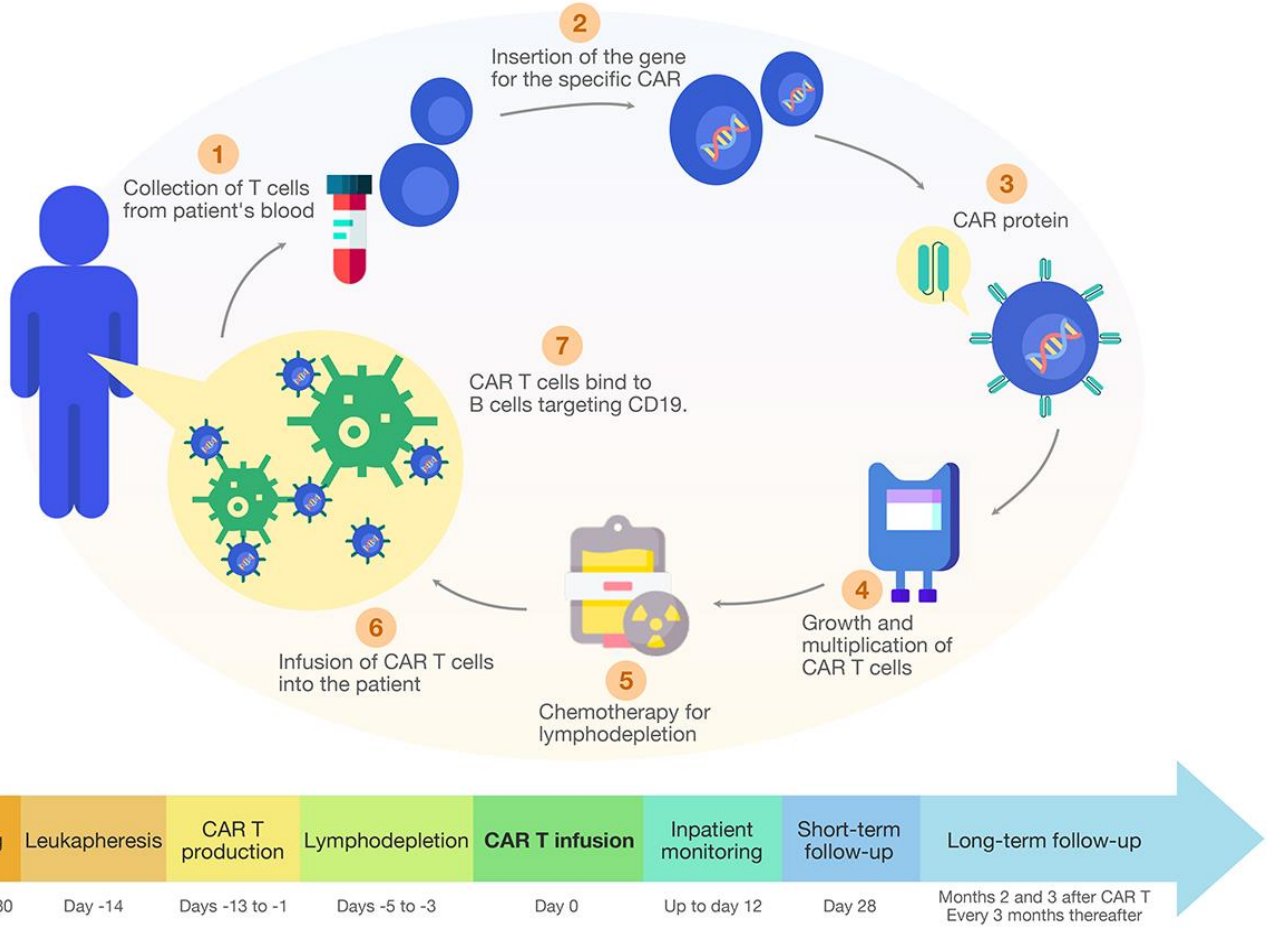
LYMPHOCYTE TARGETING THERAPIES

CAR-T

- Evolving
- Modifies pt's T-cells to target & eliminate the autoantibody-producing B cells driving the disease
- **Suggested as a possible <u>cure</u>**



www.nature.com/articles/d41591-023-00062-2



Sparks, J. A., & Sparks, M. A. (2024). CAR T Cell Therapy for Autoimmune Diseases: Dawn of a New Era Toward a Cure. *Kidney News*, *16*(7), 21-21. Retrieved Sep 22, 2025, from https://www.kidneynews.org/view/journals/kidney-news/16/7/article-p21_10.xml

Emerging Therapies

Safety and Efficacy of Autologous RNA Chimeric Antigen Receptor T-cell (rCAR-T) Therapy in Myasthenia Gravis: a prospective, multicenter, open-label, non-randomised phase 1b/2a study

Volkan Granit [1,*], Michael Benatar [1,*], Metin Kurtoglu [2], Miloš D Miljković [2], Nizar Chahin [3], Gregory Sahagian [4], Marc H Feinberg [5], Adam Slansky [6], Tuan Vu [7], Christopher M Jewell [2], Michael S Singer [2], Murat V Kalayoglu [2], James F Howard Jr [8,**], Tahseen Mozaffar [9,**]; MG-001 Study Team

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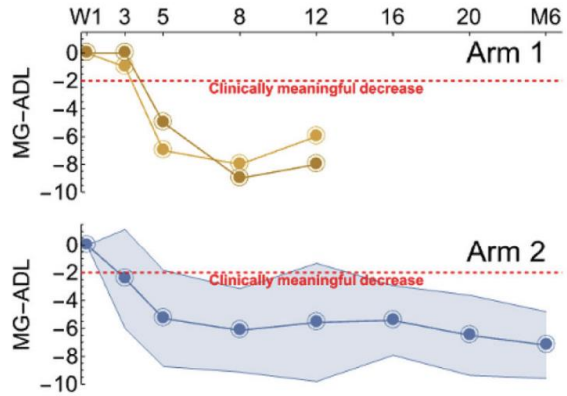
PMCID: PMC10416207 NIHMSID: NIHMS1913712 PMID: 37353278

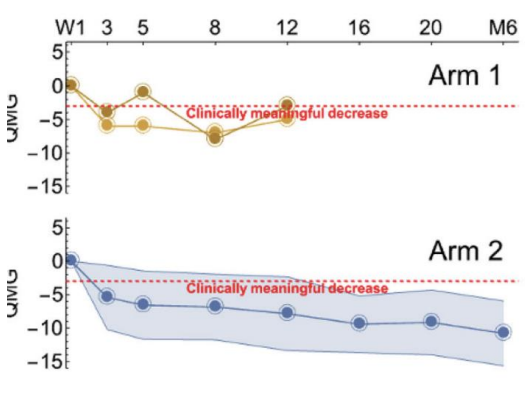
- *Primary objective*: establish safety & tolerability
- *Secondary objectives*: MG disease severity & biomarkers

- **14 pts**
- Weekly infusions x 6 wks
- Common adverse events: HA, n/v, fever - resolved within 24 hrs of infusion
- **No dose-limiting toxicity, cytokine release syndrome, or neurotoxicity**
  - 1 influenza, 1 drug-induced urticaria, 1 NSTEMI but deemed unrelated
- **No pt showed evidence of functional immunosuppression** (i.e. disappearance of therapeutic levels of vaccine titers)
- No opportunistic infections, no pts needed empiric Abx

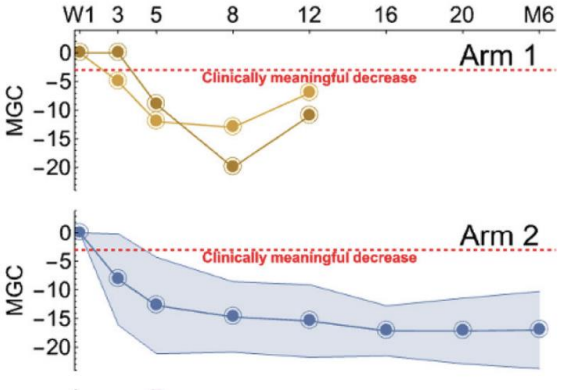
Mean improvements from baseline to wk 12



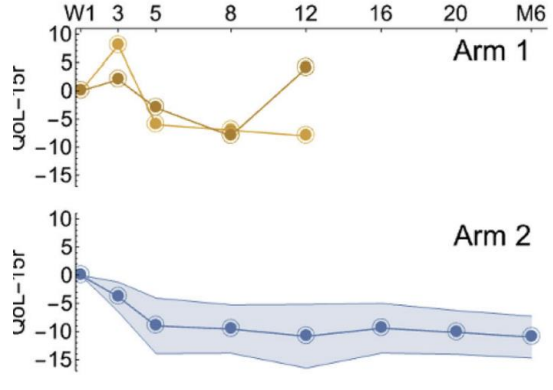
MG-ADL: **−5.9** [−9, −2.8]



QMG: **−7** [−11, −3]



MGC: **−14** [−19, −9]



MG-QoL-15r: **−9** [−15, −3]

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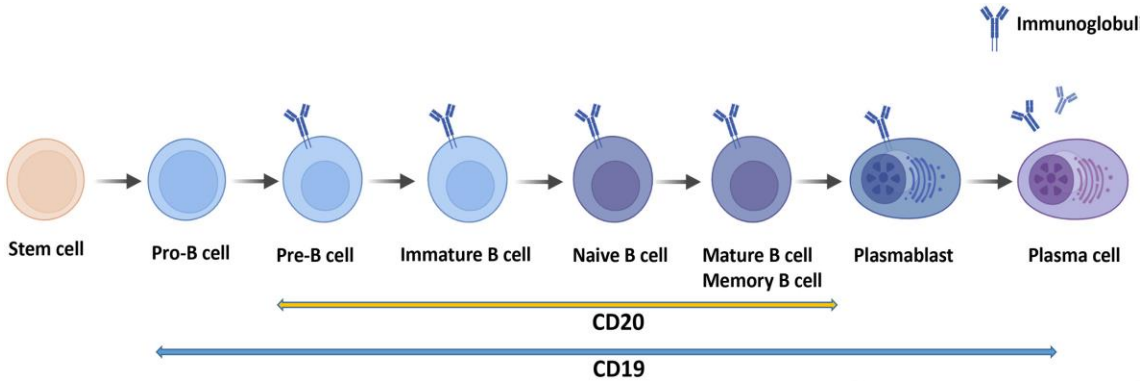
B cell depletion

MINT trial

- AchR or MuSK+ pts
- Inebilizumab - monoclonal antibody that depletes **CD19+ B cells (broad B-cell lineage marker)**



Depletes **plasmablasts → plasma cells** (plasma cells lack CD20, so Rituximab doesn't target this cell line)

Rituximab targets CD20, mature B cells only

Clinical Trial > N Engl J Med. 2025 Jun 19;392(23):2309-2320. doi: 10.1056/NEJMoa2501561. Epub 2025 Apr 8.

A Phase 3 Trial of Inebilizumab in Generalized Myasthenia Gravis

Richard J Nowak [1], Michael Benatar [2], Emma Ciafaloni [3], James F Howard Jr [4], M Isabel Leite [5], Kimiaki Utsugisawa [6], John Vissing [7], Mikhail Rojavin [8], Qing Li [8], Fengming Tang [8], Yanping Wu [8], Nishi Rampal [8], Sue Cheng [8]; MINT Investigators

Collaborators, Affiliations + expand

PMID: 40202593 DOI: 10.1056/NEJMoa2501561

- 238 participants (119 per group)
- 300 mg IV on days 1 & 15 for all, & additionally on day 183 for AChR+
  - 52 wks AchR+, 26 wks for MuSK+
- Steroid tapered starting wk 4, target 5 mg/day by wk 24
- **Inebilizumab group**: greater MG-ADL drop vs placebo (**-4.2** vs. -2.2; adjusted difference, -1.9) at wk 26
- Greater reduction in QMG score vs placebo (**-4.8** vs. -2.3; adjusted difference, -2.5)
- Most common adverse events: HA, cough, nasopharyngitis, infusion-related reactions, UTI

Shirani et al. Role of B Cells in Relapsing-Remitting and Progressive Multiple Sclerosis and Long-Term Effects of B Cell Depletion. Neurologic Clinics, Volume 42, Issue 1, 137 - 153

B cell depletion

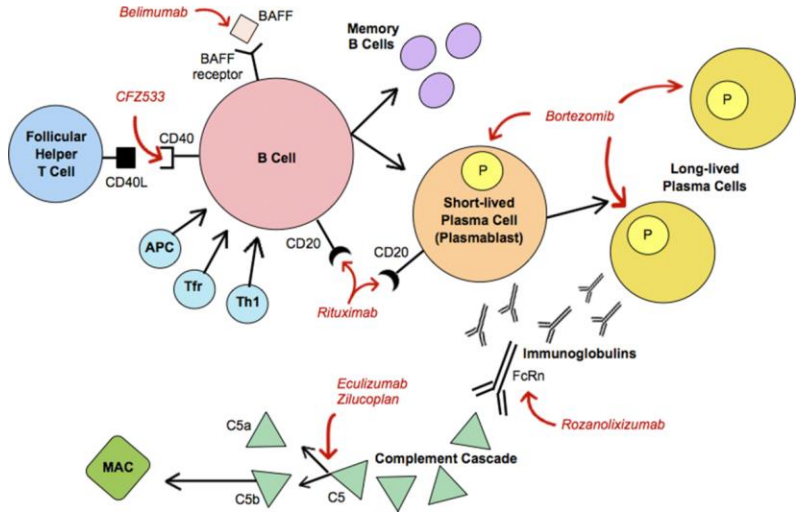
Clinical Trial > Eur J Neurol. 2024 Aug;31(8):e16322. doi: 10.1111/ene.16322.
Epub 2024 May 10.

A multicenter, randomized, open-label, phase 2 clinical study of telitacicept in adult patients with generalized myasthenia gravis

Jian Yin [1], Mingming Zhao [1], Xianhao Xu [1], Meini Zhang [2], Zucai Xu [3], Zunbo Li [4], Xinyue Qin [5], Zhuyi Li [6], Chongbo Zhao [7], Hongyu Zhou [8], Ying Ma [9], Wenfeng Cao [10], Guoping Wang [11], Yongzhong Lin [12], Jizhong Zhang [13], Xu Zhang [14], Hongbin Cai [15], Weidong Qian [16], Yiqi Wang [17], Xinghu Zhang [18], Guangzhi Liu [19], Jiawei Wang [20], Wei Qiu [21], Lianqiu Min [22], Jing Li [23], Hui Deng [24], Lan Chu [25], Yifan Zhang [25], Jianmin Fang [26]

Affiliations + expand

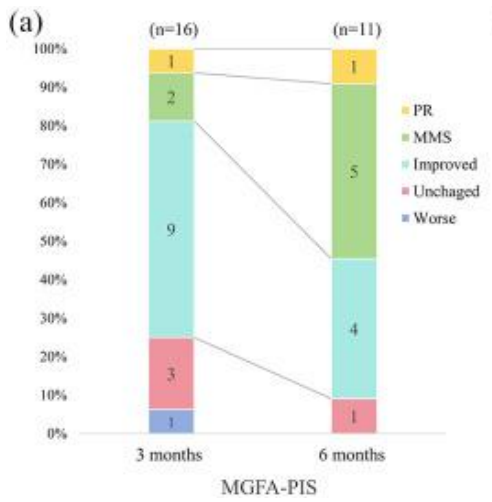
PMID: 38726639 PMCID: PMC11235933 DOI: 10.1111/ene.16322

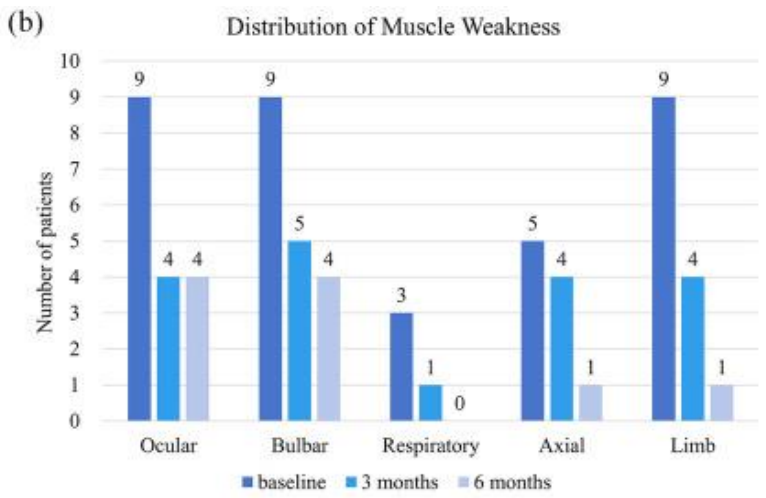


Novel recombinant fusion protein targeting BAFF/APRIL - crucial for B cell survival & maturation

Telitacicept

- Add on for refractory MG
- Effects seen at 3 mon, more at 6 mon - *significant reduction in both QMG & MG-ADL scores at 6 mon*
  - More protracted therapeutic effect
- Enduring effect might be attributed to pharmacodynamics of BLyS–telitacicept complex --- prolonged formation & elimination times, continuing therapeutic effects well beyond active dosing period
- *Able to reduce Prednisone dosage*





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Recruiting

A Phase 1 Study of Anitocabtagene Autoleucel for the Treatment of Subjects With Non-oncology Plasma Cell-related Diseases

ClinicalTrials.gov ID NCT06626919

Sponsor Arcellx, Inc.

Information provided by Arcellx, Inc. (Responsible Party)

Last Update Posted 2025-08-01

Recruiting

A Study of Telitacicept for the Treatment of Generalized Myasthenia Gravis (RemeMG)

ClinicalTrials.gov ID NCT06456580

Sponsor RemeGen Co., Ltd.

Information provided by RemeGen Co., Ltd. (Responsible Party)

Last Update Posted 2025-07-15

DISCUSSION

- **So many options** – which class do I choose?
- What role do the “newer” agents have?
- Complement vs FcRN – which one, when?
- Combo treatments?
- Predictive biomarkers for disease activity and/or treatment response?
    - Currently, treatment based only on clinical status + responses to treatment
- COST

Perpetual solace

Gena Brodie