new, safe and effective therapeutics that are publicly covered to manage gMG-related clinical manifestations.

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Therapeutic options for changing the course of disease in generalized myasthenia gravis (gMG) and fiscal consequences for Canadian governments

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Background: Generalized myasthenia gravis (gMG) is a potentially life threatening chronic autoimmune disease that can impair patients' ability to work effectively and increase reliance on public support benefits. A public economic framework was used to explore how treatment influences patients' and caregivers' economic activity, including tax revenues and public support in Canada. Methods: Natural history of gMG was simulated using a multi-state Markov cohort model. Health states were based on MG Activities of Daily Living (MG-ADL) total score in patients with AChR-Ab+ refractory gMG. Treatment, costs, and economic outcomes of patients taking efgartigimod were compared with alternative therapeutic options. Canadian public support benefits were based on official government sources. Results: Improved MG-ADL states predict higher workforce participation, lower rates of disability and less caregiving needs, resulting in higher tax revenues and less public support costs. Compared to alternative therapeutic options, efgartigimod is estimated to yield lifetime fiscal gains of $458,755 that exceed the incremental cost of $291,073, suggesting the Canadian government receives $1.6 for every $1.0 spent on efgartigimod for the treatment of gMG. Conclusions: Compared with alternative options, efgartigimod generated a positive fiscal return for the Canadian governments with additional savings from disease management, public benefits, and averted tax revenue losses.

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Investigating the bioequivalence, injection speed, and usability of subcutaneous efgartigimod PH20 administration using a prefilled syringe

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Background: Efgartigimod, a human immunoglobulin G1 (IgG1) antibody Fc fragment, reduces IgG levels through neonatal Fc receptor blockade. Efgartigimod PH20 SC (1000-mg fixed dose, coformulated with recombinant human hyaluronidase PH20) is provided in a vial administered via a separate syringe (V+S). Here, we investigate bioequivalence, safety, and tolerability of efgartigimod PH20 SC administered via prefilled syringe (PFS) vs V+S in healthy participants. Methods: Bioequivalence was assessed in a phase 1, open-label study. Healthy participants (n=72) were randomized to receive one injection of efgartigimod PH20 SC via PFS or V+S in a crossover design. Separate studies evaluated feasibility of different injection speeds and usability of the PFS. Results: Bioequivalence between efgartigimod PH20 SC via PFS or V+S was established, as the 90% CI around the geometric least-squares mean ratio of C_{max} and $AUC_{0\text{-inf}}$ was within predefined criteria (80.00%-125.00%). Most adverse events were mild to moderate. No observed differences in incidence of reported injection site reactions emerged. No serious adverse events or deaths occurred. Rapid (20-second) administration was feasible and the PFS could be safely prepared and administered by participants/caregivers. Conclusions: Efgartigimod PH20 SC administered via PFS is bioequivalent to efgartigimod PH20 SC administered via V+S, which may provide an additional convenient treatment option.

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Early and sustained response over time with zilucoplan in generalised Myasthenia Gravis: 120-week post hoc analysis of RAISE-XT

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Background: RAISE-XT (NCT04225871; Phase 3 study) showed clinically meaningful and sustained improvements in myasthenia gravis (MG)-specific outcomes with zilucoplan, a macrocyclic peptide complement component 5 inhibitor, in patients with acetylcholine receptor autoantibody-positive generalised MG. Methods: Adults self-administered once-daily subcutaneous zilucoplan 0.3mg/kg. This *post hoc* analysis assessed durability of response to Week 120 in MG-Activities of Daily Living (MG-ADL) and Quantitative MG (QMG) responders at Week 1 of two double-blind studies (NCT03315130, NCT04115293). Responder definitions: improvements of ≥3-points (MG-ADL) or ≥5-points (QMG) (interim data cut: 11 November 2023). Results: 93 patients were randomised to zilucoplan 0.3mg/kg in the double-blind studies; 43.0% (n=40/93) and 33.3% (n=31/93) were MG-ADL and QMG responders, respectively, at Week 1. Week 1 responders spent a median (range) of 98.9% (5.8–99.2) and 99.0% (2.5–99.2) time in response up to Week 120 for MG-ADL and QMG. Week 1 non-responders spent a median (range) of 84.6% (0.0–98.3) and 66.7% (0.0–98.9) time in response up to Week 120 for MG-ADL and QMG, with most responding later in the study. Conclusions: Among early (Week 1) zilucoplan responders, time in response remained high (99%) up to Week 120. These data demonstrate rapid and sustained efficacy with long-term zilucoplan treatment.