

Rozanolixizumab for ocular myasthenia gravis: Study design of a Phase 3, randomized, double-blind, placebo-controlled trial (MyVision) and open-label extension study (MyVisionXT)

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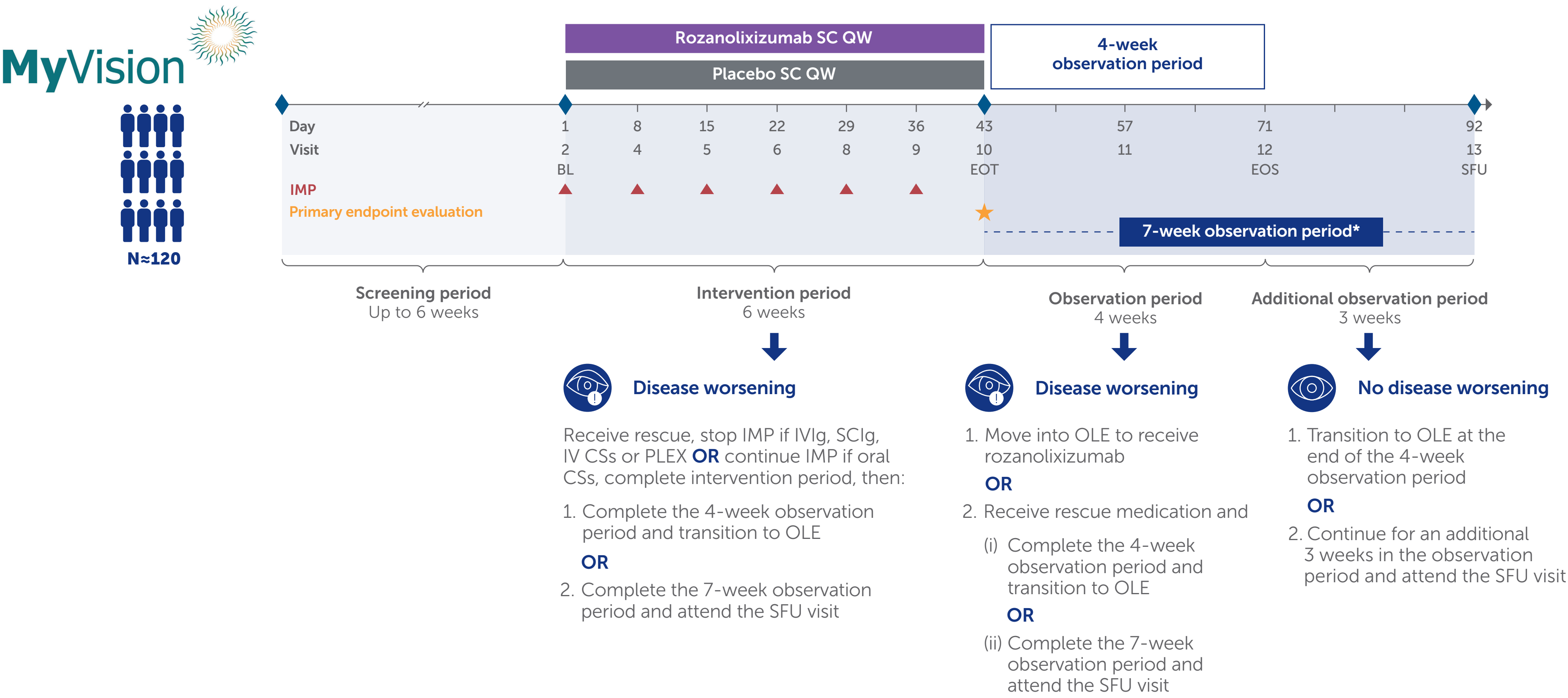
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Introduction

- oMG is a clinical subtype of MG that affects only the ocular muscles, causing ptosis and/or diplopia¹
 - Such ocular symptoms can impede daily activities and significantly reduce QoL²
- Rozanolixizumab, a humanized IgG4 mAb that targets and blocks FcRn with high affinity, is approved for the treatment of adults with anti-AChR Ab+ or anti-MuSK Ab+ gMG^{3,4}
- In the Phase 3 MycarinG study (NCT03971422), patients with gMG receiving one 6-week cycle of rozanolixizumab (7 mg/kg or 10 mg/kg) demonstrated greater improvements in ocular symptoms across MG-specific outcomes than with placebo⁵
- These improvements were maintained over repeated 6-week cycles in the OLE studies MG0004 (NCT04124965) and MG0007 (NCT04650854)⁶
- Here, we describe the study designs of the Phase 3 MyVision study (MG0038/NCT07463521) and its OLE, MyVisionXT (MG0039/NCT07465289), which will assess rozanolixizumab treatment in patients with oMG

MyVision study design

MyVision is a Phase 3, multicenter, randomized, parallel-group, placebo-controlled, double-blind study to evaluate the efficacy and safety of one 6-week cycle of rozanolixizumab in adults with anti-AChR Ab+, anti-MuSK Ab+ or seronegative oMG



Inclusion criteria

- Aged ≥18 years
- MGFA Clinical Class I MG with anti-AChR Ab+, anti-MuSK Ab or seronegative status
- MGII ocular score (PRO part) ≥6 (with ≥2 ocular items with a score ≥2 at screening and baseline)
- Ocular onset <3 years before screening, or ≥3 years provided they have demonstrated response to treatment¹ in the past year

Exclusion criteria

- Any clinically significant medical or psychiatric condition, active serious infection or history of serious infection, recent or planned major surgery and/or significant laboratory abnormality
- Other relevant ocular, autoimmune, neurological diseases or active neoplastic disease
- Previous treatment with FcRn inhibitors or prohibited medications¹
- Live vaccination within 4 weeks prior to baseline visit, or planned during the study or within 8 weeks after the final study dose

Primary endpoint:

- CFB in MGII ocular score (PRO part) at Day 43

Secondary endpoints:

- CFB to Day 43 in:
 - MGSPRO Ocular Muscle Weakness score
 - MG-ADL ocular subdomain score
 - MGII ocular score (physical examination part)
 - MG-QoL15r total score

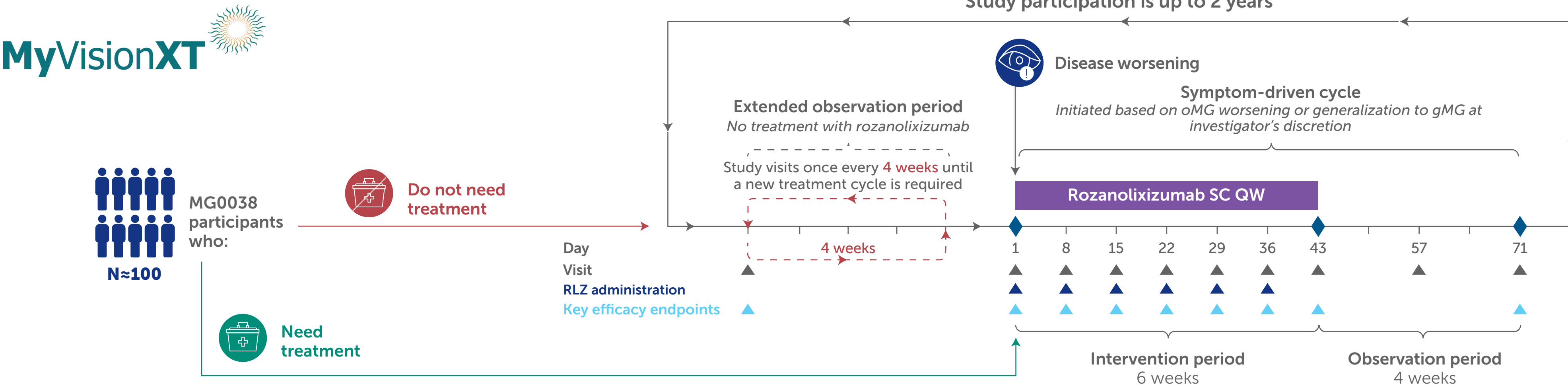
Secondary safety endpoint:

- Incidence of TEAEs

Visit 3 and Visit 7 are PK assessments. *Study participants who will not transition to the OLE study must complete a 7-week observation period from Day 43 and conclude at the SFU Visit (Day 92), corresponding to 8 weeks following the final dose on Day 36 of study intervention. ¹IVIg, PLEX, SCIg, pyridostigmine, and/or CSs. ²Prohibited medications include immunosuppressants (pimecrolimus within 4 weeks or vinca alkaloids within 12 weeks of screening), C5 inhibitors (eculizumab, ravulizumab or zilucoplan) within 6 weeks of screening and B-cell depleters (including rituximab and inebilizumab) within 6 months of screening.

MyVisionXT study design

MyVisionXT is an OLE study to evaluate the long-term safety, tolerability and efficacy of repeated symptom-driven treatment cycles of rozanolixizumab in eligible patients from MyVision



Inclusion criteria

- Received ≥1 IMP dose in MyVision and opted to receive rozanolixizumab in MyVisionXT

Primary endpoint:

- Incidence of TEAEs

Secondary endpoints:

- For the first three symptom-driven cycles, CFB to Day 43 in:
 - MGII ocular score (PRO part)
 - MGSPRO Ocular Muscle Weakness score
 - MG-ADL ocular subdomain score
 - MG-QoL15r total score
- Study patient who generalizes to MGFA Class II or above over time
- CFB in MGII total and generalized score over time
- CFB in MG-ADL total score over time

Symptom-driven cycles (defined as cycles initiated based on oMG worsening) are initiated at the investigator's discretion either immediately or following symptom worsening during the extended observation period. For any patient who receives IVIg, SCIg or PLEX rescue therapy during the intervention period or the 4-week observation period in MyVision, a ≥2-week interval must occur before the initiation of a symptom-driven rozanolixizumab cycle in MyVisionXT. The dosing strategies for MyVision and MyVisionXT align with the approved regional labels for rozanolixizumab in gMG.

Summary and conclusions



The clinical course of oMG carries a significant patient burden, characterized by impaired quality of life and daily living due to ocular symptoms, diagnostic challenges and suboptimal clinical outcomes



Rozanolixizumab has demonstrated efficacy in MG-specific ocular outcomes in *post hoc* analyses of patients with gMG



MyVision is an ongoing, Phase 3, randomized, double-blind, placebo-controlled study evaluating the efficacy and safety of rozanolixizumab in adults with oMG (currently recruiting)



MyVisionXT, an open-label extension (OLE) study, will assess the long-term safety, tolerability and efficacy of repeated, symptom-driven rozanolixizumab treatment cycles



Together, these studies will provide critical data on the short- and long-term therapeutic potential of rozanolixizumab for patients with oMG

Abbreviations: Ab+, antibody positive; AChR, acetylcholine receptor; BL, baseline; C5, component 5; CFB, change from baseline; CS, corticosteroid; EOS, end of study; EOT, end of treatment; FcRn, neonatal fragment crystallizable receptor; (g)MG, (generalized) myasthenia gravis; IgG4, immunoglobulin G subunit 4; IMP, investigational medicinal product; IV, intravenous; IVIg, intravenous immunoglobulin; mAb, monoclonal antibody; MG-ADL, Myasthenia Gravis Activities of Daily Living; MGFA, Myasthenia Gravis Foundation of America; MGII, Myasthenia Gravis Impairment Index; MGSPRO, Myasthenia Gravis Symptoms Patient-Reported Outcome; MG-QoL15r, Myasthenia Gravis Quality of Life 15-item revised; MuSK, muscle-specific tyrosine kinase; OLE, open-label extension; oMG, ocular myasthenia gravis; PK, pharmacokinetics; PLEX, plasma exchange; PRO, patient-reported outcome; QoL, quality of life; QW, once weekly; RLZ, rozanolixizumab; SC, subcutaneous; SCIg, subcutaneous immunoglobulin; SFU, safety follow-up; TEAE, treatment-emergent adverse event.

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