Transcript Details
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Investigating a gMG Therapy, Part 3: Results from the Extension Studies

Dr. Edmundson:
Hello. I'm Dr. Edmundson. I'm a neuromuscular neurologist and I've been treating patients with generalized myasthenia gravis, or gMG, for 7 years. I'm looking forward to sharing information with you about RYSTIGGO, a targeted therapy approved to treat adult patients with gMG.[1]

Generalized myasthenia gravis, or gMG, is a rare and chronic autoimmune disease.[2] Even on treatment, patients with gMG may still experience moderate to severe symptoms that impact them both physically and emotionally.[3,4] If patients continue to experience symptoms, it may be time to consider different treatment options. In this video we will focus on the safety and efficacy of RYSTIGGO in its extension studies.

RYSTIGGO is indicated for the treatment of gMG in adult patients who are anti-AChR or anti-MuSK antibody positive. It is a once-weekly subcutaneous infusion delivered in 6-week treatment cycles.[1]

Before we dive into the extension studies, let's quickly review the RYSTIGGO pivotal study. The efficacy and safety of RYSTIGGO in adults with anti-AChR or anti-MuSK antibody–positive gMG were established in MycarinG, a multicenter, randomized, double-blind, placebo-controlled Phase 3 study.[1,2] The primary endpoint measured the change from baseline to Week 6 in Myasthenia Gravis Activities of Daily Living, or MG-ADL score. Patients taking RYSTIGGO experienced a statistically significant reduction in MG-ADL total score at Week 6.[1]

The most common adverse reactions occurring in at least 10% of patients treated with RYSTIGGO were headache, infections, diarrhea, pyrexia, hypersensitivity reactions, and nausea. RYSTIGGO is associated with important warnings and precautions, including increased risk of infection, drug-induced aseptic meningitis, and hypersensitivity reactions.[1] This was just a brief overview of the RYSTIGGO pivotal study. For additional information about MycarinG, watch the RYSTIGGO MG-ADL results and secondary endpoints videos on RystiggoHCP.com. Now, let's discuss the RYSTIGGO extension studies.

Patients from the RYSTIGGO treatment groups in MycarinG could enroll in two extension studies, MG0004 and MG0007, that further evaluated the safety and efficacy of RYSTIGGO over time.[2,5,6] MG0007 was a multicenter Phase 3 study that included 165 patients from MycarinG and MG0004. It assessed the long-term safety, tolerability, and efficacy of RYSTIGGO given in repeated 6-week cycles, based on the manifestation of gMG symptoms.[6,7] Moving forward, we will talk about the pooled results for the studies.

The RYSTIGGO safety profile in the extension studies was consistent with that of the placebo-controlled phase of the study with each treatment cycle given. Headache, diarrhea, COVID-19, decrease in immunoglobulin G, nausea, and pyrexia occured in at least 10% of patients taking RYSTIGGO.[7]

Additionally, RYSTIGGO may increase the risk of infection. Delay administration of RYSTIGGO in patients with an active infection and monitor for signs and symptoms of infection in patients treated with RYSTIGGO.[1] Serious events of aseptic meningitis have been reported with RYSTIGGO. If symptoms that are consistent with aseptic meningitis develop, a diagnostic workup and treatment should be initiated according to the standard of care.[1] Angioedema and rash have occurred in patients treated with RYSTIGGO. If a hypersensitivity reaction occurs, discontinue the RYSTIGGO infusion and start appropriate therapy.[1]

Clinically meaningful improvements in MG-ADL total score were observed in patients receiving subsequent cycles of RYSTIGGO. On

average, a reduction in MG-ADL score of 2 points or greater was observed at Week 6 with each subsequent cycle in both dose groups.[2,7]

Minimal Symptom Expression, or MSE, rates were also evaluated in the extension studies. Patients who reached MSE achieved an MG-ADL score of 0 or 1 at any visit during each 6-week treatment cycle and observation period without the use of rescue therapy. MSE rates with repeated cycles of RYSTIGGO were consistent with those in the pivotal study, ultimately reaching 41% at cycle 6.[7] MSE was an exploratory endpoint and not controlled for multiplicity. Because of this, and the decreasing number of patients receiving subsequent cycles, data should be interpreted with caution and conclusions cannot be drawn. On average, patients taking RYSTIGGO initiated 4 treatment cycles per year. The safety of initiating subsequent cycles sooner than 63 days from the start of the previous treatment cycle has not been established.[1]

Clinically meaningful improvements were also observed in Quantitative Myasthenia Gravis, or QMG, and Myasthenia Gravis Composite, or MGC, total score at Week 6 with repeated cycles of RYSTIGGO. On average, a 3-point or greater improvement in these scores was observed with each subsequent treatment cycle in both dose groups. The QMG and MGC scales are widely used in gMG clinical trials, so I will not explain these scales here.[2,7,8] Additionally, improvements in all 3 domains of Myasthenia Gravis Symptoms Patient-Reported Outcome, or MG Symptoms PRO scores were observed in the extension studies in patients taking RYSTIGGO.[7] MG Symptoms PRO was part of the planned efficacy analysis; however, efficacy or clinical significance should be interpreted with caution.

MG Symptoms PRO is a new outcome measure used in the RYSTIGGO clinical studies. It includes scales assessing muscle weakness fatigability, physical fatigue, and bulbar muscle weakness.[2] MG Symptoms PRO, a UCB-developed tool, is the only myasthenia gravis clinical outcome assessment that evaluates physical fatigue.[2] To learn more about MG Symptoms PRO, you can watch the second video in this series, Secondary Endpoints Including MG Symptoms PRO.

Thank you for joining me to review the RYSTIGGO extension studies. As we've seen, improvements in MG-ADL, QMG, MGC, and MG Symptoms PRO scores, along with consistent MSE rates, were observed with repeated cycles of RYSTIGGO. The safety profile in the extension studies was also consistent with the pivotal study.[7] This video is one in a series of educational videos about RYSTIGGO. Go to RystiggoHCP.com to view all the available videos and to learn more about RYSTIGGO and its role in the treatment of adults with anti-AChR antibody–positive and anti-MuSK antibody–positive gMG.[1]

Voiceover:
INDICATION
RYSTIGGO (rozanolixizumab-noli) is indicated for the treatment of generalized myasthenia gravis (gMG) in adult patients who are anti-acetylcholine receptor (AChR) or anti-muscle-specific tyrosine kinase (MuSK) antibody positive.

IMPORTANT SAFETY INFORMATION
WARNINGS AND PRECAUTIONS
Infections: RYSTIGGO may increase the risk of infection. Delay RYSTIGGO administration in patients with an active infection until the infection is resolved. During treatment with RYSTIGGO, monitor for clinical signs and symptoms of infection. If serious infection occurs, administer appropriate treatment and consider withholding RYSTIGGO until the infection has resolved.

Immunization
Immunization with vaccines during RYSTIGGO treatment has not been studied. The safety of immunization with live or live-attenuated vaccines and the response to immunization with any vaccine are unknown. Because RYSTIGGO causes a reduction in IgG levels, vaccination with live-attenuated or live vaccines is not recommended during treatment with RYSTIGGO. Evaluate the need to administer age-appropriate vaccines according to immunization guidelines before initiation of a new treatment cycle with RYSTIGGO.

Aseptic Meningitis: Serious adverse reactions of aseptic meningitis (also called drug-induced aseptic meningitis) have been reported in patients treated with RYSTIGGO. If symptoms consistent with aseptic meningitis develop, diagnostic workup and treatment should be initiated according to the standard of care.

Hypersensitivity Reactions: Hypersensitivity reactions, including angioedema and rash, were observed in patients treated with RYSTIGGO. Management of hypersensitivity reactions depends on the type and severity of the reaction. Monitor patients during treatment with RYSTIGGO and for 15 minutes after for clinical signs and symptoms of hypersensitivity reactions. If a reaction occurs, institute appropriate measures if needed.

ADVERSE REACTIONS
In a placebo-controlled study, the most common adverse reactions (reported in at least 10% of RYSTIGGO-treated patients) were

headache, infections, diarrhea, pyrexia, hypersensitivity reactions, and nausea. Serious infections were reported in 4% of patients treated with RYSTIGGO. Three fatal cases of pneumonia were identified, caused by COVID-19 infection in two patients and an unknown pathogen in one patient. Six cases of infections led to discontinuation of RYSTIGGO.

Please see full Prescribing Information at www.RystiggoHCP.com

References:

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