Transcript Details
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Investigating a gMG Therapy, Part 1: The MG-ADL Results

Dr. Edmundson:
Hello. I'm Dr. Edmundson...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 chronic and unpredictable autoimmune disease characterized by muscle weakness and fatigue. Symptoms of gMG may have a negative impact on patients' quality of life, even in patients considered to be controlled with current therapy. Patients with MuSK+ gMG usually present with more severe disease. Early diagnosis and targeted treatment of this specific population have led to a decrease in treatment-refractory patients. There remains a need for therapies specifically indicated for gMG, particularly for patients with MuSK+ gMG.[2-4]

In this video we will discuss the pivotal study for RYSTIGGO. We will specifically cover outcomes related to the Myasthenia Gravis Activities of Daily Living, or MG-ADL, score. MG-ADL scores were evaluated as this study's primary endpoint, in the MuSK+ subgroup analysis, and through Minimal Symptom Expression rates.

RYSTIGGO is a targeted therapy for adult patients with gMG and is the first and only FDA-approved treatment option for patients with anti-MuSK antibody–positive gMG.[1] The efficacy and safety of RYSTIGGO in adults with anti-AChR and anti-MuSK antibody–positive gMG were established in MycarinG, a large multicenter, randomized, double-blind, placebo-controlled Phase 3 study.[1,3] 200 adult patients with anti-AChR and anti-MuSK antibody–positive gMG were randomized to receive weight-tiered doses of RYSTIGGO, either 7 mg/kg or 10 mg/kg or placebo subcutaneously once a week for 6 weeks, followed by an 8-week observation period. All patients continued on their current therapies during the study.[1,3]

The study evaluated a broad population of patients—ranging in factors like age, weight, race, MG-ADL score, MGFA class, and treatment history—and included adult patients with anti-AChR antibody–positive and anti-MuSK antibody–positive gMG.[1,3] The primary endpoint in the MycarinG study was the change in MG-ADL score from baseline to Week 6.[1] Compared with patients taking placebo, those who received RYSTIGGO experienced a greater reduction in MG-ADL score that was both statistically significant and clinically meaningful. Clinically meaningful was established as a 2-point or greater improvement in MG-ADL total score. Maximum efficacy was achieved at Week 6, with improvements observed 1 week after the initial dose.[1,3]

Over 2 times more patients were MG-ADL responders in both RYSTIGGO treatment groups compared with placebo. MG-ADL responders were defined as having a 2-point or greater reduction in MG-ADL total score at Week 6 compared to baseline. 72% and 69% of patients were responders in the RYSTIGGO 7 mg/kg and 10 mg/kg dose groups, respectively, vs 31% in the placebo group.[3] Responder rate was a prespecified secondary endpoint not controlled for multiplicity. These data should be interpreted with caution and conclusions cannot be drawn.

A subgroup analysis of the primary endpoint was conducted in patients with MuSK+ gMG evaluating change from baseline to Week 6 in MG-ADL total score.[3,6] MuSK+ adult patients in the RYSTIGGO 7 mg/kg dose group experienced a 7.3-point reduction in MG-ADL total score, and those in the 10 mg/kg dose group experienced a 4.2-point reduction compared with a 2.3-point increase in the placebo group. Please note that 13 patients were evaluated in the RYSTIGGO treatment groups for the subgroup analysis and 8 patients in the placebo group.[3,6]

100% of the anti-MuSK antibody–positive adult patients in the RYSTIGGO treatment groups were MG-ADL responders compared with

only 14% in the placebo group.[3,5] As I mentioned before, responder rate was a prespecified secondary endpoint not controlled for multiplicity. This data should be interpreted with caution and conclusions cannot be drawn.

Minimal Symptom Expression, or MSE, was also evaluated in the overall population in the pivotal study. Patients who reached MSE achieved an MG-ADL score of 0 or 1 at any point during the pivotal study. 26% of patients in the RYSTIGGO 7 mg/kg group and 28% of patients in the 10 mg/kg group achieved MSE compared with 3% in the placebo group.[3] MSE was an exploratory endpoint and not controlled for multiplicity. This data should be interpreted with caution and conclusions cannot be drawn.

The safety of RYSTIGGO was also established in the MycarinG pivotal study.[1,3] The most frequently reported adverse reactions for RYSTIGGO that occurred in at least 10% of patients were headache, infections, diarrhea, pyrexia, hypersensitivity reactions, and nausea.[1] 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. Angioedema and rash have occurred in patients treated with RYSTIGGO. If a hypersensitivity reaction occurs, discontinue the RYSTIGGO infusion and start appropriate therapy.[1]

Thank you for joining me today. This concludes our discussion of the MG-ADL results for the primary endpoint and MuSK+ subgroup analysis as well as the MSE rates in the RYSTIGGO pivotal study. RYSTIGGO is a targeted therapy that offers statistically significant and clinically meaningful improvements in MG-ADL scores for a broad population of adults with gMG and is the first treatment approved specifically for adult patients with anti-MuSK antibody–positive gMG.[1,3]

This video is just one in a series of educational videos about RYSTIGGO. Visit RystiggoHCP.com to view the next video in this series about the pivotal study secondary endpoints, with a deep dive into the novel outcome measure MG Symptoms PRO, or to learn more about RYSTIGGO and its role in the treatment of adult patients with anti-AChR 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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