

The first therapy approved in the UK for adults with AChR or MuSK antibody-positive gMG

This asset has been developed by UCB Pharma.

Prescribing information is available [here](#) and adverse event reporting information is available on the final page.

▼ This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions

RYSTIGGO® (rozanolixizumab)



A humanised IgG4 MAb that decreases serum IgG concentration by inhibiting the binding of IgG to FcRn, a receptor that under physiological conditions protects IgG from intracellular degradation and recycles IgG back to the cell surface

Therapeutic indications



RYSTIGGO is indicated as an add-on to standard therapy for the treatment of gMG in adult patients who are anti-AChR or anti-MuSK antibody positive

Posology and administration



A treatment cycle consists of one dose per week for 6 weeks

Subsequent treatment cycles to be administered according to clinical evaluation



It is recommended that RYSTIGGO is administered subcutaneously, preferably into the lower right or lower left part of the abdomen, below the belly button

The recommended total weekly dose of RYSTIGGO according to the patient's body weight

Body weight	≥35 to <50 kg	≥50 to <70 kg	≥70 to <100 kg	≥100 kg
Weekly dose (mg)	280 mg	420 mg	560 mg	840 mg
Weekly dose (ml)	2 ml	3 ml	4 ml	6 ml

Each vial contains excess volume for priming of the infusion line

Pivotal Phase 3 study



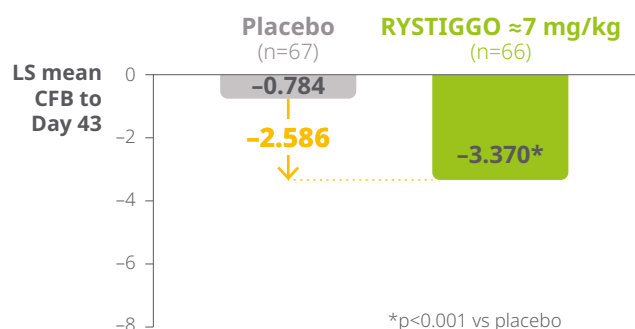
The UK approval is supported by data from the pivotal Phase 3 study MG0003, a randomised, double-blind, placebo-controlled study which enrolled 200 adult patients with AChR Ab+ or MuSK Ab+ gMG for up to 18 weeks; patients received RYSTIGGO (7 mg/kg, n=66; higher dose, n=67) or placebo (n=67) once a week for 6 weeks[†]

Long-term safety, tolerability and efficacy of RYSTIGGO were evaluated in two Phase 3 OLE studies; in the MG0007 OLE, RYSTIGGO was administered as 6-week treatment cycles based on clinical needs

MycarinG primary endpoint



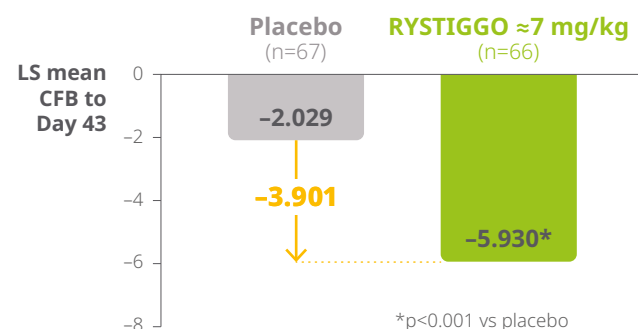
Statistically significant LS mean **CFB in MG-ADL score at Day 43** with RYSTIGGO ≈7 mg/kg vs placebo



MycarinG secondary endpoint



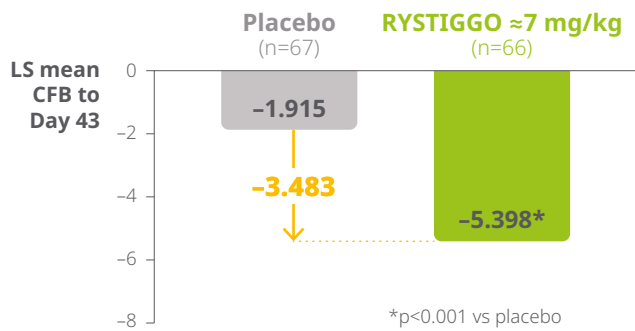
Statistically significant LS mean **CFB in MGC score at Day 43** with RYSTIGGO ≈7 mg/kg vs placebo



MycarinG secondary endpoint



Statistically significant LS mean **CFB in QMG score at Day 43** with RYSTIGGO ≈ 7 mg/kg vs placebo



MuSK Ab+ subgroup



CFB to Day 43 in MG-ADL, MGC and QMG scores



For the MuSK Ab+ patients who received RYSTIGGO ≈ 7 mg/kg and had data available at Day 43 (n=5), the CFB in MG-ADL, MGC and QMG scores were consistent with the overall group

Rescue therapy



During the **treatment period**:

- 0 patients treated with RYSTIGGO received rescue therapy
- 3 patients treated with placebo received rescue therapy

During the **observation period**:

- 1 patient treated with RYSTIGGO ≈ 7 mg/kg received rescue therapy
- 19 patients treated with RYSTIGGO ≈ 7 mg/kg rolled over early to an OLE study to receive RYSTIGGO treatment

Treatment-free intervals



In the clinical development programme:

- Most patients had treatment-free intervals of **4–13 weeks** between cycles
- From cycle to cycle, approximately 10% of patients had a treatment-free interval of **<4 weeks**

Summary of the RYSTIGGO safety profile in the gMG clinical development programme



MedDRA system organ class	Adverse reactions	Frequency*
Infections and infestations	Upper respiratory tract infections ^s	Common
	Herpes viral infection ^{¶#}	Not known
Nervous system disorders	Headache ^{**}	Very common
	Aseptic meningitis [¶]	Not known
Gastrointestinal disorders	Diarrhoea	Very common
	Nausea [¶]	Common
	Vomiting [¶]	Common
Skin and subcutaneous tissue disorders	Rash ^{††}	Common
	Angioedema ^{††}	Common
Musculoskeletal and connective tissue disorders	Arthralgia	Common
General disorders and administration site conditions	Pyrexia	Very common
	Injection site reactions ^{ss}	Common

Key warnings and precautions



- RYSTIGGO is contraindicated in patients with hypersensitivity to the active substance or to any of the excipients
 - Excipients include histidine, histidine hydrochloride monohydrate, proline, polysorbate 80 and water for injections
- Treatment with RYSTIGGO in patients with impending or manifest myasthenic crisis has not been studied
- Infusion reactions such as rash or angioedema may occur
- Aseptic meningitis (drug-induced aseptic meningitis) has been reported following RYSTIGGO treatment
- As RYSTIGGO causes transient reductions in IgG levels, the risk of infections may increase
- Immunisation with vaccines during RYSTIGGO therapy has not been studied

RYSTIGGO is approved in the UK as an add-on to standard therapy for the treatment of gMG in adult patients who are anti-AChR or anti-MuSK antibody positive

Footnotes

- [†]RYSTIGGO 7 mg/kg corresponds to the recommended dose for the treatment of gMG in the UK; however, clinical studies also included a higher dose.
- [‡]Frequency categories are defined as follows: Very common, $\geq 1/10$; common, $1/100$ to $<1/10$.
- [§]Includes cases of nasopharyngitis.
- [¶]From spontaneous post-marketing reporting.
- [#]Includes cases of Herpes Zoster, simplex and oral.
- ^{**}Includes headache and migraine.
- ^{††}Includes rash, rash papular and rash erythematous.
- ^{††}Includes swollen tongue.
- ^{§§}Includes injection site rash, reaction, erythema, inflammation discomfort, and infusion site erythema, pain.

Abbreviations

AChR, acetylcholine receptor; AChR Ab+, positive for autoantibodies against the acetylcholine receptor; CFB, change from baseline; EU, European Union; FcRn, neonatal Fc receptor; FDA, Food and Drug Administration; gMG, generalised myasthenia gravis; HCP, healthcare professional; IgG, immunoglobulin G; LS, least squares; MAb, monoclonal antibody; MedDRA, Medical Dictionary for Regulatory Activities; MG-ADL, Myasthenia Gravis Activities of Daily Living; MGC, Myasthenia Gravis Composite; MHLW, Ministry of Health, Labour and Welfare; MuSK, muscle-specific tyrosine kinase; MuSK Ab+, positive for autoantibodies against muscle-specific tyrosine kinase; OLE, open-label extension; QMG, Quantitative Myasthenia Gravis.

Reference

RYSTIGGO® Summary of Product Characteristics.

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard.
Adverse events should also be reported to UCB Pharma Ltd at ucbcares.uk@ucb.com or 0800 2793177