Cost per responder for FcRn inhibitors for generalized myasthenia gravis

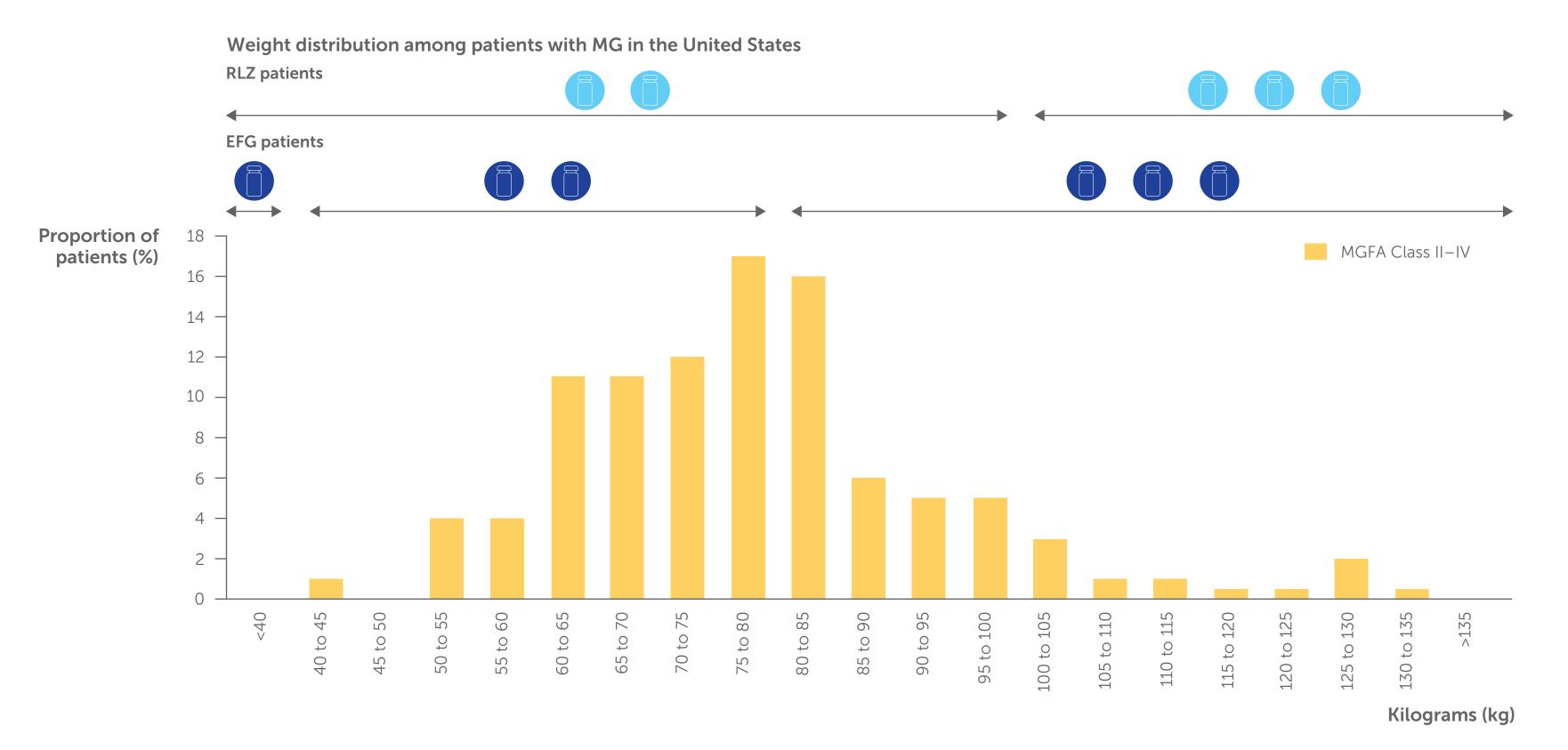
ISPOR 2024, Atlanta, GA, USA; May 5–8, 2024

Introduction

- Objective: To estimate the cost per responder of recently approved FcRn inhibitors for the treatment of gMG
- gMG is a chronic autoimmune neuromuscular disorder that causes fluctuating weakness in muscles responsible for vital functions, including breathing, swallowing and mobility^{1,2}
- There are now two FcRn inhibitors approved for the treatment of gMG, rozanolixizumab-noli and efgartigimod alfa-fcab

Methods

- An SLR identified randomized controlled Phase 3 studies in gMG, which allowed for a Bayesian NMA to be performed for the FcRn inhibitors rozanolixizumab-noli 7 mg/kg and 10 mg/kg, and efgartigimod alfa-fcab 10 mg/kg
- Response was defined as at least a 3-point improvement in the MG-ADL score from baseline, as measured after one treatment cycle
- One cycle constitutes six weekly infusions of rozanolixizumab-noli and four weekly infusions of efgartigimod alfa-fcab
- Sensitivity analysis was performed using a 2-point threshold of response; aligned with the minimal clinically important difference³
- Current evidence from long-term extension studies suggests a similar responder rate across multiple cycles up to 52 weeks^{4,5}; thus, response was assumed constant in the first year of treatment
- The mean number of infusions for the first year of treatment were derived from clinical trial data
- Rozanolixizumab-noli: mean 21.6 infusions⁴
- Efgartigimod alfa-fcab: mean 20.6 infusions⁶



Weight distribution and drug vial usage Figure 1

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- Weight di a physicia United Sta
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Results

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 For both treatments, the number of vials per infusion is dependent on the weight of the patient. The model assumed no vial sharing between patients, so cost of wastage is included Weight distributions were obtained from a physician survey of gMG patients in the United States (Figure 1)⁷
 Cost per responder was calculated as follows:
Cost per responder = (Weighted average number of vials per infusion × vial cost) × Annual number of infusions Probability of MG-ADL response
Results
 The SLR identified two placebo-controlled Phase 3 studies of FcRn inhibitors in gMG, MycarinG and ADAPT. Baseline characteristics for patients included in the two studies are detailed in Table 1
• While there were numerical differences between the calculated probability of response from the Bayesian NMA for the treatments (Table 2), there were no statistically significant differences, thus an average responder rate of 0.74 for a 3-point threshold was used. For a 2-point threshold, 0.82 was used for both treatments
• Weight distribution (Figure 1), drug vial price and

annual number of infusions were used to calculate the cost for the first year of treatment (**Table 3**) • When combining this with the responder rate, the average cost per 3-point responder for the first year of treatment was \$365,827.82 for rozanolixizumab-noli and \$403,874.26 for efgartigimod alfa-fcab (Figure 2), a saving of \$38,046.44 when choosing rozanolixizumab-noli

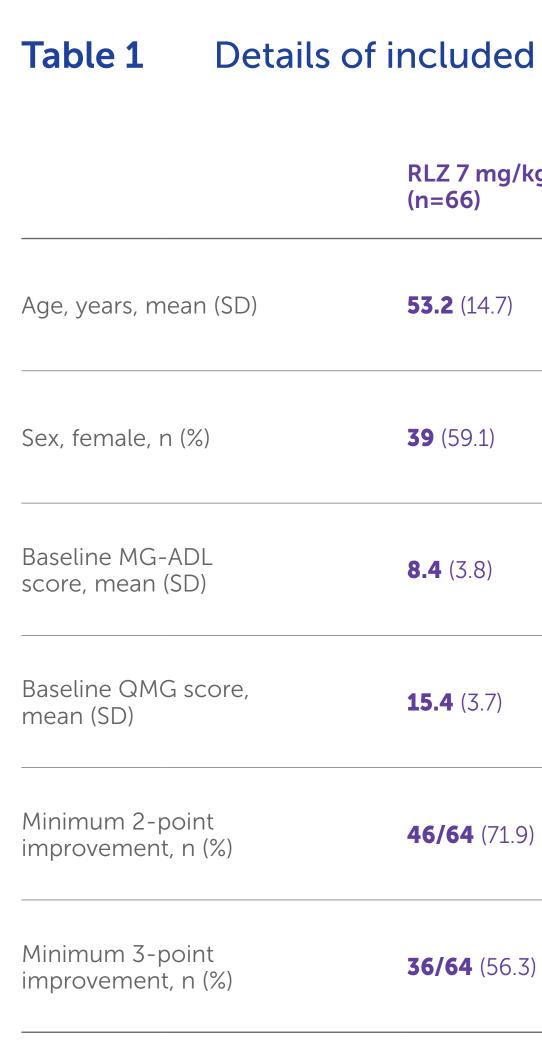
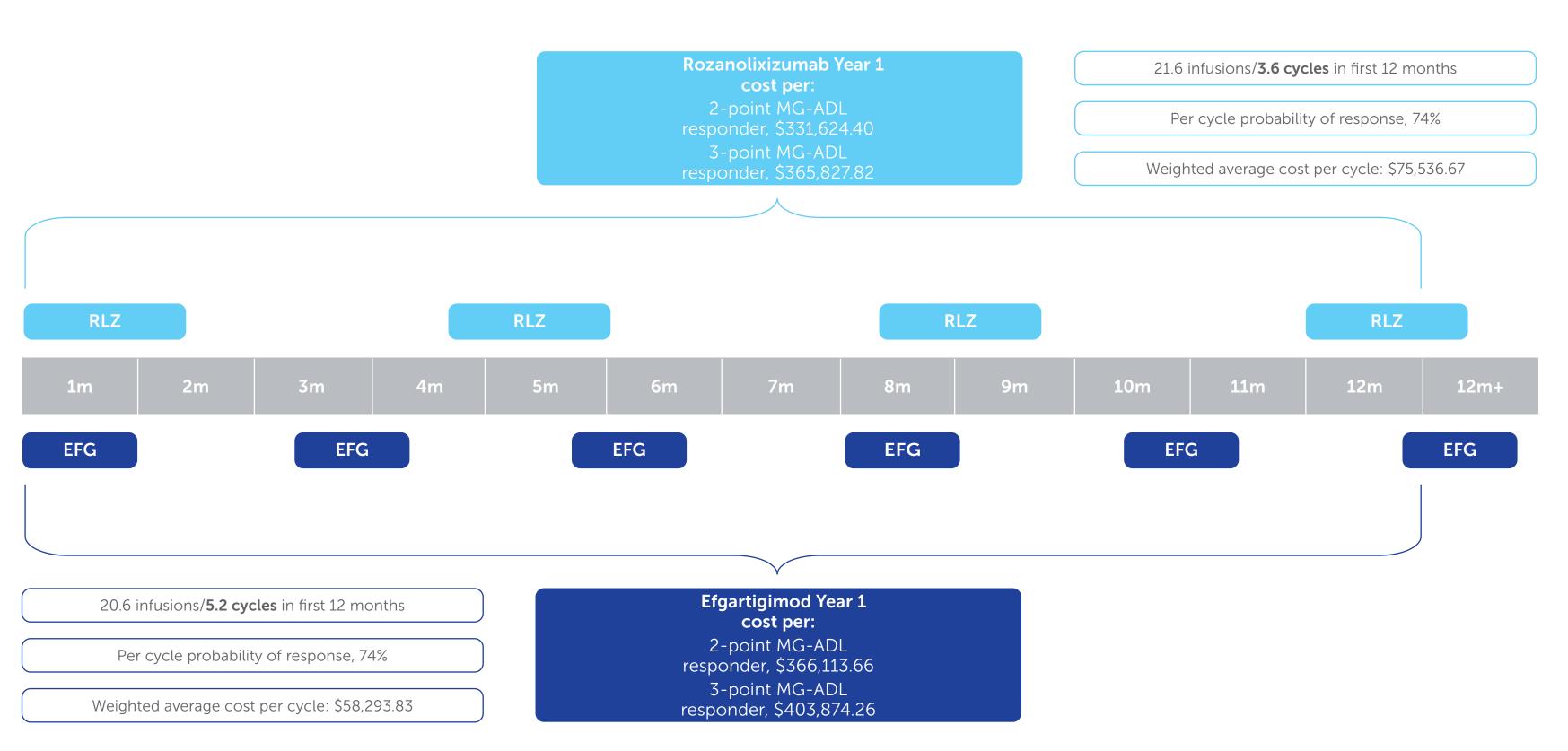
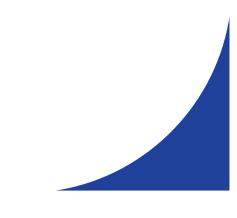


Table 2 Responder data fro

	MycarinG			ADAPT	
	RLZ 7 mg/kg (n=64)	RLZ 10 mg/kg (n=62)	PBO (n=64)	EFG (n=65)	PBO (n=64)
Calculated MG-ADL probability of a 2-point response from NMA (SE)	0.84 (0.06)	0.83 (0.06)	0.50 (0.06)	0.79 (0.08)	0.50 (0.06)
Calculated MG-ADL probability of a 3-point response from NMA (SE)	0.74 (0.09)	0.77 (0.08)	0.36 (0.05)	0.72 (0.09)	0.36 (0.05)

Figure 2 Cost per responder in Year 1





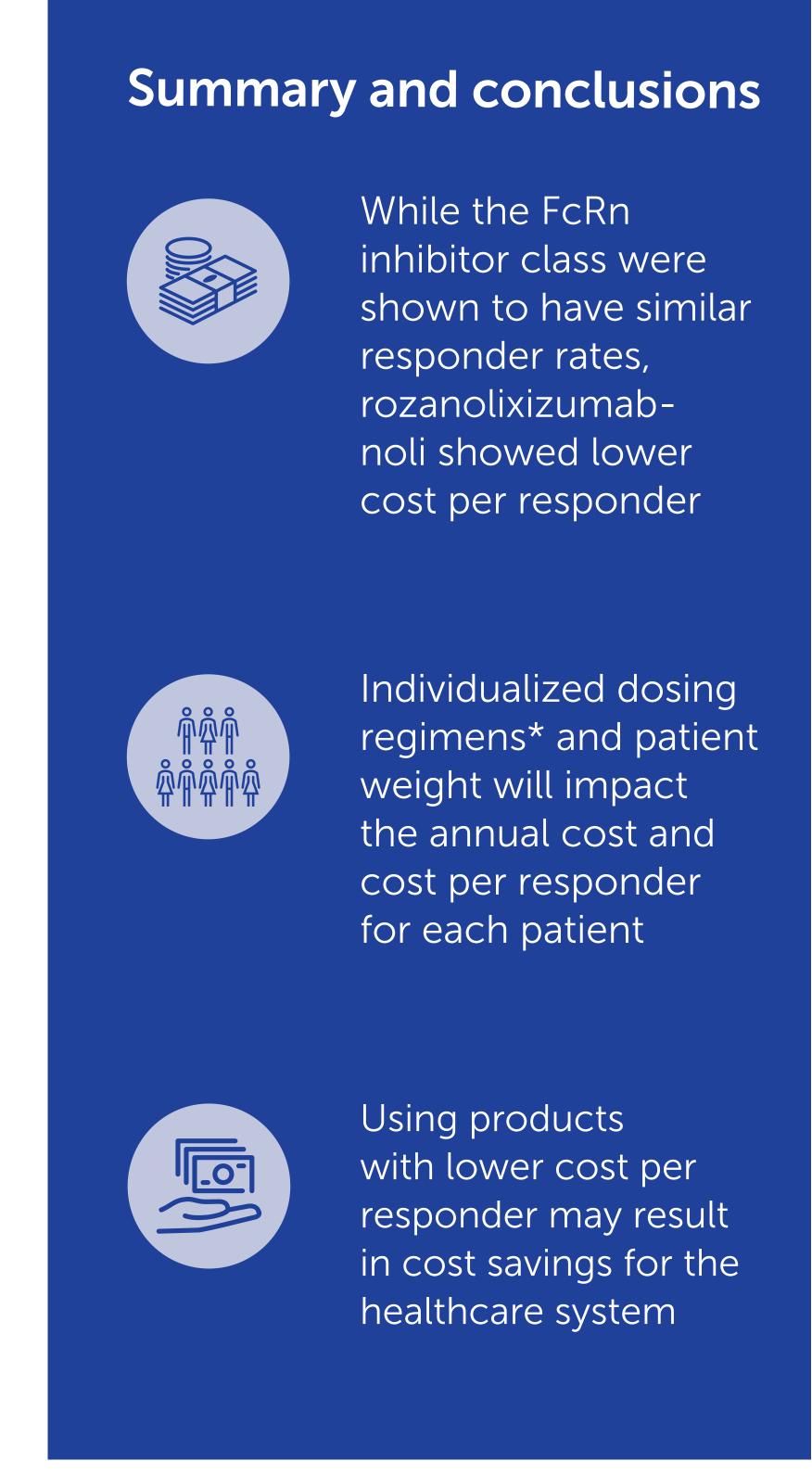
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studies	

	MycarinG		ADAPT		
kg	RLZ 10 mg/kg (n=67)	PBO (n=67)	EFG (n=65)	PBO (n=64)	
	51.9 (16.5)	50.4 (17.7)	44.7 (15.0)	49.2 (15.5)	
	35 (52.2)	47 (70.1)	46 (70.8)	40 (62.5)	
	8.1 (2.9)	8.4 (3.4)	9.0 (2.5)	8.6 (2.1)	
	15.6 (3.7)	15.8 (3.5)	16.0 (5.1)	15.2 (4.4)	
9)	43/62 (69.4)	20/64 (31.3)	51/65 (78.5)	31/64 (48.4)	
3)	38/62 (61.3)	13/64 (20.3)	47/65 (72.3)	23/64 (35.9)	

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*Frequency of treatment cycles and length of breaks will be based on individual treatment experience and medical evaluation

Table 3

Cost for the first year of treatment

	Vial WAC ⁸	Weighted average number of vials per infusion	Average cost per infusion	Number of infusions in first year of treatment	Cost of treatment – Year 1
Efgartigimod alfa-fcab IV	\$6,069	2.4	\$14,573.46	20.65	\$300,213.20
Rozanolixi- zumab-noli	\$6,030	2.09	\$12,589.45	21.6 ³	\$271,932.01

Abbreviations: EFG, efgartigimod; FcRn, neonatal FC receptor; (g)MG, (generalized) myasthenia gravis; m, month; MG-ADL, Myasthenia Gravis Activities of Daily Living; MGFA, Myasthenia Gravis Foundation of America; NMA, network meta-analysis; PBO, placebo; QMG, Quantitative Myasthenia Gravis; RLZ, rozanolixizumab; SD, standard deviation; SE, standard error; SLR, systematic literature review; WAC, wholesale acquisition price. Acknowledgments: This study was funded by UCB Pharma. The authors acknowledge Marilisa Valtazanou and Nadine Hammond of Ogilvy Health, London, UK, for editorial support, which was funded by UCB Pharma. The authors acknowledge Veronica Porkess, PhD,

of UCB Pharma, Slough, UK, for publication coordination. Author disclosures: April Betts and Angela Ting are employees and shareholders of UCB Pharma. Jonas Montilva was an employee of UCB Pharma at the time of the study.

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