

Tanruprubart Monotherapy in Guillain-Barré Syndrome (GBS): Early Week 1 Improvement in Medical Research Council Sumscore (MRCss) and GBS-Disability Score (GBS-DS) in the First Six Patients Enrolled in the FORWARD Study

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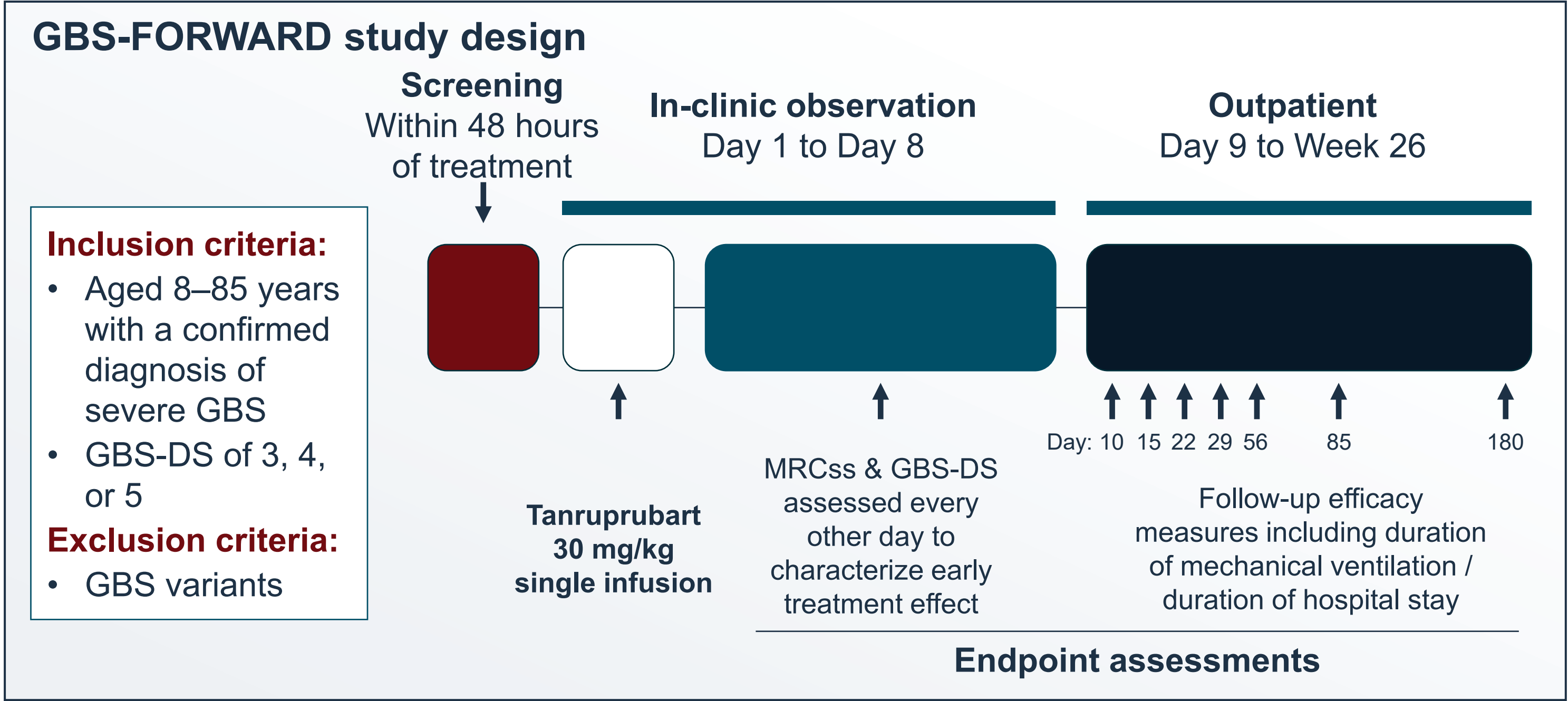
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Introduction

- Guillain-Barré syndrome (GBS) is an acute, neuromuscular emergency with rapidly progressive weakness characterized by classical complement-mediated neuroinflammation and peripheral nerve injury¹
- Tanruprubart selectively inhibits C1q, the initiating molecule of the classical complement pathway, enabling rapid upstream blockade of a key driver of this acutely progressive disease^{2,3}
- In the Phase 3 ANX005-GBS-02 study (NCT04701164), rapid and sustained C1q inhibition with a single infusion of tanruprubart 30 mg/kg was accompanied by early improvement in muscle strength and sustained clinical benefit across the disease spectrum, suggesting that rapid and early inhibition of classical complement activation may translate into rapid clinical recovery⁴
- GBS-FORWARD (NCT07020819) is evaluating tanruprubart monotherapy in GBS patients in the USA and Europe
 - Here, we report Week 1 safety, pharmacodynamics, and clinical findings from the first 6 patients dosed in GBS-FORWARD

Methods

- GBS-FORWARD is an ongoing, multicenter, open-label, single-arm study of a single 30-mg/kg intravenous infusion of tanruprubart in approximately 30 patients with recently diagnosed GBS
- Eligible patients had onset of weakness within 10 days, a baseline GBS disability score (GBS-DS; a 7-category ordinal scale that assesses functional disability in patients with GBS with a range from 0 [healthy] to 6 [death]) of 3–5, and had not received or planned to receive intravenous immunoglobulin (IVIg) or plasma exchange



MRCss, Medical Research Council sumscore.

- Patients received best supportive care and were followed through Week 26; protocol-defined therapy with either IVIg or plasma exchange was permitted for clinical deterioration using predefined criteria
- Study outcome measures**
- Assessments included safety, serum tanruprubart and C1q concentrations, MRCss (evaluates global muscle strength across six muscle groups with a sum score ranging from 0 [no contraction] to 60 [normal]), GBS-DS, Rasch-built Overall Disability Scale, and EuroQol 5-Dimension 5-Level
 - This analysis summarizes safety, C1q, MRCss, and GBS-DS through Week 1

Results: Case series of the first 6 patients enrolled in GBS-FORWARD

- Six patients (aged 30–78 years) who presented with GBS were treated with tanruprubart (**Table 1**)
- Tanruprubart was generally well tolerated in the first 6 patients (**Table 2**)
 - No life-threatening or fatal treatment-emergent adverse events (TEAEs), encapsulated bacterial infections, or new systemic autoimmune diseases were reported
 - The most common TEAE was a transient infusion-related reaction
 - The observed safety profile was consistent with the known safety experience with tanruprubart

Table 1. Participant baseline demographics^a

Clinical characteristics	Patients (N=6)
Age in years, mean (SD)	60.2 (17.9)
Male sex, n (%)	4 (66.7)
Baseline GBS-DS, range (n)	3 (3)–4 (3)
Baseline MRCss, median (range)	44.0 (39–53)

^aData cut July 21, 2026.

Table 2. Safety profile

TEAE, n (%)	Patients (N=6)
TEAEs	5 (83.3)
Grade ≥3 TEAEs ^a	2 (33.3)
TRAEs	4 (66.7)
Serious TEAEs	2 (33.3)
Infusion-related reactions	4 (66.7)

^aBased on National Cancer Institute Common Terminology Criteria for Adverse Events V5.0. TRAE, treatment-related adverse event.

- Consistent with observations in the Phase 3 ANX005-GBS-02 study, tanruprubart 30 mg/kg achieved complete C1q inhibition by the end of the single infusion
- All 6 patients demonstrated rapid improvement in muscle strength following a single infusion of tanruprubart. By Day 4, every patient achieved a ≥5-point increase in MRCss from baseline (**Figure 1**)
- Change from baseline in MRCss in the first 6 patients in FORWARD parallels the improvements observed in the Phase 3 ANX005-GBS-02 study (tanruprubart 30 mg/kg, n=79; **Figure 2**)
- Early improvements in muscle strength translated into reduced disability. By Week 1, all patients had improved by at least 1 grade on the GBS-DS (**Figure 3**)

Figure 1. MRCss from baseline to Day 8 (individual participant data, N=6) following tanruprubart administration

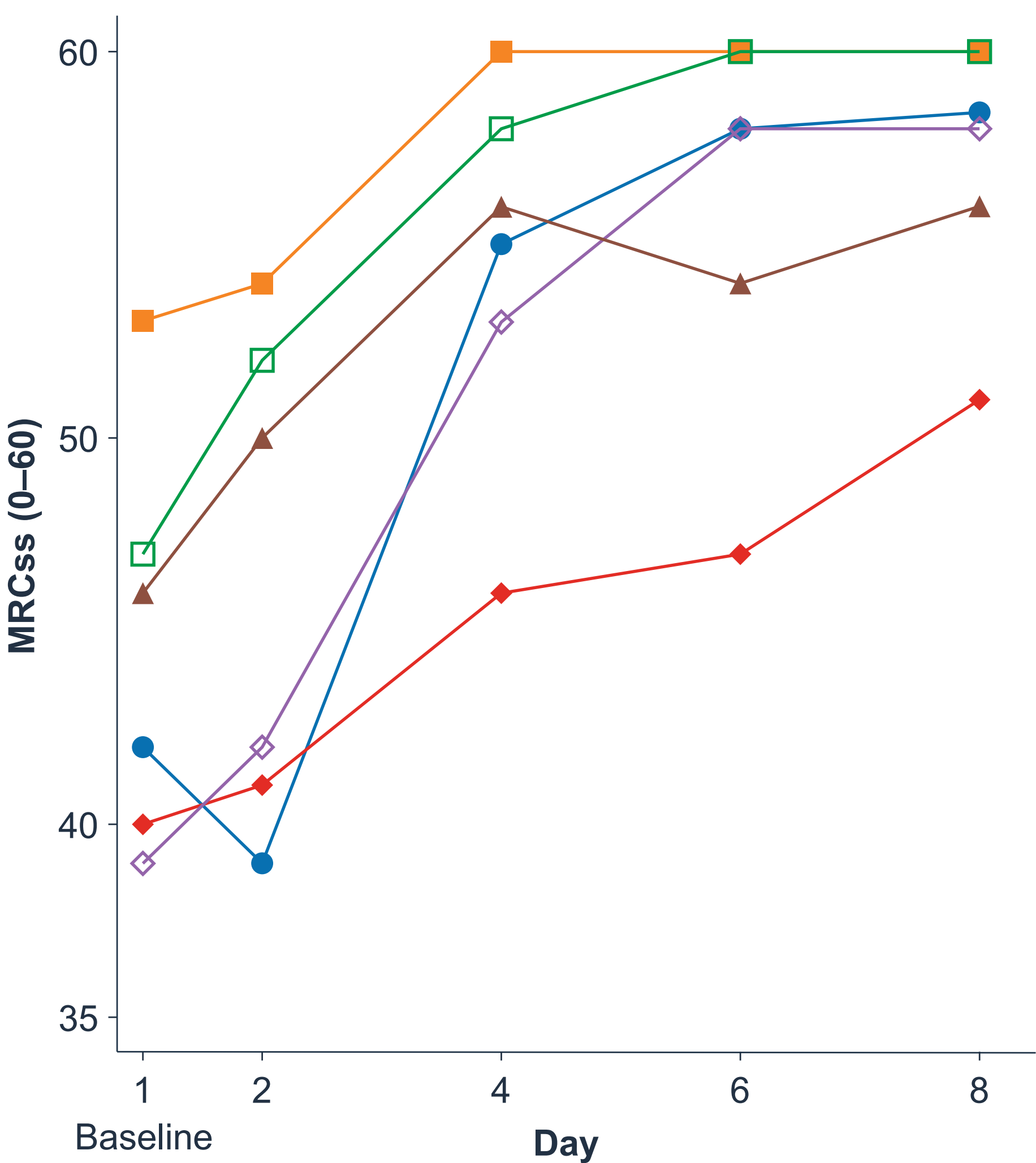


Figure 2. MRCss change from baseline in FORWARD (individual participant data, N=6) consistent with ANX005-GBS-02 tanruprubart 30 mg/kg (n=79)

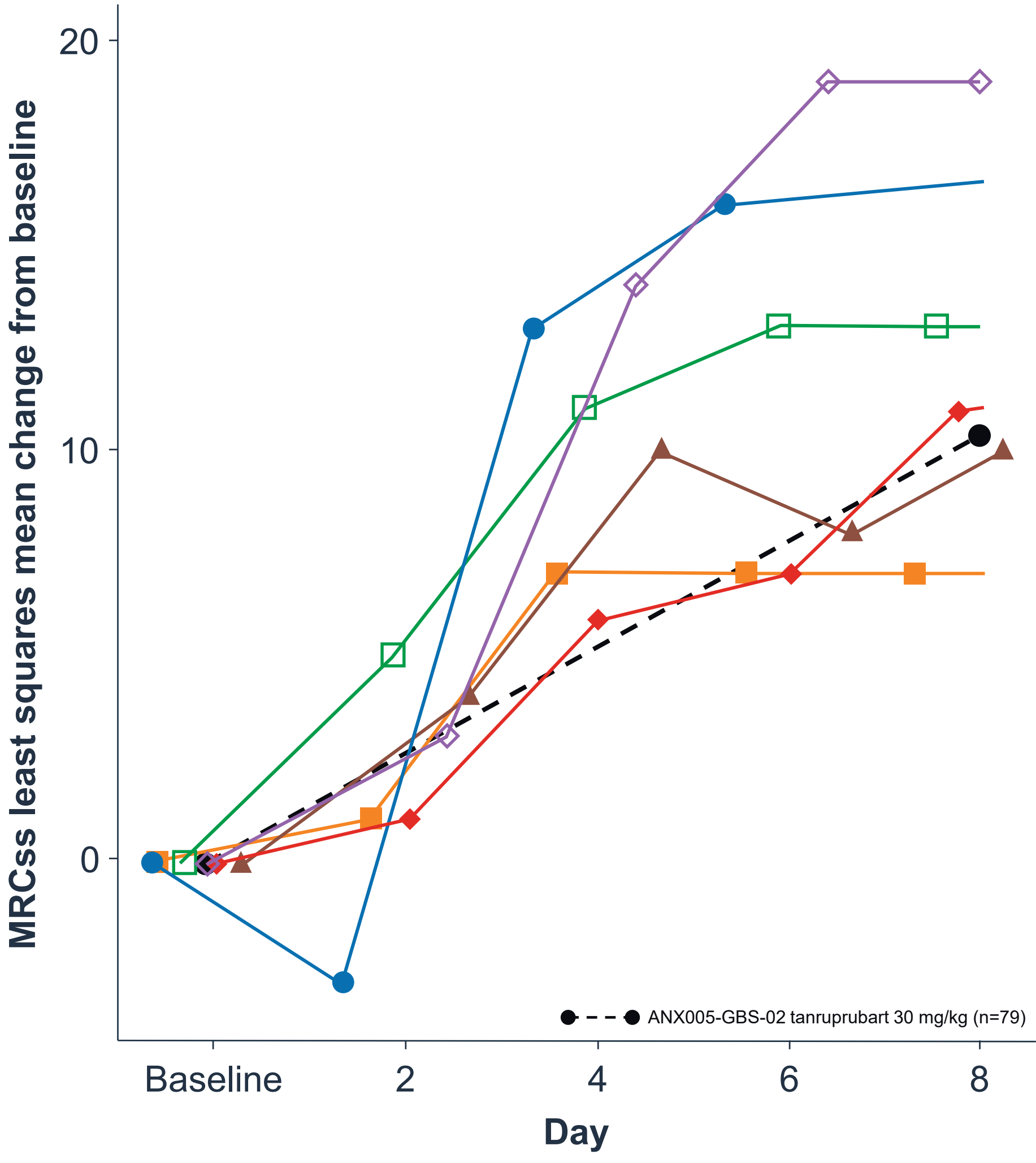
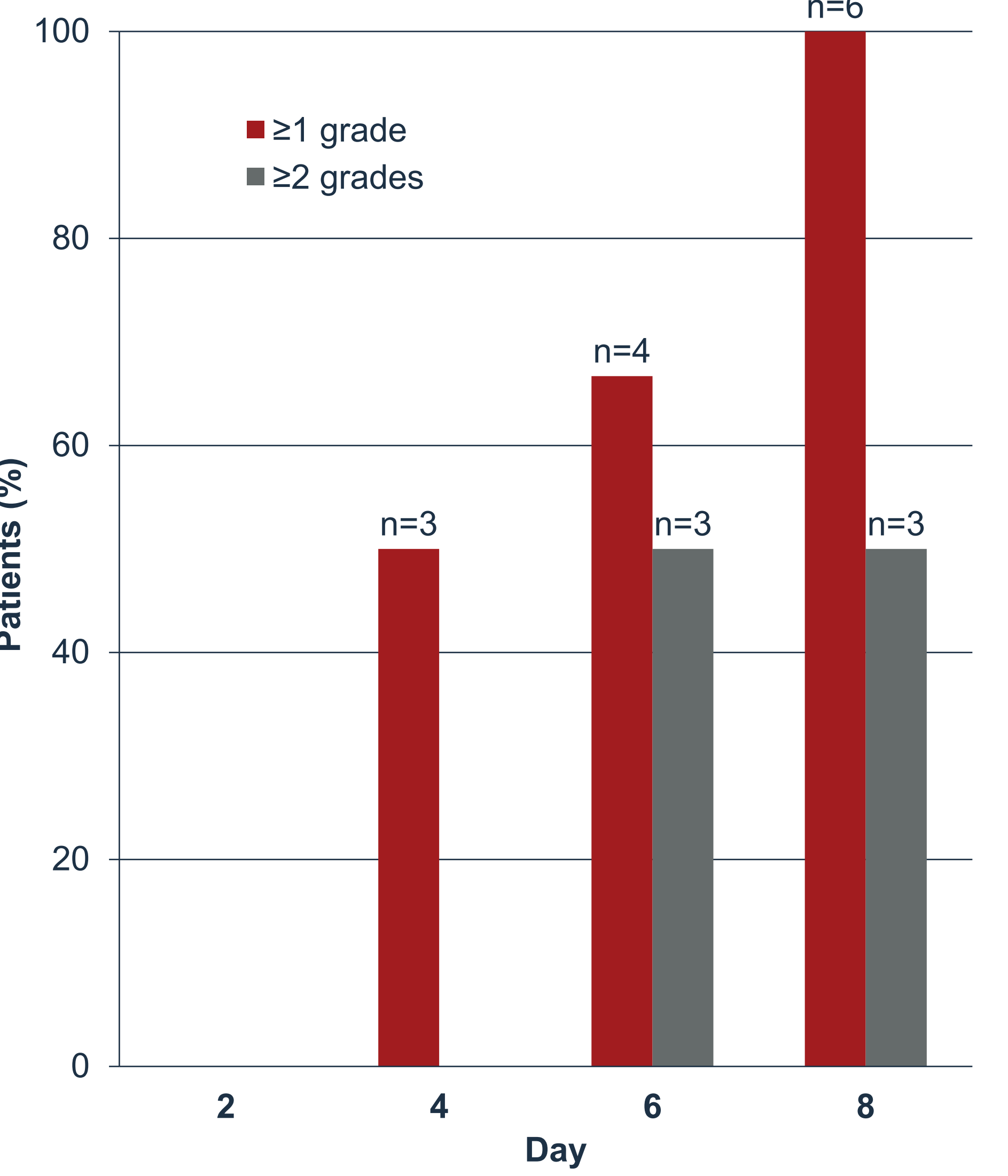


Figure 3. Improvement in GBS-DS of at least 1 or 2 grades; an improvement of 1–2 grades occurred in all 6 patients by Day 8



CONCLUSIONS

- Tanruprubart was generally well tolerated, with no new safety findings observed in the first 6 patients
- A single infusion produced rapid and sustained C1q inhibition during the acute phase of GBS
- Rapid improvements in muscle strength and disability were observed, with all patients achieving ≥5-point improvement in MRCss and ≥1-grade improvement in GBS-DS by Day 4
- These findings are consistent with observations from the Phase 3 ANX005-GBS-02 study and support continued evaluation of tanruprubart in GBS

References
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Disclosures
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