

Randomized, Double-Blind Evaluation of a Consolidated Ublituximab Initial Dosing Regimen Versus Conventional Ublituximab Regimen



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KEY FINDINGS

- 30-min infusion outcomes
 - 100% of 30-min infusions were completed
 - 93% of infusions were completed without interruption or slowing
 - 91% of participants received non-drowsy antihistamines as premedication
 - Low rate of infusion-related reactions (IRRs) was reported
- Treatment Satisfaction Questionnaire for Medication (TSQM-9) responses at Week 24
 - 93% of participants responded positively to all TSQM-9 questions

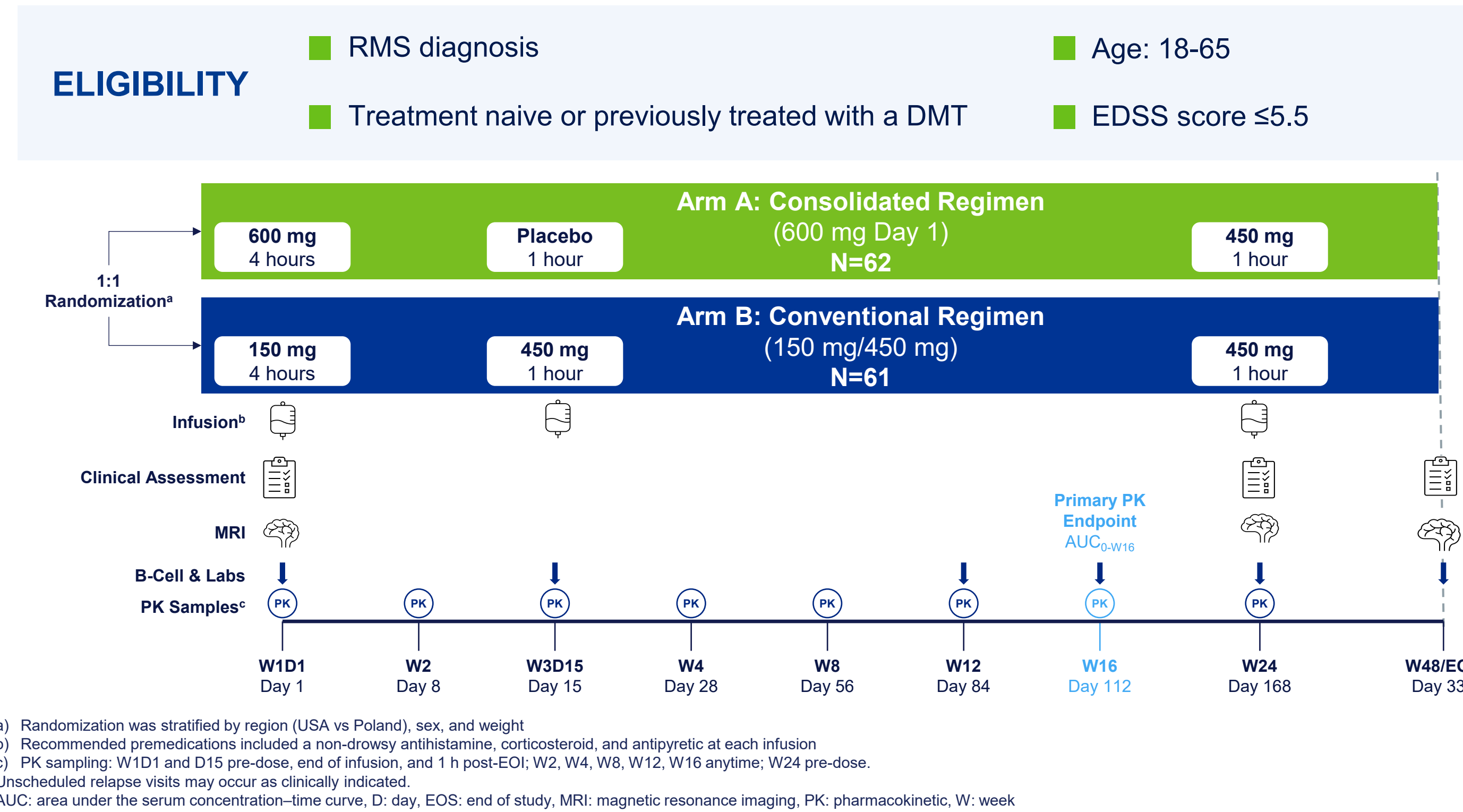
CONCLUSIONS

- Consolidating the Day 1 (150 mg) and Day 15 (450 mg) infusions into a single 600 mg dose resulted in bioequivalent pharmacokinetic exposure.
- IRRs in both regimens were lower than those reported in the ULTIMATE studies, with no Grade 3 or higher IRRs occurring in any participant.
- The consolidated regimen rapidly induced and maintained robust B-cell depletion to the same extent as the conventional regimen.
- 100% of participants treated with the consolidated regimen had no T1 Gd+ lesions at Week 24 and were relapse-free throughout the study.
- The consolidated regimen offers equivalent exposure with a favorable benefit-risk profile, providing an additional treatment option for patients and HCPs.

BACKGROUND

- Ublituximab is a novel monoclonal antibody that targets a unique epitope of CD20 and is glycoengineered for enhanced antibody-dependent cellular cytotoxicity (ADCC)¹ and enhanced Fcγ-receptor (FcγR) binding relative to all other currently approved anti-CD20 therapies in multiple sclerosis (MS).^{1,2,3}
- Ublituximab is approved for adults with relapsing forms of multiple sclerosis (RMS) with an administration schedule of 150 mg dose on Day 1 followed by 450 mg doses on Day 15, Week 24, and subsequently every 24 weeks.
- Consolidating the initial 150 mg and 450 mg doses into a single 600 mg infusion administered on Day 1 may improve patient convenience and create greater efficiency for providers.

SCHEMA



a) Randomization was stratified by region (USA vs Poland), sex, and weight.
b) Recommended premedications included a non-drowsy antihistamine, corticosteroid, and antipyretic at each infusion.
c) PK sampling: W1D1 and D15 pre-dose, end of infusion, and 1 h post-EOI; W2, W4, W8, W12, W16 anytime; W24 pre-dose. Unscheduled relapse visits may occur as clinically indicated.
AUC: area under the serum concentration–time curve; D: day; EOS: end of study; MRI: magnetic resonance imaging; PK: pharmacokinetic; W: week

RESULTS

Table 1. Demographics

Characteristic	Consolidated Regimen N=62	Conventional Regimen N=61
Mean ± SD or n (%)		
Poland	33 (53.2)	33 (54.1)
Treatment Naïve	13 (21.0)	24 (39.3)
Transitioned from Anti-CD20	37 (59.7)	25 (41.0)
Depleted ^a	27 (43.5)	18 (29.5)
Age, years	42.2 ± 11.67	39.3 ± 10.47
Female	47 (75.8)	45 (73.8)
Race		
White	53 (85.5)	57 (93.4)
Black or African American	8 (12.9)	4 (6.6)
Other	1 (1.6)	-
BMI, kg/m ²	28.4 ± 6.6	28.4 ± 7.5

a) Depleted defined as B-cell count <10 cells/μL.
Data cut-off: 24 March 2026; BMI: body mass index; SD: standard deviation

- No clinically meaningful differences in baseline characteristics between the regimens.

Table 2. Disease History

Characteristic	Consolidated Regimen N=62	Conventional Regimen N=61
Mean ± SD or n (%)		
Years Since Diagnosis	8.7 ± 8.4	5.3 ± 5.5
Months Since Last Relapse	52.0 ± 47.8	33.5 ± 36.3
Relapses in the Last 2 Years		
0	42 (67.7)	28 (45.9)
1	16 (25.8)	25 (41.0)
2	2 (3.2)	7 (11.5)
3	1 (1.6)	1 (1.6)
4	1 (1.6)	-
Relapses in the Last 2 Years	0.4 ± 0.78	0.7 ± 0.74
Baseline EDSS	2.7 ± 1.2	2.5 ± 1.1
Baseline Gd-Enhancing Lesions		
0	56 (90.3)	53 (86.9)
≥1	5 (8.1)	8 (13.1)

Gd: gadolinium; SD: standard deviation

RESULTS, CONT.

Figure 1. Pharmacokinetics

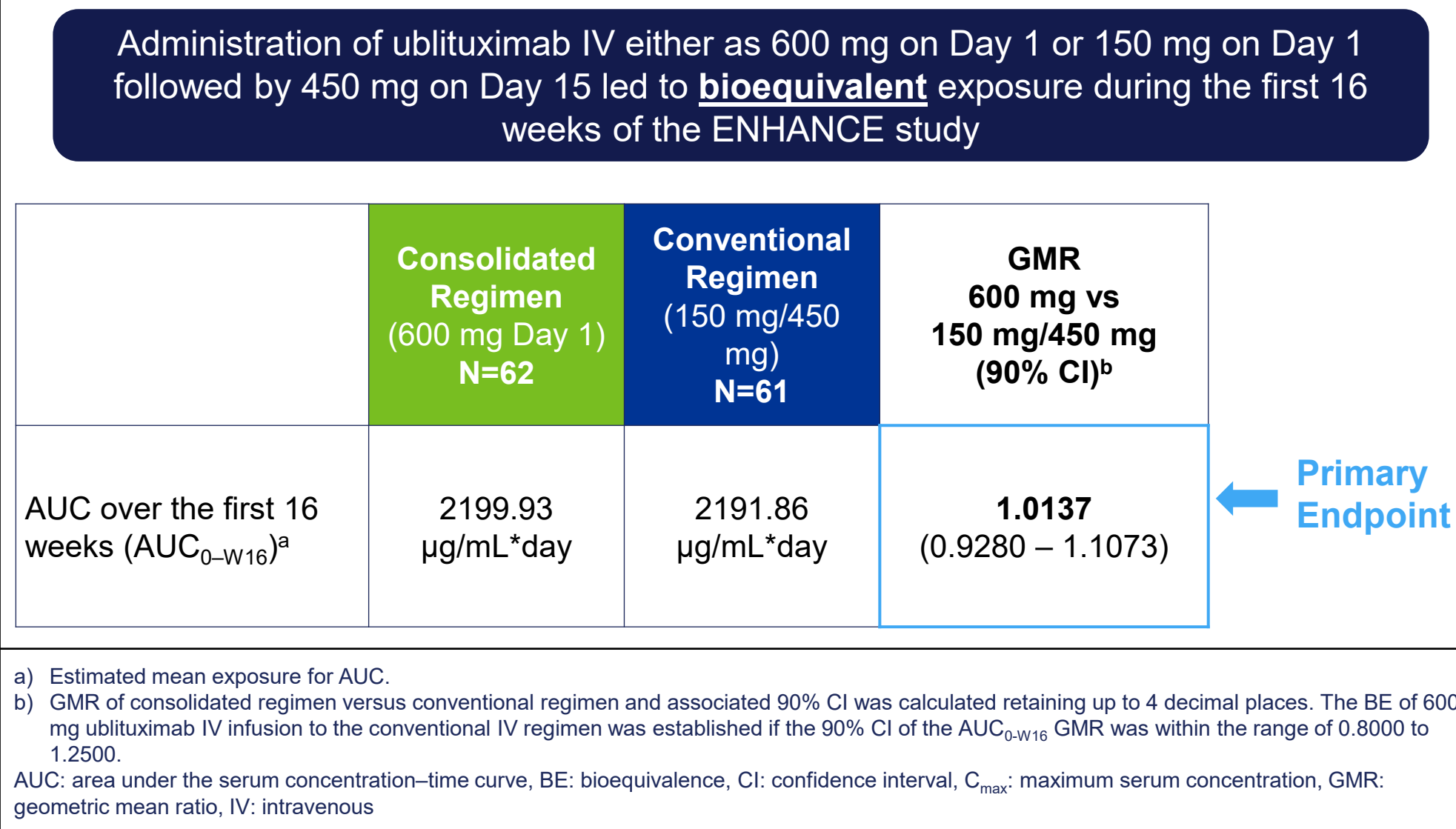


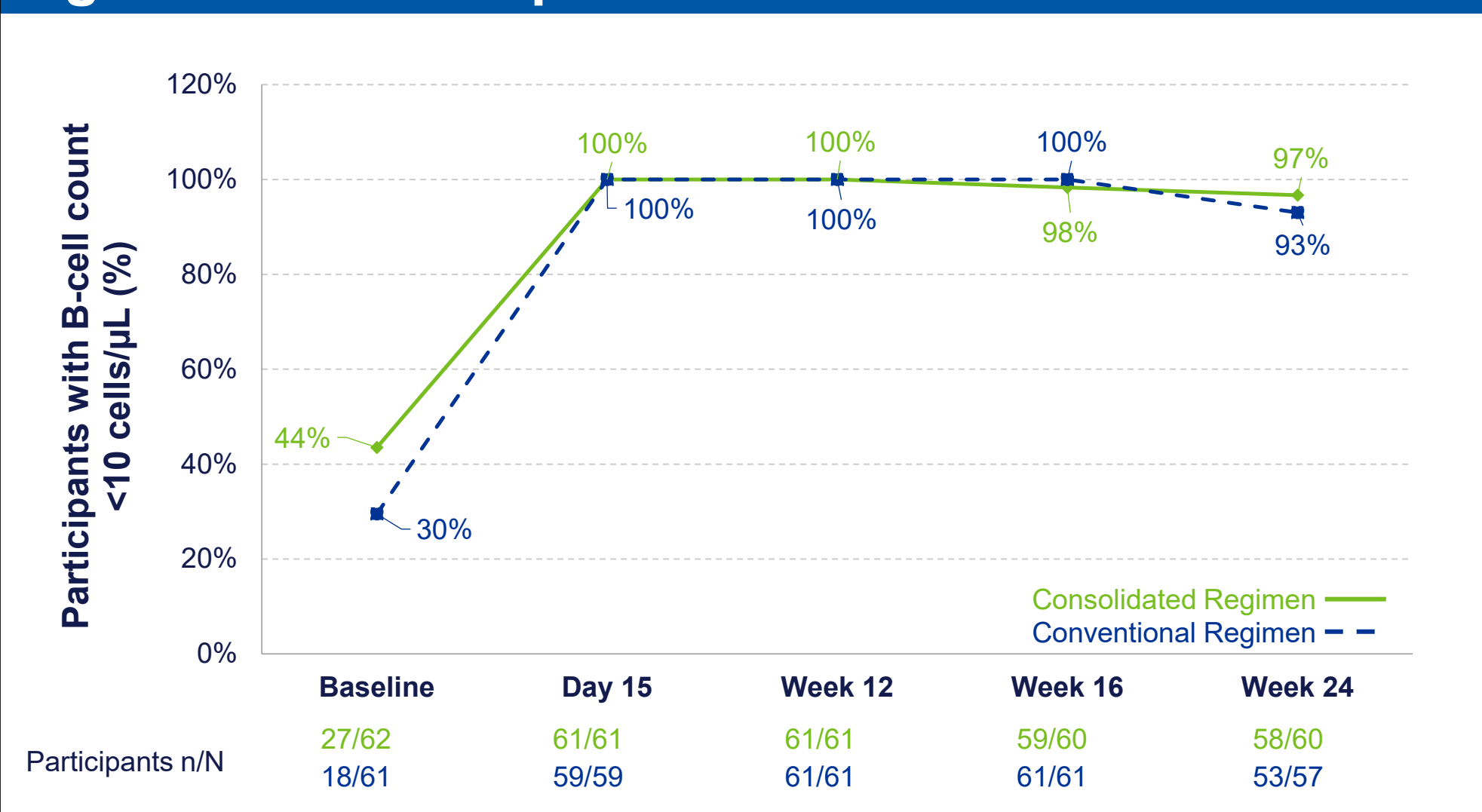
Table 3. Safety Overview

	Consolidated Regimen N=62	Conventional Regimen N=61 ^b
n (%)		
AEs	49 (79.0)	51 (83.6)
IRRs	13 (21.0)	18 (29.5)
Infections ^a	26 (41.9)	28 (45.9)
SAEs ^b	2 (3.2)	1 (1.6)
Fatal AEs	0	0

a) Infections reported in >5% of participants in either arm were urinary tract infection, upper respiratory tract infection, nasopharyngitis, oral herpes.
b) SAEs in the consolidated regimen were thoracic vertebral fracture (not related) and prostate cancer (not related) in one participant each, and in the conventional regimen were pneumonia mycoplasma (possible) in one participant.
AEs: adverse events; IRRs: infusion related reactions; SAEs: serious adverse events

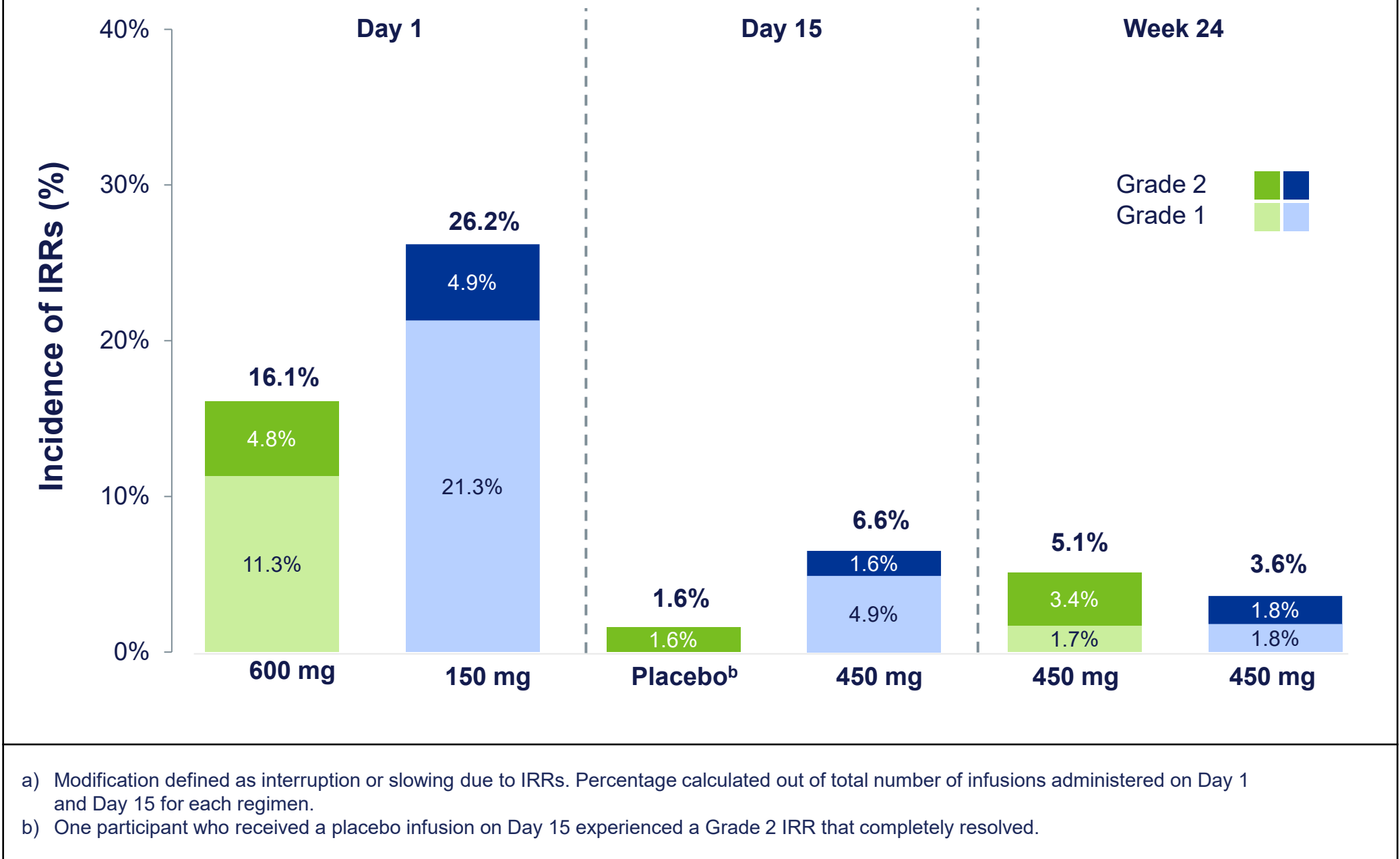
- The safety profile of consolidated regimen was consistent with the conventional regimen.
- No AEs were fatal or led to discontinuation.

Figure 3. B-Cell Depletion



- Both regimens rapidly induced B-cell depletion and maintained depletion over 24 weeks.

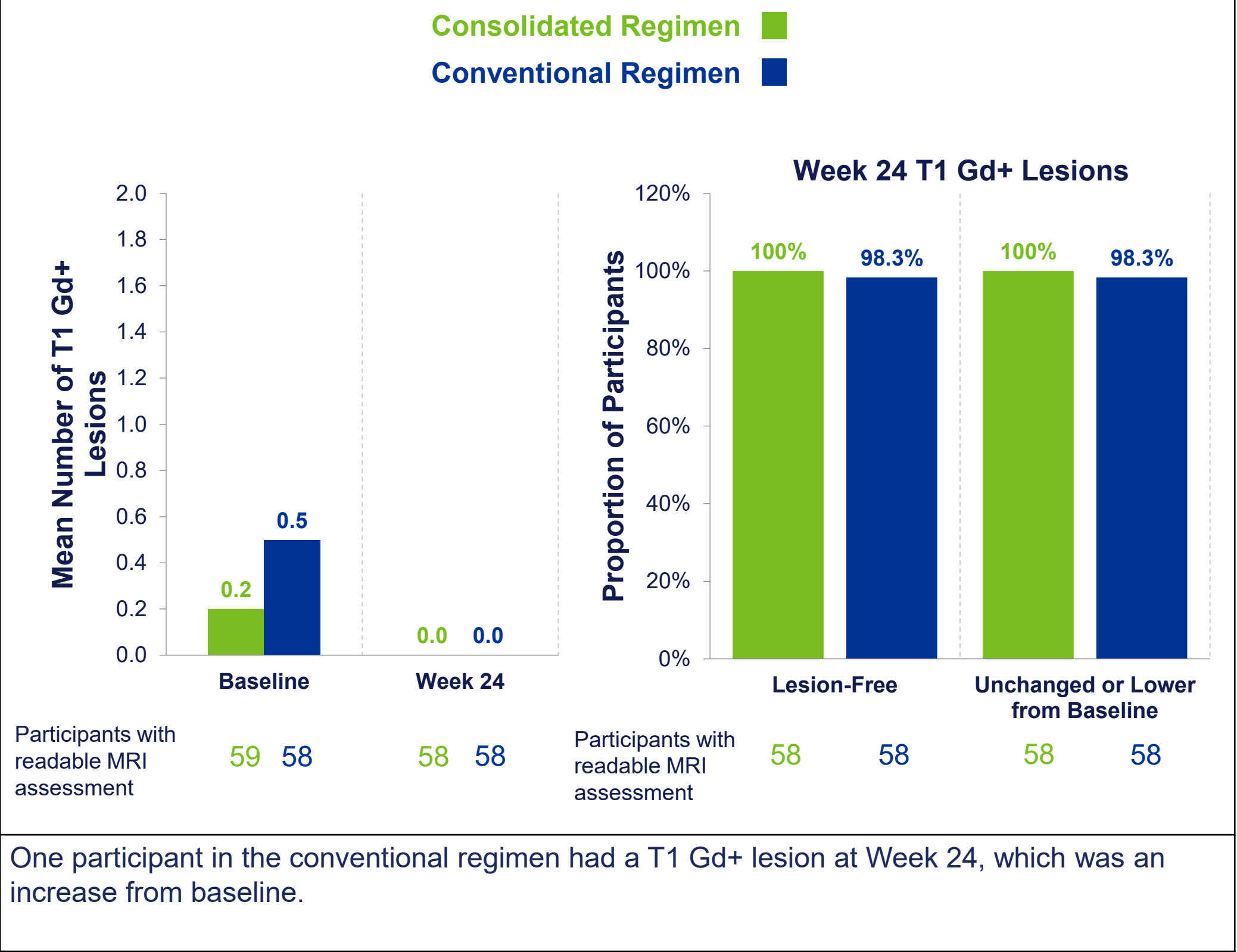
Figure 2. IRRs



Across Day 1 and Day 15 Infusions:

- No statistical difference in IRR rates between regimens.
- 98.4% of infusions were **completed without modification^a** in both regimens.
- All infusions were ultimately completed.
- Fewer participants in consolidated regimen required supportive medication for the management of IRRs (6.5% vs 11.5%).
- No IRRs were Grade 3 or 4, serious, or led to treatment discontinuation.
- All IRRs resolved without sequelae.

Figure 4. Efficacy



- 97.5%** (116/119) of participants were relapse-free across both regimens.
- Change from baseline in EDSS at Week 24 was similar in the two regimens.