

Health-Related Quality of Life Effect of Mogamulizumab by Patient Blood Involvement

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Plain Language Main Finding

- Patients in the MAVORIC trial with blood involvement who were treated with mogamulizumab experienced larger HRQoL benefits relative to those without blood involvement

Introduction

- Cutaneous T-cell lymphomas (CTCLs) are rare non-Hodgkin lymphomas that can impact the skin, blood, lymph nodes and viscera; Mycosis fungoides (MF) and Sézary syndrome (SS) are two types of CTCL^{1,2}
- CTCL can have serious negative effects on patient quality of life (QoL), which include bothersome symptoms, functional impacts, and health distress³⁻⁶
- Blood involvement in MF/SS is an independent prognostic factor for overall and disease-specific survival⁷
- The phase 3 MAVORIC trial (NCT01728805) compared vorinostat 400 mg PO daily to mogamulizumab 1.0 mg/kg IV weekly for the first 28-day cycle, then on days 1 and 15 of subsequent cycles⁸
 - Health-related QoL (HRQoL) measures were generally improved in patients receiving mogamulizumab compared to vorinostat⁹
 - Progression-free survival and global composite objective response rate were generally better across blood involvement subgroups (B0, B1, or B2) in mogamulizumab-treated patients relative to those treated with vorinostat¹⁰
- This *post hoc* analysis of the MAVORIC trial sought to determine whether baseline blood involvement impacted treatment effect on HRQoL

Methods

- Analyses of HRQoL using patient-reported outcome (PRO) measures were performed using the validated Skindex-29 and Functional Assessment of Cancer Therapy-General (FACT-G) instruments
 - Pruritus was assessed using the ItchyQoL and Pruritus Likert scales
 - All PRO measures were administered at baseline; Skindex-29 and FACT-G were then administered every 8 weeks starting on Cycle 1 and at the end of treatment, and the ItchyQoL and Pruritus Likert scales were administered every 4 weeks at each cycle
- A cross-sectional analysis was completed for each PRO measure, which included the overall score and change from baseline
 - To examine changes in QoL endpoints due to treatment, mixed models were conducted on age, sex, disease type, disease stage, and blood involvement subgroups
 - Least-squares (LS) mean, difference in LS mean between treatment groups, and 95% confidence intervals (CIs) were reported from these mixed models
- Patient blood involvement was assessed by central flow cytometry and defined as no involvement (B0; <250 malignant cells/ μ L) or involvement (B1 or B2; $\geq$ 250 malignant cells/ μ L)¹⁰
 - Flow cytometric analysis was completed at the pre-treatment visit and at the end of each treatment cycle

Results

- Approximately the same number of patients experienced blood involvement in the mogamulizumab and vorinostat treatment groups (123 [66.1%] vs 122 [66.3%], respectively; **Table 1**)
 - Full demographics and baseline characteristics for patients in MAVORIC have been previously reported⁸

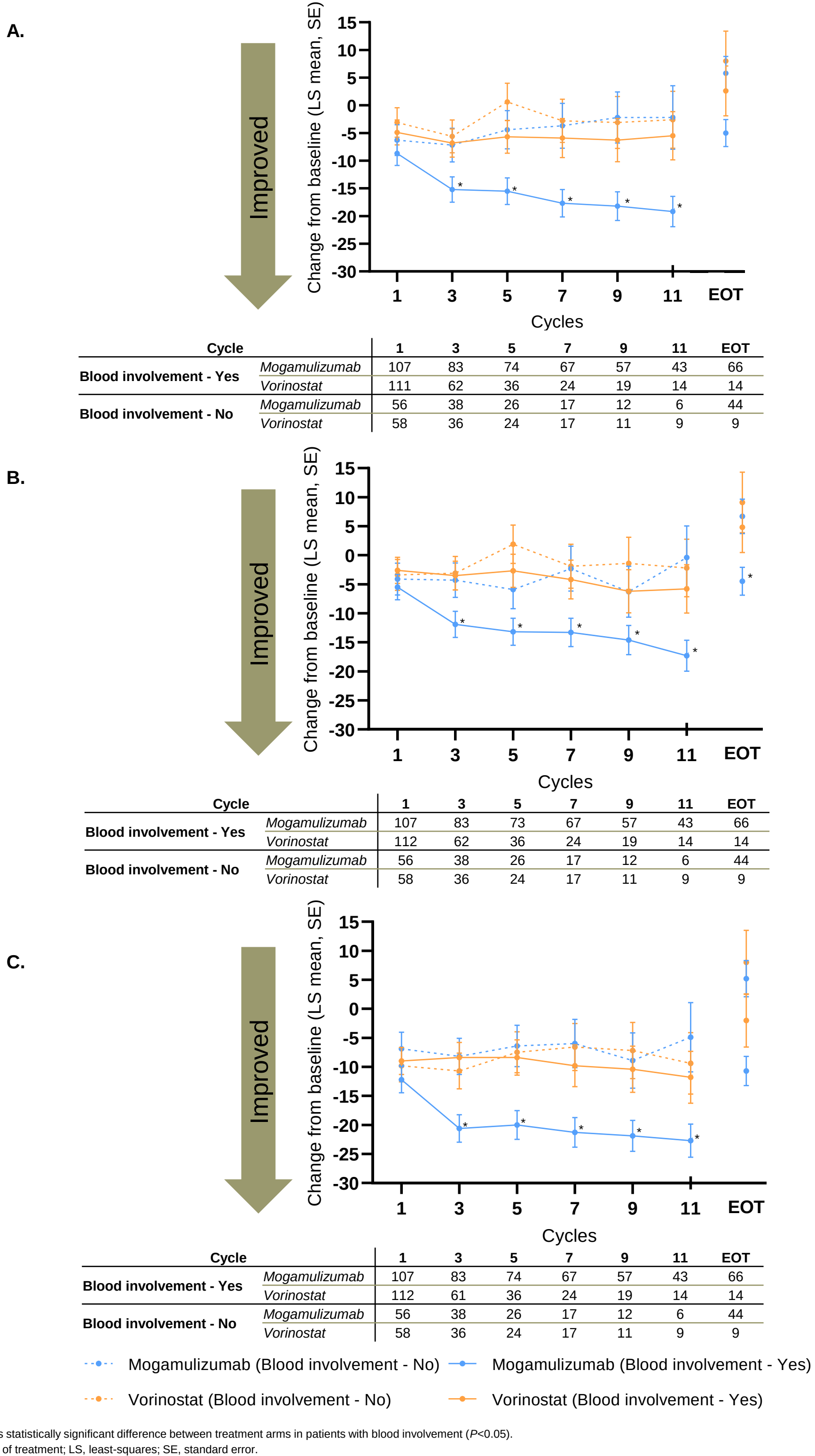
Table 1. Baseline Blood Involvement

	Mogamulizumab n=186 n (%)	Vorinostat n=186 n (%)	Total N=372 n (%)
Blood Involvement ^a			
Yes	123 (66.1)	122 (66.3)	245 (66.2)
No	63 (33.9)	62 (33.7)	125 (33.8)
Missing/no response	0 (0)	2 (1.1)	2 (0.5)

^aPatients in MAVORIC were stratified by disease type (MF or SS) and disease stage (IB/IIA or II/IV) to ensure comparability between treatment groups. As a result, the number of patients with blood involvement (B1 or B2) was approximately equal between treatment groups.

MF, mycosis fungoides; SS, Sézary syndrome.

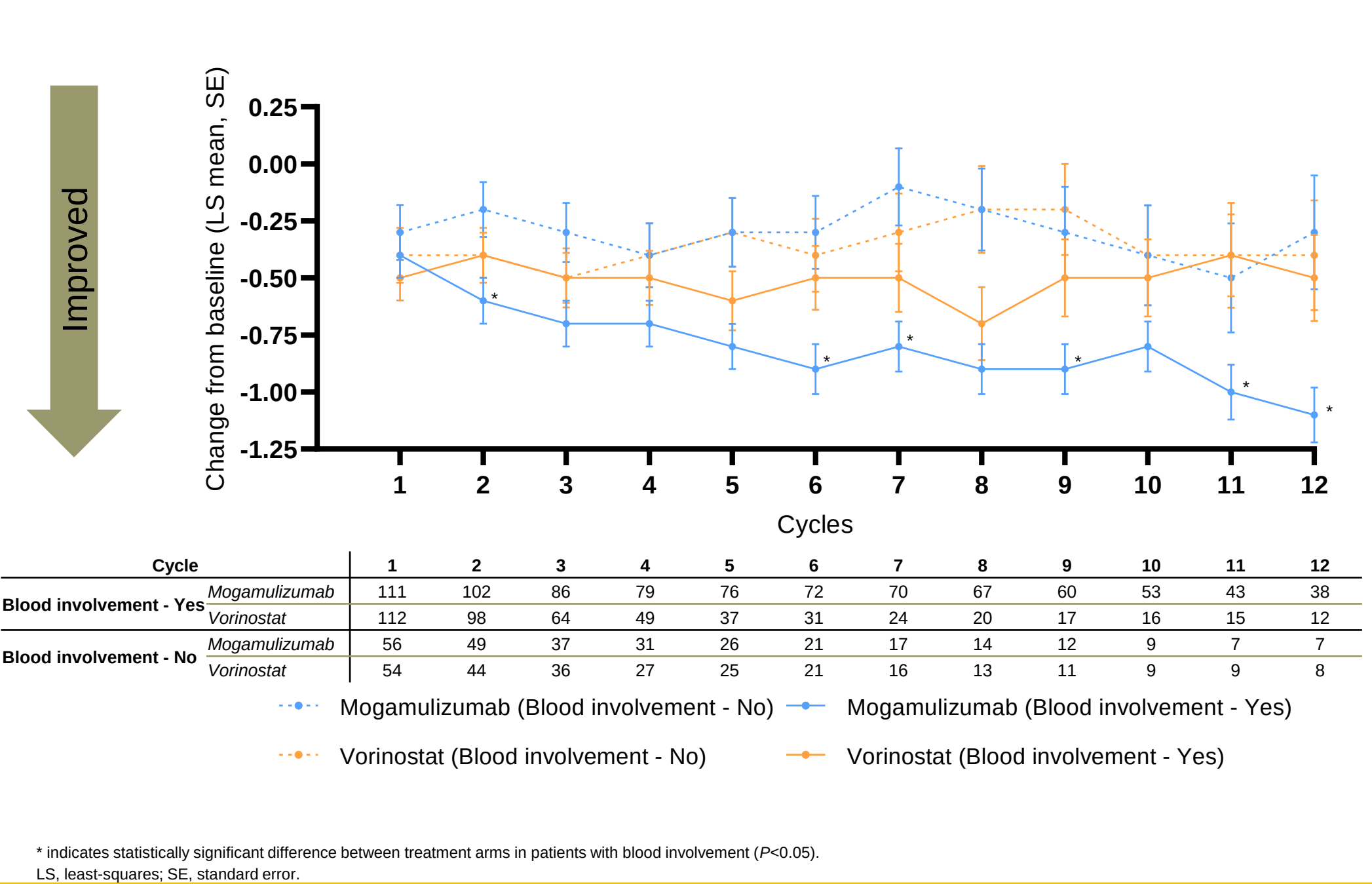
Figure 1. Treatment Effects on Skindex-29 (A) Emotional, (B) Functional, and (C) Symptoms Scales



Results

- Compared to mogamulizumab-treated patients without blood involvement or vorinostat-treated patients regardless of blood involvement, mogamulizumab-treated patients with blood involvement showed statistically significant improvements in Skindex-29 for treatment Cycles 3-11 in all domains (**Figures 1A, B, and C**) and in the functional domain of ItchyQoL for most cycles (**Figure 2**)

Figure 2. Treatment Effects on ItchyQoL (Functional Domain)



- In mogamulizumab-treated patients with blood involvement, the Pruritus Likert Scale score showed a trend towards reduced levels of itch over 12 cycles (**Figure 3**)

Figure 3. Treatment Effects on Pruritus Likert Scale

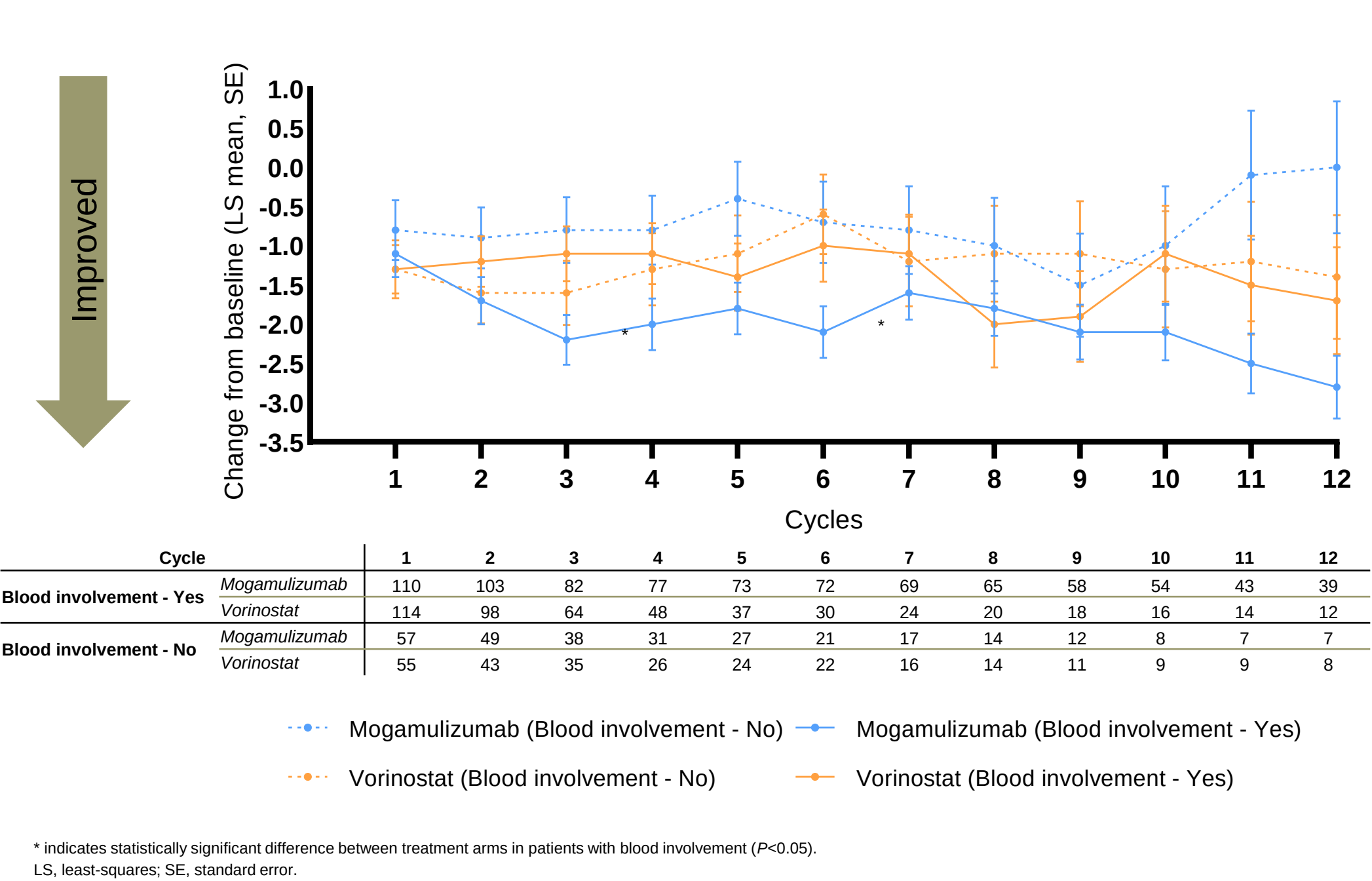
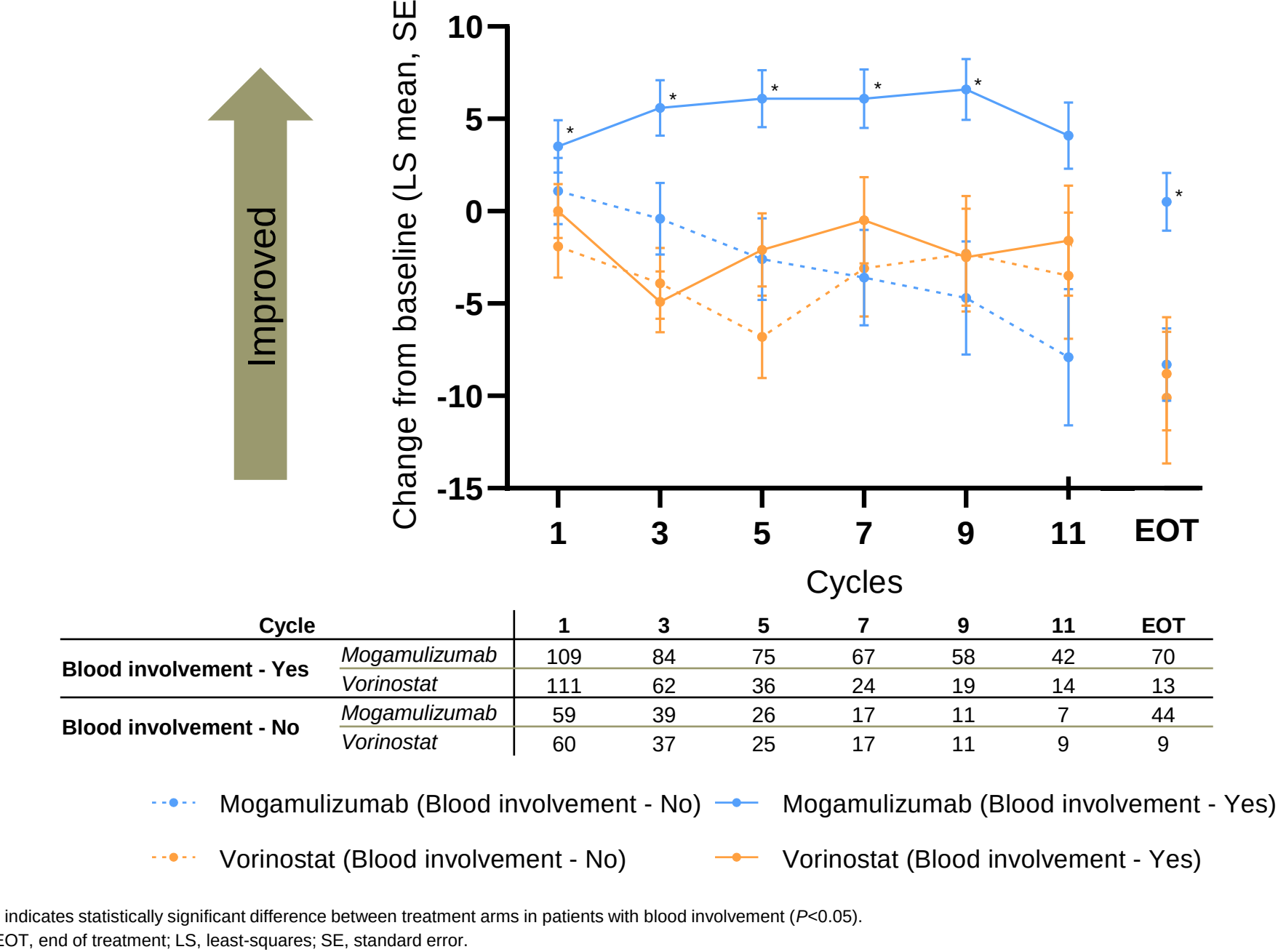


Figure 4. Treatment Effects on FACT-G Total Score



Conclusions

- Overall, mogamulizumab-treated patients with blood involvement saw greater HRQoL improvements than those without blood involvement**
- Mogamulizumab offers HRQoL benefit, assessed across a number of measured PROs, especially at the start of therapy for patients with blood involvement**

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Disclosures

PLZ: MSD: Consultancy, Honoraria, Membership on an entity's Board of Directors or advisory committees, Speakers Bureau; Eusapharma: Consultancy, Membership on an entity's Board of Directors or advisory committees, Speakers Bureau; Sanofi: Consultancy, Celltrion: Honoraria, Membership on an entity's Board of Directors or advisory committees, Speakers Bureau; Gilead: Honoraria, Membership on an entity's Board of Directors or advisory committees, Speakers Bureau; Janssen-Cilag: Honoraria, Membership on an entity's Board of Directors or advisory committees, Speakers Bureau; BMS: Honoraria, Membership on an entity's Board of Directors or advisory committees, Speakers Bureau; Servier: Membership on an entity's Board of Directors or advisory committees, Speakers Bureau; Sandoz: Membership on an entity's Board of Directors or advisory committees, Immune Design: Membership on an entity's Board of Directors or advisory committees, Speakers Bureau; Celgene: Membership on an entity's Board of Directors or advisory committees, Speakers Bureau; Portola: Membership on an entity's Board of Directors or advisory committees, Speakers Bureau; Roche: Membership on an entity's Board of Directors or advisory committees, Speakers Bureau; Kyowa Kirin, Inc: Membership on an entity's Board of Directors or advisory committees, Speakers Bureau; TG Therapeutics: Honoraria, Speakers Bureau; Vorinostat: Consultancy, Membership on an entity's Board of Directors or advisory committees, Speakers Bureau.
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