Patients with multiple sclerosis (MS) frequently have poor health-related quality of life (HRQoL) that deteriorates significantly with disease progression, affecting family life, social life, and employment status. HRQoL is also impaired by depression, fatigue, and cognitive dysfunction, which are common features of MS.

MS patients rank their HRQoL lower than the general population, with median baseline SF-36 scores of 45.1 ± 10.7, 43.7 ± 10.8, and 42.9 ± 10.0 in placebo, BG-12 BID and BG-12 TID mg TD groups, respectively.

When evaluating the effects of potential MS agents, it is valuable to assess HRQoL alongside efficacy and safety.

**BI-12 (dimethyl fumarate) is an oral treatment in development for relapsing-remitting MS.**

At baseline, HRQoL impairment was greater with increasing EDSS score: patients with baseline EDSS ≤5.5 had significantly lower mean PCS and MCS scores than those with an EDSS score of 0 (Figure 1).

- Patients with an EDSS score ≤2.5 had clinically meaningful improvement (≥2.5 point deficit in PCS and MCS scale scores relative to those with an EDSS score of 0).

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**Clinically Relevant (≥2.5 points) Improvement in SF-36 Summary Scores**

- The proportion of patients who achieved a clinically relevant ≥2.5-point improvement in PCS and MCS scores was significantly higher in the BI-12 TD group than in the placebo group (Table 2).

**Global Improvement of Well-being (VAS)**

- Mean baseline VAS scores were lower in the placebo group (44.6 ± 10.3) than in the BI-12 BID (42.8 ± 10.7) and BI-12 TD groups (43.5 ± 10.8).

- The mean change from baseline to 2 years in the VAS score in the placebo group was –4.1, compared with –0.8 (n=0.001) in the BI-12 TD group and 0.4 (p=0.001) in the BI-12 BID group.

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