**Effects of BG-12 on Magnetic Resonance Imaging Outcomes in the DEFINE Study**


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**INTRODUCTION**

- BG-12 (dimethyl fumarate) is a potential oral multiple sclerosis (MS) agent in development for relapsing MS.
- Experimental evidence suggests that BG-12 may have anti-inflammatory and reparative effects, which appear to be mediated, at least in part, through induction of the anti-inflammatory and reparative properties of signal transducer and activator of transcription 3 (STAT3).

**OBJECTIVE**

- To report the effects of BG-12 on magnetic resonance imaging (MRI) activity in patients in the Phase 2/3 DEFINE study.

**METHODS**

- **Study Design:** Patients were randomized 1:1:1 to receive oral BG-12 240 mg BID or OD or matching placebo for 2 years.

- **Endpoints:**
  - **Changes in novel enhancing T2 lesion volume:** Changes in novel enhancing T2 lesion volume at week 127 compared to baseline.
  - **Other MRI outcomes:**
    - Number of new lesions.
    - Number of lesion enhancements.
    - Number of lesion enhancements lasting at least 24 hours.

**RESULTS**

- **Patients (n=105):**
  - **Baseline demographics and disease characteristics:**
    - **Age:** 42 years.
    - **Sex:** Male 50%, Female 50%.
    - **Diagnosis:** Relapsing-remitting MS.
  - **Change in novel enhancing T2 lesion volume:**
    - **Baseline:** 1.972 mL.
    - **Week 127:** 0.574 mL.
    - **Week 127 baseline compared to baseline:** -66.9%.

**DISCUSSIONS**

- BG-12 was associated with a significant reduction in the number of new and enhancing T2 lesions and volume of T2 lesions versus placebo.
- The efficacy of BG-12 in reducing MRI activity was consistent with previous trials.

**REFERENCES**


**DEFINERS INVESTIGATORS**

- Neuroradiology Department, University Hospital Basel, Basel, Switzerland.
- Queen Mary University of London, Barts Institute, Barts and the London School of Medicine and Dentistry, London, UK.
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