In phase 3 trials, oral ozanimod HCl 0.5 mg daily for up to 24 months was superior to intramuscular interferon (IFN). Such increases, reported as TEAEs, were more common among those who switched from IFN than among those who received ozanimod HCl 1 mg. TEAE reporting was based on investigator discretion and not based on any specific level of ALC decline. Investigators were blinded to ALC and hematology results in the phase 3 parent studies and at OLE baseline; they received reports of these labs for the first time at month 3 in the OLE.

**METHODS**

**Participants with RNS who completed 12 months of ozanimod or 12 months of IFN** were eligible in an ongoing, multi-center, open-label extension (OLE) study (DAYBREAK). In this 3-arm, 36-month study, investigators continued to dosed weekly during the OLE with ozanimod 0.5 mg, ozanimod 1 mg, or IFN-β1a 30 µg.

**DAYBREAK’s primary objective was to evaluate long-term safety and tolerability of ozanimod, which included treatment-emergent adverse event (TEAE) monitoring and safety assessments.**

**Analysis Population**

- 2,639 participants completed the parent trial; 2,495 (84.6%) consented to DAYBREAK (NCT02797015).
- Of these, 2,189 were randomized to continue ozanimod and 306 continued IFN.

**RESULTS (cont’d)**

- **Safety**
  - **Daily use of ozanimod** in the OLE was assessed in Table 1.
  - The strip nonteaching ATLAST (ALT) and aspartate transaminase (AST) were mildly increased in 350 (27.0%) and 42.8% of participants, respectively.
  - **Newly observed** decreases in lymphocyte count and increase in platelet count were noted in 51 (12.5%) and 20 (5.7%) participants during the OLE.
  - **Recurrent** increases in lymphocyte count were noted in 14 (3.7%) participants.
  - **Oxidative stress** and antioxidant levels were generally consistent across OLE and parent trials.

**REFERENCES**


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LAWRENCE STEINMAN—disclosures available online.

**DISCLOSURES**

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