Amiselimod: A New Oral Agent in the Treatment of Multiple Sclerosis

Amiselimod is a new oral agent that was recently approved for the treatment of multiple sclerosis (MS). It is a sphingosine-1-phosphate (S1P) receptor modulator that reduces lymphocyte numbers by blocking their exit from lymphoid tissues. Fingolimod, the first approved S1P modulator, has a similar mechanism of action but differs in its receptor specificity.

MOMENTUM was a randomized, double-blind, phase 2 trial that compared the effectiveness and safety of Amiselimod with placebo. This study included patients with relapsing-remitting multiple sclerosis (RRMS) aged between 18-60 years who had an attack within the last 12 months, patients who had at least 2 attacks within the last 24 months and had an enhancing lesion within last 12 months, and patients who had an enhancing lesion within the last 3 months. Patients who were using an S1P modulator or previously used a lymphocyte-depleting agent were excluded. The patients were randomized equally to placebo, or 0.1 mg, 0.2 mg or 0.4 mg Amiselimod. After a 24-week treatment period, the patients were followed up for 12 weeks due to safety concerns, and magnetic resonance imaging, blood, and safety evaluations were performed every 4 weeks.

The primary endpoint of the study was the total number of enhancing lesions during the 8-24-week period. Two higher doses of Amiselimod caused a significant dose-related decrease in the number of enhancing lesions during the 8-24-week period (for 0.2 mg, 72% (p=0.0005) and for 0.4 mg 80% (p<0.0001)). Also, during the 4-24-week period, the total number of new or growing T2 lesions was decreased (for 0.2 mg p=0.0018, and for 0.4 mg p<0.0001). The drug had no significant effect on brain atrophy.

The authors explained this noting that no significant effect was seen in previous S1P modulator clinical trials during the first 6 months and the effect was detected later; MOMENTUM was a short-term study, as such, the detection of an effect was not expected.

Amiselimod was well tolerated in all treatment groups and treatment-related adverse effects were similar in all groups, including the placebo group. The most frequent adverse effects were headache and nasopharyngitis, and mild elevations in hepatic enzymes occurred. Macular edema was not seen in any patient and no effect was detected on cardiac rhythm.
In conclusion, the effectiveness of Amiselimid was like fingolimod in RRMS and it had no significant effect on cardiac rhythm. Although studies with longer durations and more powerful are still needed, it is seen as a potential treatment choice in both RRMS and other autoimmune disorders.

Reference