Comparative Efficacy of AXS-07 (MoSEIC™ Meloxicam/Rizatriptan) versus Rizatriptan in the Acute Treatment of Migraine

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**BACKGROUND**

- Migraine is a highly disabling neurological disorder.
- Characterized by recurrent attacks of pulsating head pain accompanied by nausea, photophobia, and phonophobia.
- Many of these symptoms are often severe and incapacitating, requiring bed rest.
- The World Health Organization classifies severe migraine attacks as among the most disabling diseases, comparable to diabetes, rheumatoid arthritis, and ocular disease.
- Current treatments are suboptimal.
- There is an urgent need to new acute treatments that provide rapid, sustained, and improved efficacy for the serious neurological disease.

**AXS-07: A Multi-mechanistic Approach**

- **AXS-07** consists of MoSEIC™ meloxicam and rizatriptan.
- MoSEIC™ meloxicam is a potent, rapidly absorbed, COX-2 preferential non-steroidal anti-inflammatory, such as bracing headache, wearing glasses or taking a shower, severe migraine pain, obesity, and morning migraine, are all known risk factors for poor treatment outcomes.
- There is an urgent need for new acute treatments that provide rapid, sustained, and improved efficacy for the serious neurological disease.

**MOMENTUM Trial Design**

- Randomized, double-blind, multicenter, active-placebo controlled, single-dose trial in patients with a history of inadequate response to prior acute migraine treatments.
- Eligible patients were randomized in a 2:2:2 ratio to treatment with AXS (20 mg MoSEIC™ meloxicam/10 mg rizatriptan), rizatriptan (10 mg), MoSEIC™ meloxicam (20 mg), or placebo.

**RESULTS**

- AXS-07 demonstrated statistically significant superiority to placebo on 2-hour pain freedom (20% vs. 7%; p<0.001) with a placebo corrected difference of 13%.
- AXS-07 demonstrated statistically significant superiority to placebo on time to pain relief (1.5 vs. 4.0 hours, p<0.001).

**CONCLUSIONS**

- AXS-07 was generally safe and well tolerated. The most commonly reported adverse events with AXS-07 were headache, dizziness, and somnolence, none of which occurred at a rate greater than placebo or greater than 3 percent.

**Safety and Tolerability**

- **AXS-07** demonstrated statistically significant superiority to placebo on time to pain relief, sustained pain relief, and pain relief after a single dose.
- **AXS-07** was generally safe and well tolerated in this study.

**REFERENCES**

- Ducros J, et al. The co-mitochondrial endpoint of pain freedom and freedom from most bothersome symptoms at 2 hours, compared to placebo.
- Axsome Therapeutics Inc. New York, NY.