**Effectiveness and Safety of Intrathecal Ziconotide as the First Agent in Pump for Adult Patients With Severe Chronic Pain**

Timothy Dee, MD,1 Richard L. Rausch, MD,2 Michael F. Saullino, MD, PhD,2 Philip Kim, MD,3 Mark Wallace, MD,4-Ju-Hua Ng, MD,5 Geertfrt F. Vanhove, MD, PhD,2 Gladstone McDowell, MD,2

1The Center for Pain Relief, Charlotte, NC; 2Cardinals Pain Institute and The Center for Clinical Research, Whiston Salen, NC; 3Mount Sinai, Elithee Park, Rh; 4Center for Interventional Pain and Spine, LLC, Newark, DE; 5University of California, San Diego, La Jolla, CA; 6Aza Pharmaceuticals, Palo Alto, CA. 7Imagined Pain Solutions, Columbus, OH

**Introduction**

- Ziconotide is an intrathecally delivered, nonopioid analgesic agent approved in the United States for the management of severe chronic pain. Prior studies of ziconotide as a single agent in treatment-resistant pain have been reported. This study evaluated the safety and efficacy of ziconotide therapy in patients with severe chronic pain.

**Objectives**

- To evaluate the short-term and long-term effectiveness and long-term safety associated with ziconotide therapy in the management of patients with severe chronic pain.

**Methods**

**Study Design**

- Analysis included evaluation of IT ziconotide therapy in patients for whom ziconotide was the first or later agent in pump; N=93 patients; enrollment has closed at 93 patients; 51 patients (54.8%) received ziconotide as first agent in pump; 42 patients (45.2%) did not receive ziconotide as first in pump; primary diagnosis information was missing for 3 patients.

**Study Population**

- Adulthood ≥18 years with severe chronic pain (life expectancy of at least 5 years) for whom IT therapy is anticipated and who are interested in or referred for other treatments, such as systemic analgesics, adjuvant therapies, RF, spinal cord stimulation, and initial IT ziconotide as the agent in the pump.

**Ziconotide Dosing Details**

- 4 μg/hour intrathecal ziconotide bolus (Pallabe) infusion system, which allows for an initial dose of 1 mg/hour using the standard weight, ziconotide bolus formula.

**Statistical Methods**

- No prior powered hypothesis is identified for this observational study; data are summarized using descriptive statistics.

**Results**

**Patients**

- For treatment response defined as ≥2 unit reduction in NPRS score from baseline, 51.9% of patients (N=51) with ziconotide as first in pump; 51.9% of patients (N=42) with ziconotide not first in pump; primary diagnosis information was missing for 3 patients.

**Ziconotide as First Versus Second-or-Later Agent in Pump**

- For treatment response defined as ≥2 unit reduction in NPRS score from baseline, 51.9% of patients (N=51) with ziconotide as first in pump; 51.9% of patients (N=42) with ziconotide not first in pump; primary diagnosis information was missing for 3 patients.

**Efficacy: Patients With Ziconotide as the First Versus Second-Or-Later Agent in Pump**

- Another primary study endpoint was not one of the predefined categories was reported for 42 patients (10%) with ziconotide as the second-or-later agent in pump; primary diagnosis information was missing for 3 patients.

**Conclusions**

- This research is funded by Jazz Pharmaceuticals. Technical editorial and medical writing support for the development of this poster was provided by Imagine Pain Solutions, Columbus, OH.

**References**