Sustained Effectiveness of Intrathecal Ziconotide Use as the First Agent in Pump in Patients With Severe Chronic Pain

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Introduction: The Patient Registry of Intrathecal Ziconotide Management (PRIZM) evaluated the effectiveness and safety of intrathecal ziconotide treatment in the clinical practice setting.

Methods: PRIZM was an open-label, long-term, multicenter, observational study of adult patients with severe chronic pain who meet ziconotide prescribing information criteria and initiate ziconotide as the sole agent in the pump. Enrollment in this study has closed; however, patients may remain in the study for up to 18 months if they continue to receive ziconotide. This interim subset analysis (as of 07/05/16) of ziconotide as the first versus second-or-later intrathecal agent in pump reports change from baseline over time (month 3, 6, 9, and 12) in average pain for the past 24 hours with the 11-point Numeric Pain Rating Scale (NPRS; primary efficacy endpoint).

Results: Enrollment closed at 93 patients; data are available for these patients in this interim analysis. Of 93 patients enrolled, 44 were active in the study at month 12, 33/44 had NPRS scores at all data collection timepoints, 18/33 received ziconotide as first-in-pump (FIP+) and 15/33 did not (FIP-). Mean (SD) baseline NPRS scores were 7.4 (1.2) in FIP+ and 8.3 (1.2) in FIP- patients. Mean percentage change (SE) in NPRS scores for FIP+ and FIP- patients were -18.7 (6.7)% and -12.2 (4.7)% at month 3, -36.0 (7.5)% and -12.0 (5.4)% at month 6, -16.7 (7.8)% and -30.0 (6.0)% at month 9, and -30.3 (7.7)% and -14.5 (7.7)% at month 12, respectively. The most common adverse events (AEs; in ≥25% of patients combined) were auditory hallucination (38.9% in FIP+ versus 20.0% in FIP-), peripheral edema (38.9% versus 0%), and amnesia (27.8% versus 6.7%).

Conclusion: These data from a limited number of patients suggest that there may be a greater sustained treatment response for up to 12 months when ziconotide was initiated as first-line intrathecal therapy versus second-or-later agent in the pump. The AE profile of ziconotide was consistent with the prescribing information.

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