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

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Introduction: Ziconotide is an intrathecally delivered, non-opioid analgesic agent approved in the United States for management of severe chronic pain in adult patients for whom intrathecal therapy is warranted, and who are intolerant of or refractory to other treatments. The Patient Registry of Intrathecal Ziconotide Management (PRIZM) evaluates effectiveness and safety associated with intrathecal (IT) ziconotide use in clinical practice settings.

Materials and Methods: PRIZM was an open-label, long-term, multicenter, observational study of adult patients with severe chronic pain who meet ziconotide prescribing information criteria. This interim analysis (data as of July 5, 2016) of ziconotide as the first versus second-or-later IT agent in pump reports percentage change from baseline to month 6 and month 12 in “average pain for the past 24 hours” on the 11-point Numeric Pain Rating Scale (NPRS; primary efficacy endpoint at week 12) and Patient Global Impression of Change (PGIC) score at months 6 and 12.

Results: Enrollment closed at 93 patients (June 30, 2015). All 93 patients were enrolled ≥ 12 months prior to this interim analysis; 66 patients and 44 patients were still active in the study at months 6 and 12, respectively, of whom 77.3% (51/66, month 6) and 59.1% (26/44, month 12) remained on ziconotide monotherapy. Fifty-one patients (54.8%) received ziconotide as the first agent in pump (FIP+); 42 (45.2%) did not (FIP-). Mean (SD) baseline NPRS scores were 7.4 (1.9) and 7.9 (1.6) in FIP+ and FIP- patients, respectively. Mean (SEM) percentage changes in NPRS scores at month 6 were â€“28.2% (5.4%) in FIP+ (n=30) and 0.7% (6.6%) in FIP- (n=26) patients and at month 12 were â€“31.6% (7.4%) in FIP+ (n=19) and â€“12.8% (7.4%) in FIP- (n=16) patients. Improvement from baseline in PGIC score was reported in 66.7% of FIP+ patients (n=30) versus 40.9% of FIP- patients (n=22) at month 6, and 92.9% of FIP+ patients (n=14) versus 76.9% of FIP- patients (n=13) at month 12. The most common adverse events (AEs; â‰¥15% of patients combined) were nausea (25.5% vs. 21.4%; FIP+ vs. FIP- patients, respectively), confusional state (15.7% vs. 21.4%), dizziness (17.6% vs. 16.7%), auditory hallucination (17.6% vs. 11.9%), and diarrhea (15.7% vs. 14.3%).

Conclusions: In this interim PRIZM analysis, greater improvements in NPRS and PGIC scores from baseline to month 6 and month 12 were observed when ziconotide was initiated as first-line IT therapy versus second-or-later IT agent in pump. The AE profile of ziconotide was consistent with the prescribing information.

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