Interim Subset Analyses

Study Design

Introduction

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Results for the Acute SF-36 version 2 are normalized to the 1998 US general population

Programmed at their previous clinic visit

No protocol-specified tests of hypotheses are presented for this observational study; the data

It is warranted and who are intolerant of or refractory to other treatments, such as systemic analgesics,

is a prospective, open-label, long-term, multicenter, observational study (registry) of IT ziconotide in patients with severe chronic

Ziconotide is administered via the Medtronic SynchroMed II Infusion System, which allows

COLONIC Pain and Spine, LLC, Newave, DE; Jazz Pharmaceuticals, Palo Alto, CA; Integrated Pain Solutions, OH;

The Patient Registry of Intrathecal Ziconotide Management (PRIZM) is a prospective, open-label, randomized, double-blind, placebo-controlled trials3–5; however, few studies evaluating the

Although PRIZM enrollment is closed, data collection is ongoing

Fig. 2: brief pain inventory short form, change in pain severity and pain interference through month 6 (All treated population)

Long-term, multicenter, observational study (registry) of IT ziconotide in patients with severe chronic

The study was reported by 69.2% of patients with ziconotide first in pump and 35.7% of patients

In general, greater improvement than baseline to month 6 on the SF-36 mental component was observed in patients with ziconotide first in pump versus patients with ziconotide 2nd or later in pump

For all adverse events. The mean square change from baseline was calculated to be

Figure 3: Brief Pain Inventory Short Form, Change in Pain Severity and Pain Interference Through Month 6 (All Treated Population)

Table 3: Adverse Events Occurring in ≥5% of Patients in Either Subgroup (All Treated Population)

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Ziconotide First in Pump

Ziconotide Not First in Pump

(n=14)

(n=24)

(n=26)

(n=14)

Patient Global Impression of Change, Month 6 (All Treated Population)

Figure 5: Patient Global Impression of Change, Month 6 (All Treated Population)

Intervention

Results

Methods

Sample sizes represent observed cases with a PGIC score at each assessment. The number of patients is lower at postbaseline assessments

Above a level of 3, pain was considered as severe in the acute SF-36 version 2

In this study, 2012 was considered as a baseline in the acute SF-36 version 2

Assess patients' perceptions of the impact of treatment on health and functioning9,10

Ziconotide is an intrathecally delivered, nonopioid analgesic agent approved in the United States for the management of severe chronic pain in adult patients for whom intrathecal (IT) therapy is considered a reasonable treatment option


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REFERENCES

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Wallace MS, et al.


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