The PRIZM (Patient Registry of Intrathecal Ziconotide Management) Study for Patients With Severe Chronic Pain: Results From an Interim Analysis

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Introduction

Ziconotide, a synthetic conopeptide, is produced by a venemous marine snail, Ctenoloma fasciculata. The drug inhibits the release of neurotransmitters and neuropeptides that mediate pain. Ziconotide is administered by intrathecal (IT) pump to patients with chronic pain, including cancer-related pain.

Methods

Study Design

This is a prospective, noninterventional, observational study. The study design is descriptive, uncontrolled, and nonrandomized. The primary outcomes of the study are efficacy and safety of ziconotide treatment. The study was conducted in the United States and Canada. The study is ongoing, and patients were enrolled from March 2015 to September 2016.

Study Population

Patients who are ≥18 years old, with chronic pain and history of IT ziconotide treatment at least 12 months prior to first follow-up visit, are eligible for inclusion. Patients who have had previous ziconotide therapy are eligible for inclusion. The study includes both treatment-naive and treatment-experienced patients. Patients with previous ziconotide exposure may be included in either or both groups of patients with or without Ziconotide Baseline Details.

Statistical Methods

This study is a descriptive analysis of the PRIZM database and includes all patients with riesome baseline characteristics. No test was performed to check for PRIZM database adequacy. The results of the study are presented as descriptive statistics. The study is considered a postmarketing surveillance study and was approved by the U.S. Food and Drug Administration. The study involved more than 1,000 patients.

Results

Patients

No formal hypothesis is being tested in this observational study; data are summarized using descriptive statistics. More than 1 diagnosis permitted for each patient.

Intrathecal Ziconotide Procedures and Dosing

This prospective, observational study of current clinical practice was designed to evaluate the effectiveness of IT ziconotide in the treatment of chronic pain. No mean dose is shown for each subgroup at each time point. Sample sizes for mean dose values vary from sample sizes for NPRS scores. Sample sizes represent observed cases at each assessment. The authors have no financial disclosure, and the authors report receiving no research grants, no consultancy fees, and no honorarium.

Conclusions

The results of this study may not be generalizable to all patients treated with IT ziconotide. This study is subject to the limitations of observational studies. This is a descriptive study, and statistical analysis was not performed.