

FOR IMMEDIATE RELEASE

Contact: Ann Hill
Ann Hill Communications
415.491.5901
ann@ahcommunications.com

**ZICONOTIDE (PRIALT) INTRATHECAL INFUSION
INCLUDED IN NEWLY UPDATED POLYANALGESIC ALGORITHMS**

2007 Polyanalgesic Consensus Panel Updates Guidelines for Intraspinal Infusion

CHARLESTON, WV (February 5, 2007)-- Ziconotide intrathecal infusion (PRIALT; Elan Pharmaceuticals, Inc., San Diego, Ca) was recently included as both a line 1 and line 2 approach for long-term intraspinal infusion for the treatment of chronic pain that is unresponsive to less invasive approaches.

The new guidelines represent the recommendations of the 2007 Polyanalgesic Consensus Conference held on January 20. The major outcome of this conference is the continuing development of an algorithmic approach to the management of chronic pain by intraspinal drug delivery. This algorithm for drug selection is based on best evidence and expert opinion as determined by an expert panel of leading pain management physicians throughout the United States.

The algorithm represents a hierarchy of six lines of drug therapy based on evidence of safety, efficacy and clinical experience. The drug therapies listed on line 1 of the algorithm are those drugs that are supported by extensive clinical experience and published preclinical and clinical data. Intrathecal infusion therapy most often commences with a line 1 drug and only progresses to lower line drugs if intolerable side effects occur, or if the initial drug is no longer effective at a dosage and concentration that is safe or convenient in clinical practice. The drugs listed below line 1 are supported by fewer published preclinical data, clinical experience or both.

2007 Algorithm Revisions

The key recommendations of the 2007 Polyanalgesic Consensus Conference panel are as follows;

Line 1 Approach

Based on controlled randomized trials that have confirmed the analgesic efficacy of ziconotide, as well as FDA approval of ziconotide for use as an intrathecal analgesic, the

-MORE-

Polyanalgesic Consensus Panel Updates Guidelines for Intraspinal Infusion/Page 2

2007 Polyanalgesic Consensus Conference panel has included ziconotide to the algorithm as a line 1 drug. As such, ziconotide joins morphine as the only analgesic drug approved by the US Food and Drug Administration (FDA) for long-term intrathecal administration. In fact, ziconotide is the first intrathecal analgesic approved in the United States in more than two decades. Further, unlike morphine and hydromorphone (a line 1 drug for which usage is supported by the medical literature and broad clinical experience), ziconotide is not associated with the formation of catheter-tip inflammatory masses.

Line 2 Approach

In addition to being utilized as a line 1 approach, ziconotide has been added to the algorithm as a line 2 approach. As such, ziconotide is to be used in combination with either morphine or hydromorphone. In addition, fentanyl was moved up the hierarchy, from a line 4 approach to a line 2 approach. These revisions now provides for four combinations of line 2 treatment:

- Morphine (or Hydromorphone) + Ziconotide
- Morphine (or Hydromorphone) + Bupivacaine
- Morphine (or Hydromorphone) + Clonidine
- Morphine (or Hydromorphone) + Fentanyl

Line 3 Approach

If a line 2 approach results in inadequate analgesia or intolerable side effects, the options include changing to an alternative line 2 combination or adding a third drug as a line 3 Approach. Ziconotide has now been added as a line 3 combination drug therapy approach. Line 3 now includes the following options:

- Morphine (or Hydromorphone) + Ziconotide + Bupivacaine
- Morphine (or Hydromorphone) + Ziconotide + Clonidine
- Morphine (or Hydromorphone) + Bupivacaine + Clonidine

Other Changes To The Algorithm

In addition to the inclusion of ziconotide as a first, second and third line approach, and the moving of fentanyl from a line 4 to a line 2 approach, other changes have been also been made to the algorithm. These include the removal of baclofen, neostigmine, adenosine and ketorolac from the algorithm altogether.

About the Polyanalgesic Consensus Panel

The PCP is an expert panel of leading pain management physicians from throughout the United States who meet periodically to evaluate the efficiency of various treatments. Members of the 2007 Panel include Timothy R. Deer, MD (The Center for Pain Relief, Charleston, WV), Allen W. Burton, MD (UT M.D. Anderson Cancer Ctr., Houston, TX),

-MORE-

Polyanalgesic Consensus Panel Updates Guidelines for Intraspinal Infusion/Page 3

Stuart DuPen, MD (Overlake Medical Center Pain Medicine Clinic, Bellevue, WA), Michael A. Erdek, MD (Johns Hopkins University, Baltimore, MD), Philip S. Kim, MD (Center for Pain Medicine, Wilmington, DE), Robert M. Levy, MD, PhD (Northwestern University, Chicago, IL), Judith A. Paice, RN, PhD (Northwestern University Feinberg School of Medicine, Chicago, IL), Joshua P. Prager, MD, MS (Ctr. For Rehabilitation of Pain Syndromes, Los Angeles, CA), Michael Saulino, MD, PhD (Moss Rehab, Thomas Jefferson Univ., Elkins Parks, PA), B. Todd Sitzman, MD, MPH (Advanced Pain Therapy, Forrest General Cancer Ctr., Hattiesburg, MS), K. Dean Willis, MD (Alabama Pain Center, Huntsville, AL), David Caraway, MD, PhD (The Center for Pain Relief Tri-State, Huntington, WV), James C. Eisenach, MD (Wake Forest University School of Medicine, Winston-Salem, NC), Eric Grigsby, MD (SpectrumCare Pain Treatment Ctr., Napa, CA), Elliot Krames, MD, DABPM (Pacific Pain Treatment Centers, San Francisco, CA), Gladstone C. McDowell, II, MD (Integrated Pain Solutions, Columbus, OH), Sunil J. Panchal, MD (COPE Foundation, Tampa, FL), Peter S. Staats, MD, MBA (Premier Pain/American Pain Medicine, Colts Neck, NJ), Richard L. Rauck, MD (The Center for Clinical Research, Winston-Salem, NC), Lisa Jo Stearns, MD (Valley Cancer Pain Treatment Ctr., Division of Valley Anesthesiology Cons., Scottsdale, AZ), and William D. Witt, MD (Interventional Pain Associates, Lexington, KY).

###