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**FOR IMMEDIATE RELEASE**

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**FDA Approves LUSEDRA™ (fospropofol disodium) Injection  
for Monitored Anesthesia Care (MAC) Sedation**

**Woodcliff Lake, NJ, December 14, 2008** – Eisai Corporation of North America today announced that the U.S. Food and Drug Administration (FDA) has approved LUSEDRA™ (fospropofol disodium) Injection, an intravenous sedative-hypnotic agent for monitored anesthesia care (MAC) sedation in adult patients undergoing diagnostic or therapeutic procedures.

In the approval, the FDA required that LUSEDRA be used only by persons trained in the administration of general anesthesia and that all patients should be continuously monitored by persons not involved in the conduct of the procedure.

On May 7, 2008, the FDA Advisory Committee on Anesthetic and Life Support Drugs voted 6 to 3 in favor (with one abstention) of approval of LUSEDRA for use as an intravenous sedative-hypnotic agent for sedation in adult patients undergoing diagnostic or therapeutic procedures. The committee recommended use of LUSEDRA by healthcare providers who are appropriately trained.

“We are pleased with the FDA’s decision to approve Lusedra, as it provides a new option for monitored anesthesia care (MAC) sedation in adult patients,” said Cynthia Schwalm, President, Eisai Inc. “With the approval of Lusedra, Eisai continues to fulfill its *human health care* mission to address the unmet needs of patients.”

The FDA has recommended that LUSEDRA be classified as a controlled substance. A final scheduling decision is expected from the U.S. Drug Enforcement Administration (DEA) after publishing a proposed rule in the Federal Register and allowing for public comment. Once LUSEDRA receives final scheduling designation, the label will be amended.

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### **About LUSEDRA™ (fospropofol disodium) Injection**

LUSEDRA™ (fospropofol disodium) Injection is a proprietary water-soluble prodrug of propofol that, after intravenous injection, is converted by alkaline phosphatase enzymes in the body into propofol. LUSEDRA is an intravenous sedative-hypnotic agent indicated for monitored anesthesia care (MAC) sedation in adult patients undergoing diagnostic or therapeutic procedures.

### **Important Safety Information**

**LUSEDRA should be administered only by persons trained in the administration of general anesthesia and not involved in the conduct of the diagnostic or therapeutic procedure. Patients should be continuously monitored during sedation and through the recovery process for early signs of hypotension, apnea, airway obstruction, and/or oxygen desaturation. Facilities for providing cardiopulmonary resuscitation must be immediately available.**

The following serious adverse reactions have been reported with the use of LUSEDRA.

- Hypotension
  - Hypotension was reported in 18/455 (4%) patients treated with LUSEDRA using the standard or modified dosing regimen.
  - Patients with compromised myocardial function, reduced vascular tone, or who have reduced intravascular volume may be at an increased risk for hypotension.
- Hypoxemia
  - Hypoxemia was reported in 20/455 (4%) patients treated with LUSEDRA using the standard or modified dosing regimen. Retention of purposeful responsiveness did not prevent patients from becoming hypoxemic following administration of LUSEDRA.
- Respiratory depression
  - Apnea was reported in 1/455 (< 1%) patients treated with LUSEDRA using the standard or modified dosing regimen.
- Loss of purposeful responsiveness
  - LUSEDRA has not been studied for use in general anesthesia. However, administration of LUSEDRA may inadvertently cause patients to become unresponsive or minimally responsive to vigorous tactile or painful stimulation. The incidence of patients who became minimally responsive or unresponsive to vigorous tactile or painful stimulation was 7/183 (4%) for colonoscopy and 24/149 (16%) for bronchoscopy. The duration of minimal or complete unresponsiveness ranged from 2 to 16 minutes in colonoscopy patients and from 2 to 20 minutes in bronchoscopy patients.

The use of supplemental oxygen is recommended in all patients receiving LUSEDRA. Airway assistance maneuvers may be required. As with other sedative-hypnotic agents, LUSEDRA may produce additive cardio-respiratory effects when administered with other cardio-respiratory depressants such as benzodiazepines and narcotic analgesics. When LUSEDRA is used at greater than the recommended doses, the incidence of serious adverse reactions is increased.

The most common adverse reactions (reported in greater than 20%) are paresthesia and pruritis.

Please see FDA-approved labeling text at <http://www.eisai.com/presskit.asp?ID=217>.

### **About Eisai Corporation of North America**

Eisai Corporation of North America is a wholly-owned subsidiary of Eisai Co., Ltd., a research-based *human health care (hhc)* company that discovers, develops and markets products throughout the world. Eisai focuses its efforts in three therapeutic areas: neurology, gastrointestinal disorders and oncology/critical care.

Eisai Corporation of North America supports the activities of its operating companies in North America, which include: Eisai Research Institute of Boston, Inc., a discovery operation with strong organic chemistry capabilities; Morphotek, Inc., a biopharmaceutical company specializing in the development of therapeutic monoclonal antibodies; Eisai Medical Research Inc., a clinical development group; Eisai Inc., a commercial operation with manufacturing and marketing/sales functions; and Eisai Machinery U.S.A., which markets and maintains pharmaceutical manufacturing machinery. For more information about Eisai, please visit [www.eisai.com](http://www.eisai.com).

### **About Eisai Inc.**

Eisai Inc. is a U.S. pharmaceutical subsidiary of Eisai Co., Ltd. that was established in 1995 and is ranked among the top-20 U.S. pharmaceutical companies (based on retail sales). Eisai Inc. began marketing its first product in the United States in 1997 and has rapidly grown to become an integrated pharmaceutical business with fiscal year 2007 (year ended March 31, 2008) sales of approximately \$3 billion, including the results of the acquisition of MGI PHARMA, Inc.

Eisai Inc. employs approximately 1,900 people at its headquarters in Woodcliff Lake, NJ, at its state-of-the-art pharmaceutical production and formulation research and development facility in Research Triangle Park, NC, and in the field. For more information about Eisai, please visit [www.eisai.com](http://www.eisai.com).

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