



**Eisai Co., Ltd.**

4-6-10 Koishikawa, Bunkyo-ku, Tokyo 112-8088, Japan

Phone: 03- 3817-5120

Fax: 03- 3811-3077

*Eisai is a Human Health Care Corporation striving for innovative solutions in prevention, cure and care for the health and well-being of people worldwide. We combine our talents to understand and meet the needs of patients and their families to enhance the quality of life.*

---

**FOR IMMEDIATE RELEASE**

May 8, 2008

Eisai Co., Ltd.

**FDA ADVISORY COMMITTEE VOTES IN FAVOR OF APPROVAL  
OF FOSPROPOFOL DISODIUM INJECTION FOR SEDATION**

Eisai Corporation of North America and its U.S. subsidiary, MGI PHARMA, INC., today announced that the U.S. Food and Drug Administration (FDA) Advisory Committee on Anesthetic and Life Support Drugs (ALSDAC) has voted 6 to 3 in favor (with one abstention) of approval of fospropofol disodium injection for use as an intravenous sedative-hypnotic agent for sedation in adult patients undergoing diagnostic or therapeutic procedures.

The Committee recommended use of fospropofol disodium injection to health care providers who are appropriately trained. Further, the Committee recommended additional studies be conducted in specific patient populations, including those with a variety of comorbidities, for example, in patients who weigh less than 60 kg and the elderly.

“We are encouraged by ALSDAC’s support of the efficacy and safety results of fospropofol disodium demonstrated in our clinical studies, and we look forward to continuing our discussions with FDA as they finalize their review of our application,” said Mary Lynne Hedley, PhD, Executive Vice President of Eisai Corporation of North America. “We believe the clinical trial data support the use of this product by anesthesiologists and nonanesthesia health care professionals.”

FDA reviewers will consider ALSDAC’s recommendation in its review of the NDA for fospropofol disodium injection. The FDA is not bound by its Advisory Committees’ recommendations.

Data from one Phase II and one Phase III trial in patients undergoing colonoscopy, a Phase III trial in patients undergoing bronchoscopy, and an open-label study in patients undergoing a variety of minor surgical procedures form the foundation of the fospropofol disodium injection NDA. In total, data from 21 clinical studies involving 1,611 individuals are included in the application. The clinical trials were conducted by nonanesthesia health care professionals, and

study drugs were administered by medical personnel as dictated by local investigative site guidelines.

“Fospropofol disodium injection was designed to help meet the need for new minimal to moderate sedation agents, and therefore is representative of our human health care mission to address the unmet medical needs of patients,” said Hajime Shimizu, Chairman and CEO, Eisai Corporation of North America.

**[Please refer to the following note for Fospropofol Disodium Injection]**

About Fospropofol Disodium Injection

Fospropofol disodium injection is a proprietary water-soluble prodrug of propofol that, after intravenous injection, is converted by an enzyme (alkaline phosphatase) in the body into propofol. Fospropofol disodium injection is a product candidate in development for sedation of patients undergoing therapeutic or diagnostic procedures. Fospropofol disodium injection has not yet been approved for marketing by the Food and Drug Administration or any other regulatory agencies.