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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.

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Eisai Co., Ltd.

Eisai Receives Action Letter on Fospropofol Disodium Injection For Sedation in Diagnostic or Therapeutic Procedures

FDA's Not Approvable Letter Outlines Pathway to Potential Approval

Eisai Corporation of North America (Headquarters: New Jersey, United States, Chairman & CEO: Hajime Shimizu), a U.S. subsidiary of Eisai Co., Ltd. (Headquarters: Tokyo, President & CEO: Haruo Naito), today announced that it has received a not approvable letter from the U.S. Food and Drug Administration (FDA), which outlines a pathway to potential approval of fospropofol disodium for use by appropriately trained physicians. Fospropofol disodium injection has been in review at the FDA for use as an intravenous sedative-hypnotic agent for sedation in adult patients undergoing diagnostic or therapeutics procedures.

" We are confident that our continued discussions with FDA will lead to the timely approval of this important new therapy" said Mary Lynne Hedley, PhD, Executive Vice President of Eisai Corporation of North America, "We look forward to working with FDA to help ensure that appropriately trained physicians have this new option for patients. We believe that our clinical data submitted to FDA supports the approval of fospropofol disodium as a potential new option for sedation of patients undergoing important diagnostic or therapeutic procedures."

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 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 by healthcar

About Fospropofol Disodium Injection

Fospropofol disodium injection is a proprietary 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 adult patients undergoing diagnostic or therapeutic procedures.