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Eisai Co., Ltd.

**SANNOVA RECEIVES APPROVAL FOR ADDITIONAL INDICATION, ADDITIONAL DOSAGE AND ADMINISTRATION OF KAYTWO® SYRUP 0.2% FOR PREVENTION OF VITAMIN K DEFICIENCY HEMORRHAGE IN NEONATES AND INFANTS**

Eisai Co., Ltd. (Headquarters: Tokyo, President & CEO: Haruo Naito, "Eisai") announced today that its pharmaceutical manufacturing and sales subsidiary Sannova Co., Ltd. (Headquarters: Gunma, President: Toshio Kaneko) has received approval for an additional indication and additional dosage and administration of its vitamin $K_2$ syrup formulation, Kaytwo® Syrup 0.2% (menatetrenone), for the prevention of vitamin K deficiency hemorrhage in neonates and infants.

In Japan, vitamin K deficiency hemorrhage is classified into two types—vitamin K deficiency hemorrhage in neonates, which occurs within seven days of birth, and vitamin K deficiency hemorrhage in infants, which presents during infancy. Although rather rare, vitamin K deficiency hemorrhage in infants, in particular, is a very serious condition involving intracranial hemorrhaging that often results in death or permanent neurological damage.

In Europe and the United States, vitamin K is already approved as a preventive measure against vitamin K deficiency hemorrhage. In Japan, however, despite the fact that majority of newborn babies are administered vitamin $K_2$ syrup formulations for preventative purposes in accordance with recommendations in treatment guidelines published by the former Ministry of Health (currently Ministry of Health, Labour and Welfare: MHLW) Research Group and the Japan Pediatric Society, there have been no medicines approved for the prevention of vitamin K deficiency hemorrhage in neonates and infants up until now. Against this backdrop, MHLW's Study Group on Unapproved and Off-label Drugs of High Medical Need deemed that there was a significant need for Kaytwo Syrup 0.2% to be approved for the prevention of vitamin K deficiency hemorrhage in this patient population, and therefore designated it as a drug for which an application based on public knowledge may be submitted. In response to the study group's recommendation, Sannova submitted an application based on public knowledge to the MHLW on November 30, 2011 seeking approval for this additional indication and corresponding additional dosage and administration.

Eisai is taking proactive steps to obtain approval for unapproved and off-label drugs. In the field of cardiovascular diseases, the company received additional pediatric indication approval for the tachyarrhythmia treatment Tambocor® Tablets, the oral anticoagulant Warfarin Tablets, as well as the calcium channel-blocking anti-arrhythmic agent Vasolan® Tablets 40 mg and Vasolan® for intravenous Injection 5 mg, in May 2010, February 2011 and May 2011, respectively. Eisai is also carrying out Phase III studies of the antiepileptic agent rufinamide (generic name) in patients with Lennox-Gastaut syndrome, a form of childhood epilepsy. Having received this latest pediatric indication approval for Kaytwo® Syrup 0.2%, the Eisai Group seeks to establish other drug therapies suitable for use in the pediatric setting and remains committed to making further contributions to patients.

**[Please refer to the following notes for details of the newly approved indication and further information on "application based of public knowledge"]**

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**[Notes to editors]**

**1. Kaytwo® Syrup 0.2% Approval Outline**

(Underlined parts indicate newly approved indication/dosage and administration)

1) Indications

Treatment of neonatal hemorrhage and hypoprothrombinemia

Prevention of vitamin K deficiency hemorrhage in neonates and infants

2) Dosage and Administration

Treatment of neonatal hemorrhage and hypoprothrombinemia

The usual neonate dosage for oral use is 1 mL (2 mg of menatetrenone), once a day.

The dose may be increased up to 3 mL (6 mg of menatetrenone) depending on the patient's symptoms.

Prevention of vitamin K deficiency hemorrhage in neonates and infants

The usual initial dosage for oral use, once the neonate is satisfactorily able to ingest milk, is 1 mL (2 mg of menatetrenone). This should be followed by a second 1mL dose one week after birth or upon discharge from the maternity ward, whichever is earlier, and a third 1 mL dose one month after birth.

**2. Application Based on Public Knowledge**

An application based on public knowledge is a marketing authorization application that seeks additional indication approval for a currently approved drug. This type of application is submitted on the pretense that overseas usage of the drug and medical literature published both in Japan and other countries are sufficient to prove that the drug's safety and efficacy is public knowledge within the medical and pharmacological community, and does not require that additional clinical studies be conducted, either in whole or in part.