No.11-18

February 23, 2011
Eisai Co., Ltd.

EISAI'S ORAL ANTICOAGULANT WARFARIN TABLETS APPROVED FOR PEDIATRIC USE IN JAPAN

Eisai Co., Ltd. (Headquarters: Tokyo, President & CEO: Haruo Naito) announced today that it has received approval in Japan for additional dosage and administration of its oral anticoagulant Warfarin (generic name: warfarin potassium) Tablets for the treatment and prevention of thromboembolism in pediatric patients. Warfarin is the first oral anticoagulant to be approved in Japan for the treatment and prevention of thromboembolism in the pediatric setting.

Pediatric thromboembolism is an extremely serious and highly life-threatening medical condition that is caused by a wide range of factors including congenital heart disease, cardiovascular disease, Kawasaki disease, and catheterization. With many pediatric thromboembolism cases unable to be adequately treated or prevented with drugs currently approved in Japan, the Japanese medical community has been calling for the approval of alternative treatment options to fulfill this unmet medical need.

Warfarin has already been approved for pediatric use in France, and its clinical usefulness in treating thromboembolism in pediatric patients has been widely reported in medical literature. Against this backdrop, the Japanese Ministry of Health, Labour and Welfare's "Study Group on Unapproved and Off-label Drugs of High Medical Need" concluded that there is a substantial need to make the drug available for use in pediatric patients and designated it as a drug for which an Application Based on Public Knowledge may be submitted. In response to the decision reached by the study group, Eisai submitted an Application Based on Public Knowledge on September 22, 2010 seeking approval for additional pediatric dosage and administration.

Warfarin expresses anticoagulant effects by antagonizing vitamin K and inhibiting the production of blood coagulant factor. In Japan, the drug has been widely used to treat and prevent thromboembolism in adults since it was first launched in 1962.

In regards to pediatric indications for other cardiovascular products, Eisai received approval to market the anti-arrhythmic agent Tambocor® Tablets in Japan for treatment of tachyarrhythmia in pediatric patients in May 2010, and submitted an Application Based on Public Knowledge in November 2010 for the calcium channel blocking anti-arrhythmic agents Vasolan® Tablets and Vasolan® for Intravenous Injection. Having received approval for pediatric dosage and administration of Warfarin Tablets, Eisai seeks to establish other drug therapies suitable for use in the pediatric setting and make further contributions to patients.

[Please refer to the following notes for further information on the newly approved dosage and administration and Application Based on Public Knowledge]

Media Inquiries:
Public Relations Department,
Eisai Co., Ltd.
+81-(0)3-3817-5120

[Notes to editors]

1. Warfarin Tablets (Underlined parts indicate newly approved dosage and administration)

1) Product Name

Warfarin Tablets 0.5 mg, Warfarin Tablets 1 mg, Warfarin Tablets 5 mg

2) Indications and Usage

Treatment and prevention of thromboembolism (venous thrombosis, myocardial infarction, pulmonary embolism, cerebral embolism, slowly progressing cerebral thrombosis, etc.)

3) Dosage and Administration

The prothrombin time, as measured by the Quick one-stage method, and Thrombotest values are used to control dosage and dosing intervals.

In most cases, the target therapeutic range is approximately twice the normal coagulation time, or 15 to 30% of normal prothrombin activity for the prothrombin time and approximately 10% for the Thrombotest.

The recommended initial adult dosage for oral use is 20 to 40 mg of warfarin potassium. Administration of Warfarin should then be discontinued for one or two days and resumed at a daily maintenance dose of 1 to 5 mg once it has been confirmed that coagulation levels are within the target therapeutic range. Alternatively, Warfarin may be administered orally at a daily dose of 5 to 6 mg for several days until coagulation levels are within the target therapeutic range and then the dose should be adjusted to maintain target levels for the duration of treatment.

As sensitivity to Warfarin varies greatly from person to person and varying degrees of sensitivity may be observed even in the same patient, prothrombin times should be measured and the Thrombotest conducted frequently, especially during the early stage of therapy to ensure that coagulation levels remain within the target therapeutic range.

In order to accelerate the anticoagulant effect, heparin may be coadministered with the initial dose of Warfarin.

<u>The following maintenance doses (mg/kg/day) may be administered to pediatric patients:</u>

<u>Patients under 12 months old: 0.16 mg/kg/day</u>

<u>Patients between one and 14 years old: 0.04~0.10 mg/kg/day</u>

2. Application Based on Public Knowledge

An Application Based on Public Knowledge is a marketing authorization application that seeks supplemental indication approval for a currently approved drug. This kind of application is submitted based on medical and pharmacological public knowledge of a drug's safety and efficacy and does not require that additional clinical studies be conducted, in whole or in part.