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Eisai Co., Ltd.

EISAI RECEIVES APPROVAL FOR ADDITIONAL INDICATION OF CALCIUM CHANNEL BLOCKING ANTI-ARRHYTHMIC AGENT VASOLAN® FOR PEDIATRIC PATEINTS IN JAPAN

Eisai Co., Ltd. (Headquarters: Tokyo, President & CEO: Haruo Naito, "Eisai") announced today that it has received approval in Japan for an additional indication of its calcium channel blocking anti-arrhythmic agent Vasolan® (verapamil hydrochloride) Tablets 40 mg and Vasolan® for Intravenous Injection 5 mg for the treatment of supraventricular tachyarrhythmia in pediatric patients.

Pediatric arrhythmia, in addition to causing heart palpitations, dizziness, shortness of breath and other symptoms that impact the daily lives of patients, is said to be one of the most common causes of sudden death among children. With currently approved anti-arrhythmic agents often providing insufficient effects and some patients being unable to undergo catheter-based therapy due to age or body build, the treatment of arrhythmia represents an area of unmet need that exists in Japan's pediatric healthcare system.

While Vasolan® is approved for pediatric use in Europe and the United States and is positioned as a standard treatment option for pediatric tachyarrhythmia, there are few treatments approved for use in the pediatric setting in Japan, and until now, there have been no therapeutic agents approved for the treatment of such patients amongst anti-arrhythmic drugs with the same mechanism of action as Vasolan®. Against this backdrop, the Ministry of Health, Labour and Welfare of Japan's "Study Group on Unapproved and Off-label Drugs of High Medical Need" concluded that there is a substantial need to make Vasolan® available for use in the treatment of 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 for the agent on November 16, 2010 seeking approval for an additional pediatric indication as well as additional pediatric dosage and administration.

Vasolan® suppresses tachyarrhythmia by blocking the influx of calcium ions into cells and slowing cardiac excitation. It is the first calcium channel blocking agent to be approved in Japan for the treatment of pediatric tachyarrhythmia.

In regards to pediatric indications for other cardiovascular products, Eisai received approval to market the anti-arrhythmic agent Tambocor® Tablets and the oral anticoagulant Warfarin Tablets in May 2010 and February 2011, respectively. Having received approval for additional pediatric dosage and administration of the calcium channel blocking agent Vasolan® Tablets 40 mg and Vasolan® for Intravenous Injection 5 mg, Eisai 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 a product outline and definition of Application Based on Public Knowledge]

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[Notes to editors]

1. Vasolan® Tablets 40 mg Product Outline (Underlined text indicates newly approved dosage and administration)

1) Indications and Usage

Adults:

Treatment of tachyarrhythmia (atrial fibrillation/flutter, paroxysmal supraventricular tachycardia), angina, myocardial infarction (excluding treatment during the acute phase) and other types of ischemic heart disease

Pediatric patients:

Treatment of tachyarrhythmia (atrial fibrillation/flutter, paroxysmal supraventricular tachycardia)

2) Dosage and Administration

Adults:

○Tachyarrhythmia (atrial fibrillation/flutter, paroxysmal supraventricular tachycardia)

The usual adult dosage is one or two tablets (40 mg - 80 mg of verapamil hydrochloride per dose) administered orally three times daily. However, dosage may be decreased according to the patient's age and symptoms.

○Angina, myocardial infarction (excluding treatment during the acute phase) and other types of ischemic heart disease

The usual adult dosage is one or two tablets (40 mg - 80 mg of verapamil hydrochloride per dose) administered orally three times daily. However, dosage may be increased or decreased according to the patient's age and symptoms.

Pediatrics:

○Tachyarrhythmia (atrial fibrillation/flutter, paroxysmal supraventricular tachycardia)

The usual pediatric daily dosage of verapamil hydrochloride is 3 - 6 mg/kg (maximum daily dosage should not exceed 240 mg) administered orally and divided into three equals doses. However, dosage may be decreased according to the patient's age and symptoms.

2. Vasolan® for Intravenous Injection 5 mg Product Outline (Underlined text indicates newly approved dosage and administration)

1) Indications and Usage

Tachyarrhythmia (paroxysmal supraventricular tachycardia, paroxysmal atrial fibrillation, paroxysmal atrial flutter)

2) Dosage and Administration

Adults:

The usual adult dosage is one single-dose vial (5 mg of verapamil hydrochloride) administered slowly by intravenous infusion over at least five minutes, and if necessary, diluted with a saline or glucose solution. However, dosage may be increased or decreased according to the patient's age and symptoms.

Pediatric patients:

The usual pediatric dosage of verapamil hydrochloride is one single 0.1 - 0.2 mg/kg dose (maximum single dose should not exceed 5 mg) administered slowly by intravenous infusion over at least five minutes, and if necessary, diluted with a saline or glucose solution. However, dosage may be increased or decreased according to the patient's age and symptoms.

3. 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.