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Eisai Co., Ltd.

EISAI RECEIVES APPROVAL IN JAPAN FOR FINE GRANULE FORMULATION OF ANTI-ARRHYTHMIC AGENT TAMBOCOR® SUITABLE FOR PEDIATRIC PATIENTS

Eisai Co., Ltd. (Headquarters: Tokyo, CEO: Haruo Naito, "Eisai") announced today that it has received marketing and manufacturing approval in Japan for Tambocor® Fine Granules 10%, a new formulation of anti-arrhythmic agent Tambocor (flecainide acetate).

Tambocor suppresses tachyarrhythmia by blocking cardiac sodium channels and slowing down cardiac conduction. Approved and launched as Tambocor Tablets in Japan in 1991, the drug was originally indicated for the treatment of tachyarrhythmia in adults. Determining the need to make the drug available to treat pediatric patients in Japan, the Japanese Ministry of Health, Labour and Welfare's Council for Pediatric Pharmacotherapy approved Tambocor as indicated for the treatment of tachyarrhythmia (paroxysmal atrial fibrillation/flutter, paroxysmal supraventricular tachycardia, ventricular tachycardia) in pediatric patients in May 2010. Furthermore, Tambocor is the only sodium channel blocking agent in Japan to be approved for the treatment of tachyarrhythmia in pediatric patients.

When administering Tambocor Tablets to pediatric patients, it is necessary to adjust the dosage depending on age and body surface area, which means that the tablets need to be crushed into powder for dosage adjustment. As such, there have been requests for development of a formulation that is suitable for pediatric administration. In consideration of an appropriate formulation that would meet clinical needs, Eisai developed a 10% fine granule formulation which enables precise dosage adjustment for pediatric patients and can be administered to patients who have difficulty with taking tablets. Having confirmed bioequivalence to the tablet formulation through clinical studies, Eisai submitted an application for the approval of the additional formulation in January 2014.

Pediatric arrhythmia not only causes heart palpitations, dizziness, shortness of breath and other symptoms that impact the daily lives of patients, it is also said to be one of the most common causes of sudden death among children. Regarding pediatric arrhythmia, Eisai has received approval of additional indications for pediatric patients for Tambocor Tablets in May 2010, and for the calcium channel blocking agents Vasolan® Tablets 40 mg and Vasolan for intravenous injection 5 mg in May 2011. By providing a fine granule formulation that is easy to measure and administer in addition to Tambocor Tablets, Eisai will continue to make further contributions to address their needs of patients with tachyarrhythmia.

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[Notes to editors]

1. About Tambocor Fine Granules 10%

1) Product Name

Tambocor[®] Fine Granules 10%

2) Indications, Dosage & Administration

• Indications

The following conditions where other antiarrhythmic drugs cannot be used or are ineffective:

Adults: Tachyarrhythmia (paroxysmal atrial fibrillation/flutter, ventricular tachycardia)

Children: Tachyarrhythmia (paroxysmal atrial fibrillation/flutter, paroxysmal supraventricular tachycardia, ventricular tachycardia)

• Dosage & Administration

Adults:

• Tachyarrhythmia (paroxysmal atrial fibrillation/flutter)

The recommended starting dose is 100 mg (1 g of fine granules) of flecainide acetate per day, taken orally and divided into two equally spaced doses. The recommended dose may be increased to a maximum of 200 mg (2 g of fine granules) per day if efficacy is not achieved. It may also be decreased according to age and symptoms.

• Tachyarrhythmia (ventricular tachycardia)

The recommended starting dose is 100 mg (1 g of fine granules) of flecainide acetate per day, taken orally and divided into two equally spaced doses. The recommended dose may be increased to a maximum of 200 mg (2 g of fine granules) per day if efficacy is not achieved. It may also be decreased or increased according to age and symptoms.

Children:

• Tachyarrhythmia (paroxysmal atrial fibrillation/flutter, paroxysmal supraventricular tachycardia, ventricular tachycardia)

The recommended dose for infants over six months of age, toddlers, and children is 50-100 mg/m² (body surface area) [0.5-1 g/m² (body surface area) of fine granules] of flecainide acetate per day, taken orally and divided into two or three equally spaced doses. The recommended dose may be adjusted according to age and symptoms, however, the maximum recommended dose is 200 mg/m² per day [2 g/m² of fine granules].

The recommended dose for infants under six months of age is 50 mg/m² (body surface area) [0.5 g/m² (body surface area) of fine granules] of flecainide acetate per day, taken orally and divided into two or three equally spaced doses. The recommended dose may be adjusted according to age and symptoms, however, the maximum recommended dose is 200 mg/m² per day [2 g/m² of fine granules].