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Eisai Co., Ltd.

EISAI TO LAUNCH NEW FINE GRANULE FORMULATION OF TACHYARRHYTHMIA TREATMENT TAMBOCOR® SUITABLE FOR PEDIATRIC PATIENTS IN JAPAN

Eisai Co., Ltd. (Headquarters: Tokyo, CEO: Haruo Naito, "Eisai") announced today that it will launch Tambocor® Fine Granules 10%, a new formulation of anti-arrhythmic agent Tambocor (flecainide acetate), on June 29 in Japan. Eisai received marketing and manufacturing approval for this formulation on February 16, 2015, and the product was added to Japan's National Health Insurance drug price list on June 19 of the same year.

This product is a fine granule formulation that can be adjusted to account for age and body surface area for administration to pediatric patients, and can be administered to patients who have difficulty taking tablets. In addition, Eisai has made special efforts, such as reducing the bitterness, to make Tambocor Fine Granules easy to administer.

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, and was approved for the treatment of tachyarrhythmia (paroxysmal atrial fibrillation/flutter, paroxysmal supraventricular, ventricular) 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.

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 blocker Vasolan® Tablets 40 mg and Vasolan for intravenous injection 5 mg in May 2011. By providing the easy to measure and administer Tambocor Fine Granules 10% 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) Generic Name

Flecainide acetate

3) Indications, Dosage & Administration

• **Indications**

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

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

Pediatric patients: Tachyarrhythmia (paroxysmal atrial fibrillation/flutter, paroxysmal supraventricular, ventricular)

• **Dosage & Administration**

Adults:

• Tachyarrhythmia (paroxysmal atrial fibrillation/flutter)

The usual initial adult dose is 100 mg (1 g as fine granule) of flecainide acetate daily. If the effect is insufficient, the dose may be increased up to 200 mg (2 g as fine granule) daily, which should be administered in two divided doses. The dose may be reduced depending on the patient's age and symptoms.

• Tachyarrhythmia (ventricular)

The usual initial adult dose is 100 mg (1 g as fine granule) of flecainide acetate daily. If the effect is insufficient, the dose may be increased up to 200 mg (2 g as fine granule) daily, which should be administered in two divided doses. The dose may be adjusted depending on the patient's age and symptoms.

Pediatric patients:

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

The usual oral dosage for infants over 6 months old or over, toddlers, and children is 50-100 mg/m² (body surface area) [0.5-1 g/m² (body surface area) as fine granule] of flecainide acetate daily in two to three divided doses. The dose may be adjusted depending on the patient's age and symptoms. The maximum dose is 200 mg/m² per day [2 g/m² (body surface area) as fine granule] daily.

The usual oral dosage for infants under the age of 6 months is 50 mg/m² (body surface area) [0.5 g/m² (body surface area) as fine granule] of flecainide acetate daily in two to three divided doses. The dose may be adjusted depending on the patient's age and symptoms. The maximum dose is 200 mg/m² per day [2 g/m² (body surface area) as fine granule] daily.

4) Price

Tambocor Fine Granules 10%: 202.20 yen per 1 g containing 10% (package price: 10,110 yen)

5) Packaging

Bottles of 50 g

[Product photograph]

