

® TABLETS FOR TACHYARRHYTHMIA IN PEDIATRIC PATIENTS IN JAPAN

Eisai Co., Ltd. (Headquarters: Tokyo, President & CEO: Haruo Naito, "Eisai") announced today that the Company has received approval of an additional indication of anti-arrhythmic agent Tambocor® 50mg Tablets and Tambocor® 100mg Tablets (generic name: flecainide acetate) for the treatment of tachyarrhythmia (paroxysmal atrial fibrillation/flutter, paroxysmal supraventricular tachycardia, ventricular tachycardia) in pediatric patients in Japan.

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. As there are currently few anti-arrhythmic agents with limited indications approved for pediatric use in Japan, arrhythmia ha

[Notes to editors]

1. About Tambocor[®] Tablets (underlined parts indicate newly added information)

1) Product Name

Tambocor[®] Tablets 50mg, Tambocor[®] Tablets 100mg

2) Indications, Dosage & Administration

• **Indications**

Tambocor[®] Tablets are indicated for the treatment of the following conditions in patients who are unable to use or are unresponsive to other anti-arrhythmic drugs:

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 100mg of flecainide acetate per day, taken orally and divided into two equally spaced doses. The recommended dose may be increased to a maximum of 200mg 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 100mg of flecainide acetate per day, taken orally and divided into two equally spaced doses. The recommended dose may be increased to a maximum of 200mg 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 50-100mg/m²(body surface area) 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 200mg/ m² per day.

The recommended dose for infants under six months of age is 50mg/ m² (body surface area) 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 200mg/ m² per day.