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Eisai Co., Ltd.

EISAI RECEIVES APPROVAL FOR ADDITIONAL INDICATION OF ANTI-ARRHYTHMIC AGENT TAMBOCOR® 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 superventricular 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 has represented an area of unmet medical need in the pediatric care.

With Tambocor® already approved for the treatment of tachyarrhythmia in children in the United States, and its clinical usefulness widely reported in medical literature, the Japanese Ministry of Health, Labour and Welfare's Council for Pediatric Pharmacotherapy determined the need to make the drug available to treat pediatric patients in Japan. Tambocor® Tablets will provide a new drug treatment option to those patients who due to age or body size have difficulty using catheter treatments or who do not respond to currently marketed anti-arrhythmic drugs. Furthermore, Tambocor® will be the first drug in Japan to be indicated for the treatment of ventricular tachycardia in pediatric patients.

Tambocor® Tablets suppress tachyarrhythmia by blocking cardiac sodium channels and slowing down cardiac conduction. Approved and launched in Japan in 1991, the drug has up until now been indicated for the treatment of tachyarrhythmia in adults.

By offering Tambocor® Tablets as a new treatment option, Eisai will now be able to provide pediatric patients with tachyarrhythmia with an appropriate new drug therapy and will continue to make further contributions to address their needs.

[Please refer to the following notes for product information]

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[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 superventricular 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 superventricular tachycardia, ventricular tachycardia)

The recommended dose for infants over six months of age, toddlers, and children is 50-100mg/m^2(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/ m^2 per day.

The recommended dose for infants under six months of age is 50mg/ m^2 (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/ m^2 per day.