

Eisai is a Human Health Care Corporation striving for innovative solutions in prevention, cure and care for the health and well-being of people worldwide. We combine our talents to understand and meet the needs of patients and their families to enhance the quality of life.

FOR IMMEDIATE RELEASE No. 07-28 June 26, 2007

Eisai Co., Ltd.

# *Tambocor*<sup>®</sup> (Antiarrthymic Treatment) Received Approval for Paroxysmal Atrial Fibrillation/Flutter

Eisai Co., Ltd. (Headquarters: Tokyo, President & CEO: Haruo Naito) announced today that an additional indication for *Tambocor*<sup>®</sup> Tablets 50 mg /100 mg (generic name: flecainide acetate) for the treatment of paroxysmal atrial fibrillation/flutter received approval in Japan.

Paroxysmal atrial fibrillation/flutter is a condition associated with tachyarrhythmia. In paroxysmal atrial fibrillation, sudden episodes of abnormal impulses occur in the atria resulting in irregular heart beats, while in paroxysmal atrial flutter, the heartbeat is in a regular rhythm, but beats rapidly. This condition causes severe palpitation and the patients with paroxysmal atrial fibrillation/flutter are also at risk of cardioembolic stroke.

In Japan, it has been reported that the number of patients with paroxysmal atrial fibrillation/flutter is estimated to be greater than one million, and also the incidence increases in parallel with age. Since the patient population is estimated to increase annually, the medical need treatment will grow in the future.

 $Tambocor^{\text{®}}$  suppresses or prevents paroxysmal atrial fibrillation/flutter by blocking sodium channels. The effects of  $Tambocor^{\text{®}}$  can be sustained stably with a twice-daily administration.

Eisai received approval in Japan for *Tambocor*<sup>®</sup> for the indication of ventricular tachyarrhythmia in June, 1991. This approval, together with Eisai's other related products including *Warfarin*<sup>®</sup> (anticoagulant agent) and *Vasolan*<sup>®</sup> (calcium antagonistic antiarrthymic treatment which controls increased heart rate in paroxysmal atrial fibrillation/flutter), will enable Eisai to make further contributions to patients by offering treatment options for managing paroxysmal atrial fibrillation/flutter.

## [Please see the following notes for the glossary and approved product information]

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#### <Notes to Editor>

### Glossary

### Arrhythmia

Usually, a healthy adult has an average heart rate between 60 to 100 beat per minutes (BPM). This rate can increase/decrease due to some factors. An abnormal heart rate of more than 100 BPM is called "tachyarrhythmia" and a low rate below 50 BPM is called "bradyarrhythmia" (slow arrhythmia), whereas the appearance of the unstable pulse is called "extrasystole". In general, an abnormal pulse condition including these described above is referred to as an "arrhythmia".

## **Product Information**

- Product Name: *Tambocor*<sup>®</sup> Tablets 50 mg, *Tambocor*<sup>®</sup> Tablets 100 mg
- Applied Indication :

Treatment for tachyarrhythmia (paroxysmal atrial fibrillation/flutter and ventricular), in case other antiarrhythmic drugs cannot be used or are ineffective.

• Dosage and Administration :

For treatment of paroxysmal atrial fibrillation/flutter, the usual initial adult dose is 100 mg daily. If the effect is insufficient, the dose may be increased up to 200 mg, which should be administered in two divided doses daily. The dose may be adjusted up to 200 mg depending on the patient's age and symptoms.

For treatment of ventricular tachyarrhythmia, the usual initial adult dose is 100 mg daily. If the effect is insufficient, the dose may be increased up to 200 mg, which should be administered in two divided doses daily. The dose may be increased/decreased depending on the patient's age and symptoms.

## Date the additional indication (for paroxysmal atrial fibrillation/flutter) approved

June 21, 2007

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