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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

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Eisai Co., Ltd.

# Vasolan® (Ischaemic Heart Disease Treatment) Received Approval for Atrial Fibrillation/Flutter and Paroxysmal Supraventricular Tachycardia

Eisai Co., Ltd. (Headquarters: Tokyo, President & CEO: Haruo Naito) announced today that *Vasolan*<sup>®</sup> Tablets 40mg (generic name: verapamil hydrochloride) received approval for the additional indications of the treatment of atrial fibrillation/flutter and paroxysmal supraventricular tachycardia. This approval makes *Vasolan*<sup>®</sup> the first oral form of calcium channel blockers approved for the treatment of tachyarrhythmia in Japan.

Vasolan® is a calcium channel blocker with coronary/peripheral vasodilator actions. It has been used to treat ischaemic heart disease for more than forty years. For many years, Vasolan® has been used to treat arrhythmia in the U.S. and European countries because of its beneficially effects on heart rate control in artial fibrillation/flutter and stopping/preventing paroxysmal supraventricular tachycardia. In Japan, Vasolan® for intravenous injection 5mg that contains the same active ingredients as the oral form tablet has been approved for the treatment of tachyarrhythmia (paroxysmal atrial fibrillation/flutter and paroxysmal supraventricular tachycardia). The additional indications approved today for the oral form of Vasolan® will provide a wider range of treatment options for patients who are suffering from tachyarrhythmia.

Atrial fibrillation is the most common tachyarrhythmia. Its risk increases with age, and medical need to treat atrial fibrillation becomes more critical in Japan's aging society. There are three general strategies to treat atrial fibrillation: rate control, rhythm control, and prevention of thromboembolic events. *Vasolan*<sup>®</sup> Tablets 40mg is beneficial in rate control.

This approval, together with Eisai's other related products including  $Tambocor^{\otimes}$  for the indication of tachyarrhythmia and  $Warfarin^{\otimes}$  as an anticoagulant, will enable Eisai to make further contributions to patients by offering treatment options for managing atrial fibrillation.

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

# **Contacts:**

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#### <Notes to Editor>

## **Glossary**

## (1) Arrhythmia

Usually, a healthy adult has an average heart rate between 60 to 100 beats per minute (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 unexpected pulse is called "extrasystole". In general, abnormal pulse conditions including the ones these described above are referred to as "arrhythmia".

## (2) Atrial fibrillation/flutter

Atrial fibrillation occurs when rapid, disorganized electrical signals in the heart's two upper chambers, called the atria, cause them to contract very fast and irregularly. Atrial flutter is a condition where the top chambers of the heart beat much faster than they should. In both events, patients will suffer from rapid heart beat. There is an increased risk of cardiogenic cerebral embolism for the patient of atrial fibrillation/flutter.

## (3) Paroxysmal Supraventricular Tachycardia

Paroxysmal supraventricular tachycardia is a very fast heart rate, usually faster than 150 to 250 BPM. If this condition is prolonged, the rapid heart rate eventually may cause decreased blood pressure and cardiac failure.

#### **Product Information**

- Product Name: Vasolan® Tablets 40 mg
- Applied Indication:

Treatment for tachyarrhythmia (atrial fibrillation/flutter and paroxysmal supraventricular tachycardia), angina, cardiac infracts (excluding for the treatment of acute phase) and other ischaemic heart disease.

• Dosage and Administration :

For treatment of tachyarrhythmia (Atrial Fibrillation/Flutter and Paroxysmal Supraventricular Tachycardia), the usual adult dose is 40 ~ 80 mg of verapamil hydrochloride, 3 times daily The dose may be decreased depending on the patient's age and symptoms.

For treatment of angina, cardiac infracts (excluding for the treatment of acute phase) and other ischaemic heart disease, the usual adult dose is  $40 \sim 80$  mg of verapamil hydrochloride, 3 times daily. The dose may be increased/decreased depending on the patient's age and symptoms.

Date the additional indication (for Atrial Fibrillation/Flutter and Paroxysmal Supraventricular Tachycardia) approved

February 29, 2008

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