

PRESS RELEASE

Toa Eiyo Ltd.
Astellas Pharma Inc.

Approval in Japan for Bisono® Tape, Transdermal Patch of β_1 Blocker for The First Time in The World

Tokyo: June 28, 2013 – Toa Eiyo Ltd. (Tokyo; Unlisted; “Toa Eiyo”) and Astellas Pharma Inc. (Tokyo: 4503; “Astellas”) announced today that Toa Eiyo has obtained the marketing approval for Bisono® Tape 4mg and Bisono® Tape 8mg (collectively “Bisono® Tape”; nonproprietary name: bisoprolol), a transdermal patch of β_1 blocker for the first time in the world.

Bisono® Tape was co-developed by Toa Eiyo and Nitto Denko Corporation. Toa Eiyo is the marketing approval holder, Astellas will distribute and sell the product, and both companies will promote it.

Bisono® Tape is a transdermal hypertension medication which contains 4 mg or 8 mg of bisoprolol, a β_1 selective blocking agent, which can be applied to the chest, brachial or dorsal regions once per day and changed every 24 hours.

Bisono® Tape has the following characteristics:

- Bisono® Tape maintains a stable antihypertensive effect for long periods through once-daily administration over a period of 24 hours;
- Bisono® Tape can be administered to patients with essential hypertension when oral administration is not feasible; and
- Bisono® Tape is highly visible, reducing the risk of missed or excessive dose, thus expected to improve medication adherence.

The Phase III clinical trials in Japan revealed the sufficient continuous antihypertensive effects over a period of 24 hour in Japanese mild to moderate essential hypertensive patients. In terms of safety, frequencies of side effects observed were similar to those reported for other orally administered β blocking agents’ medication, excluding those on the applied region.

Currently, there are anticipated to be a wide variety of the pathogenesis in about 40 million Japanese people suffering from hypertension, and thus it is recommended that the treatment should be given on an individual basis using a suitable antihypertension medication either alone or combination. Bisono® Tape, a unique patch, is expected to contribute the treatment of hypertension for patients having difficulties with oral administration (including dysphagia), and improvement of medication adherence.

Attachments: Summary of Approval

For inquiries or additional information Astellas Pharma Inc. Corporate Communications TEL: +81-3-3244-3201 http://www.astellas.com/en/
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Summary of Approval

Bisono® Tape 4mg

Bisono® Tape 8mg

Product Name: Bisono® Tape 4mg and Bisono® Tape 8mg

Nonproprietary Name: Bisoprolol

Approval Date: June 28, 2013

NHI Drug Price Standard: Unlisted

Composition:

Product Name	Bisono® Tape 4mg	Bisono® Tape 8mg
Content of Active Substance (per patch)	Bisoprolol 4 mg	Bisoprolol 8 mg
Inactive Substances	Polyisobutylene, isopropyl myristate, alicyclic saturated hydrocarbon	

Formulation: Transdermal patch

Indication: Essential Hypertension (mild to moderate cases)

Dosage Regimen: Under normal conditions, adult dosage of bisoprolol is 8 mg dose, once daily, applied to the chest, brachial or dorsal regions and changed every 24 hours. Depending on age and or symptoms, administration is to be commenced at 4 mg once daily, with a total dosage of no more than 8 mg per one day.

Packaging: Bisono® Tape 4mg: 70 patches ((1 patch × 7) × 10)

Bisono® Tape 8mg: 70 patches ((1 patch × 7) × 10)

Marketing approval holder: Toa Eiyo Ltd.

Distributor/Seller: Astellas Pharma Inc.