

June 7, 2019

Press Release

TOA EIYO Ltd.
Astellas Pharma Inc.**Bisono[®] Tape 2 mg, a Transdermal Patch of β_1 Blocker, Launched in Japan**

Tokyo: June 7, 2019 - TOA EIYO Ltd. (President: Atsuo Takahashi, Ph.D., "TOA EIYO") and Astellas Pharma Inc. (TSE: 4503, President and CEO: Kenji Yasukawa, Ph.D., "Astellas") announced today that Bisono[®] Tape 2 mg (non-proprietary name: bisoprolol), a transdermal patch containing a β_1 blocker has been launched in Japan. The patch is a new strength of Bisono[®] Tape intended for flexible dose-adjustment in atrial fibrillation treatment.

Bisono[®] Tape was co-developed by TOA EIYO and Nitto Denko Corporation (TSE: 6988, President and CEO: Hideo Takasaki). Bisono[®] Tape 4 mg and Bisono[®] Tape 8 mg were launched in September, 2013 in Japan as the world's first transdermal medication for essential hypertension (mild to moderate cases) containing 4 mg and 8 mg of bisoprolol, a β_1 blocking agent, respectively. In January 2019, the Bisono[®] Tape 4 mg and 8 mg were approved in Japan for the new indication of atrial fibrillation, and the new strength, Bisono[®] Tape 2 mg received approval for atrial fibrillation as well. Furthermore, the formulations for Bisono[®] Tape 4 mg and Bisono[®] Tape 8 mg were improved to increase adhesive strength for better water resistance.

Through the additional launch of Bisono[®] Tape 2 mg, TOA EIYO and Astellas expect that Bisono[®] Tape will further contribute to improvement in medication adherence and in treatment of patients suffering from atrial fibrillation who have difficulties in swallowing oral medication.

Approved indications for each strength of Bisono[®] Tape:

Indications	Bisono [®] Tape 2 mg	Bisono [®] Tape 4 mg	Bisono [®] Tape 8 mg
Essential hypertension (mild to moderate cases)	-	○	○
Atrial fibrillation	○	○	○

○: Approved -: Not available

Product profile of Bisono® Tape 2 mg

Brand name	Bisono® Tape 2 mg
non-proprietary name	Bisoprolol
Indication	Atrial fibrillation
Dosage and administration	A bisoprolol tape 2 mg is, for adults, attached to the skin on the chest, the upper arm or the back, and is replaced by a new tape every 24 hours. The usual starting dose for bisoprolol is 4 mg and the dose may suitably be adjusted according to patient's age or symptoms. The maximum daily dose should not exceed 8 mg.
NHI drug price	JPY 59.40/patch
Marketing approval	January 8, 2019
Listed in NHI drug price list	May 29, 2019
Launch	June 7, 2019

Product image



About TOA EIYO

TOA EIYO Ltd., based in Tokyo, Japan, is a company dedicated to contributing to the health of people through unique medicines primarily in the cardiovascular fields. TOA EIYO aims to be a specialized pharmaceutical company that is truly indispensable to the medical front lines via our research and development of new medicines and value-added generic drugs in the cardiovascular fields including ischemic heart disease, arrhythmia and heart failure, and other related fields. For more information, please visit our website at <https://www.toaeiyo.co.jp/english/>

About Astellas

Astellas Pharma Inc., based in Tokyo, Japan, is a company dedicated to improving the health of people around the world through the provision of innovative and reliable pharmaceutical products. For more information, please visit our website at <https://www.astellas.com/en/>

Cautionary Notes(Astellas)

In this press release, statements made with respect to current plans, estimates, strategies and beliefs and other statements that are not historical facts are forward-looking statements about the future performance of Astellas. These statements are based on management's current

assumptions and beliefs in light of the information currently available to it and involve known and unknown risks and uncertainties. A number of factors could cause actual results to differ materially from those discussed in the forward-looking statements. Such factors include, but are not limited to: (i) changes in general economic conditions and in laws and regulations, relating to pharmaceutical markets, (ii) currency exchange rate fluctuations, (iii) delays in new product launches, (iv) the inability of Astellas to market existing and new products effectively, (v) the inability of Astellas to continue to effectively research and develop products accepted by customers in highly competitive markets, and (vi) infringements of Astellas' intellectual property rights by third parties. Information about pharmaceutical products (including products currently in development) which is included in this press release is not intended to constitute an advertisement or medical advice.

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