January 8, 2019

Press Release

Toa Eiyo Ltd.
Astellas Pharma Inc.

Additional Approvals for Bisono® Tape, a Transdermal Patch containing a β1 Blocker, for Atrial Fibrillation, for a 2 mg strength and for improved formulations of 4 mg and 8 mg strengths in Japan

Tokyo: January 8, 2019 - Toa Eiyo Ltd. (President: Atsuo Takahashi, Ph.D., "Toa Eiyo") and Astellas Pharma Inc. (TSE: 4503, President and CEO: Kenji Yasukawa, Ph.D.) announced today that Toa Eiyo received approvals for Bisono® Tape 2 mg, Bisono® Tape 4 mg and Bisono® Tape 8 mg (collectively, "Bisono® Tape", non-proprietary name: bisoprolol), transdermal patches containing a β_1 blocker, in Japan for the new indication of atrial fibrillation. These approvals cover a marketing approval for the new 2 mg strength intended for therapeutic dose reduction, as well as approvals for improved formulations of Bisono® Tape 4 mg and Bisono® Tape 8 mg to achieve functional improvements including water resistance.

Bisono® Tape was co-developed by Toa Eiyo and Nitto Denko Corporation (TSE: 6988, President and CEO: Hideo Takasaki, "Nitto"). 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.

Since Bisono® Tape has been expected to show clinically significant efficacy for the control of heart rate in patients suffering from atrial fibrillation as based on recommendation in a pharmacotherapy guideline* for administration of the β blocking agent as well as to ease the treatment of patients with swallowing difficulties, the development was conducted to obtain approval for this new indication of atrial fibrillation. Furthermore, to realize a therapeutic dose reduction, a new strength, Bisono® Tape 2 mg, was co-developed by Toa Eiyo and Nitto. The Bisono® Tape 2 mg will be launched following listing in the National Health Insurance drug price list in Japan.

Moreover, the formulations for Bisono® Tape 4 mg and Bisono® Tape 8 mg were improved to increase water resistence and to prevent reduction of adhesiveness due to reasons such as sweating at the site of application.

These additional approvals will provide new treatment options for patients suffering from essential hypertension or atrial fibrillation, who have difficulties in swallowing oral medication, and are expected to contribute to improvement in medication adherence and thereby supporting treatment continuation for this group of patients.

*Group JCSJW. Guidelines for Pharmacotherapy of Atrial Fibrillation (JCS 2013). Circulation Journal : official journal of the Japanese Circulation Society. 2014;78(8):1997-2021.

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 ishchemic heart disease, arrthythmia 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

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.

Contacts for inquiries or additional information

TOA EIYO LTD.
General Affairs Section
TEL：+81-3-5542-8800
FAX：+81-3-5542-8743

Astellas Pharma Inc.
Corporatate Communications
TEL：+81-3-3244-3201
FAX：+81-3-5201-7473