



September 28, 2016

Press Release

Nippon Boehringer Ingelheim Co., Ltd.
Astellas Pharma Inc.

Approval for Manufacturing and Marketing of “Micatrio[®]

Combination Tablets,” an Antihypertensive Drug

Japan’s first ARB/CCB/diuretic three ingredients combination

Nippon Boehringer Ingelheim Co., Ltd. (Head Office: Tokyo; President and Representative Director: Yoshiaki Aono, hereafter “Nippon Boehringer Ingelheim”) and Astellas Pharma Inc. (Head Office: Tokyo; President and CEO: Yoshihiko Hatanaka, hereafter “Astellas”) announced that manufacturing and marketing approval for “Micatrio[®] Combination Tablets,” a combination of “Micardis[®] Tablets” (AT1 receptor blocker [ARB]), long-acting calcium channel blocker (CCB) amlodipine besylate and the thiazide diuretic hydrochlorothiazide (HCTZ) was obtained on September 28.

“Micatrio[®] Combination Tablets” is the first combination drug in Japan to contain the three ingredients of a renin-angiotensin inhibitor, a CCB and small dose diuretic. Compared to ARB/CCB combination formulations and ARB/HCTZ combination formulations, it is expected to have a strong antihypertensive effect that lasts for 24 hours. In addition, hypertension is a major risk factor for cardiovascular death, yet the rate of the patient undergoing treatment and keeping their blood pressure under control remains at approximately 30% for men and approximately 40% for women. By increasing the medication adherence, a combination drug in general has a superior antihypertensive effect to the concomitant use of the respective drugs alone, and is expected to improve the rate to achieve target blood pressure values.¹

“Micatrio[®] Combination Tablets” which obtained manufacturing and marketing approval, constitute the Micardis[®] family along with “Micardis[®] 20mg/40mg/80mg Tablets”, “Micombi[®] Combination Tablets AP/BP”, a combination drug with HCTZ and “Micamlo[®] Combination Tablets AP/BP,” a combination drug with the long-acting CCB amlodipine besylate.

“Micatrio[®] Combination Tablets,” like the other telmisartan formulations, will be manufactured by Nippon Boehringer Ingelheim, distributed by Astellas and co-promoted by both companies. Nippon Boehringer Ingelheim and Astellas remain committed to further contribute to hypertension treatment through the Micardis family.

Product overview

Date of Approval: September 28, 2016

Brand Name: Micatrio[®] Combination Tablets

Generic Name: Telmisartan/amlodipine besylate/hydrochlorothiazide

Dosage Form/Content: Film-coated tablet containing 80 mg, 5 mg and 12.5 mg of telmisartan, amlodipine, and hydrochlorothiazide per tablet, respectively

Indication: Hypertension

Precautions with related to indication

Since patients may experience hypotension, this fixed dose combination is not indicated for initial therapy of hypertension.

Dosage and Administration: For adults, one tablet (80 mg/ 5 mg/ 12.5 mg of telmisartan/ amlodipine/ hydrochlorothiazide) to be administered orally once daily. This drug is not to be used as a first-line drug in the treatment of hypertension.

Precautions with related to dosage and administration

In principle, switching to Micatrio[®] Combination Tablet should be considered in patients who are receiving both telmisartan 80 mg, amlodipine 5mg and hydrochlorothiazide 12.5 mg for a certain period continuously with same dosage and administration and have maintained stable blood pressure control.

For Reference

About Telmisartan

Telmisartan is a drug that was discovered and developed by Boehringer Ingelheim, and it has been approved in over 100 countries including Japan, the US, and Europe. In Japan, telmisartan is available as Micardis[®] Tablets 20 mg / 40 mg / 80 mg, Micombi[®] Combination Tablets AP/BP, a combination drug with HCTZ, and Micamlo[®] Combination Tablets AP/BP, a combination drug with the long-acting CCB amlodipine besilate. These drugs comprise the Micardis[®] family of products including Micatrio. They are number one in terms of sales in the ARB family in Japan². In ONTARGET³, the largest ARB clinical study published in 2008, it was reported to have effectiveness for suppressing cardiovascular events equivalent to ACE inhibitor Ramipril (unapproved in Japan).

About Nippon Boehringer Ingelheim

Boehringer Ingelheim is one of the world's 20 leading pharmaceutical companies. Headquartered in Ingelheim, Germany, Boehringer Ingelheim operates globally through 145 affiliates and a total of some 47,500 employees. The focus of the family-owned company, founded in 1885, is on researching, developing, manufacturing and marketing new medications of high therapeutic value for human and veterinary medicine. In 2015, Boehringer Ingelheim achieved net sales of about 14.8 billion euros. R&D expenditure corresponds to 20.3 per cent of net sales.

As a holding company, Boehringer Ingelheim Japan, Inc. manages four business segments under the following companies: Nippon Boehringer Ingelheim Co., Ltd. (prescription medicine), SSP CO., LTD. (Consumer Health Care), Boehringer Ingelheim Vetmedica Japan (veterinary medicines), and Boehringer Ingelheim Seiyaku (manufacture of pharmaceutical products).

Nippon Boehringer Ingelheim Co., Ltd. provides effective pharmaceutical products in Japan in the areas of cardiovascular, respiratory, diabetes, oncology and the central nervous system, amongst others.

For further information, please visit our website at

<http://www.boehringer-ingelheim.com/> (Boehringer Ingelheim)

<http://www.boehringer-ingelheim.co.jp/> (Boehringer Ingelheim Japan)

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. We focus on Urology, Oncology, Immunology, Nephrology and Neuroscience as prioritized therapeutic areas while advancing new therapeutic areas and discovery research leveraging new technologies/modalities. We are also creating new value by combining internal capabilities and external expertise in the medical/healthcare business. Astellas is on the forefront of healthcare change to turn innovative science into value for patients. For more information, please visit our website at 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.

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References

1. JSH guideline 2014
2. ©2016 IMSHealth JPM August 2016 MAT
3. The ONTARGET Investigators: N Engl J Med 2008; 358(15): 1547-1559
4. Circulation. 2000;102:1503-1510

Company Profile

◇ **Nippon Boehringer Ingelheim Co., Ltd.** (www.boehringer-ingelheim.jp)

Established: June 1961

Location of the Head Office:

ThinkPark Tower, 2-1-1 Osaki, Shinagawa-ku, Tokyo

Representative: President and Representative Director Yoshiaki Aono

Sales: 256.0 billion JPY (January-December 2015)

No. of employees: 1,916 (as of December 31, 2015)

Description of business: Research and development, import, manufacture and sale of drugs

Import/export and sale of active pharmaceutical ingredients and intermediates

◇ **Boehringer Ingelheim GmbH** (www.boehringer-ingelheim.com)

Established: 1885

Location: Ingelheim, Federal Republic of Germany

Representative: Chairman of the Board of Managing Directors Hubertus von Baumbach

Sales (consolidated): 14.8 billion euros (January-December 2015)

No. of employees (consolidated): Approximately 47,500

Description of business: Research/development, manufacture and sale of ethical drugs, consumer healthcare products, animal drugs, biopharmaceuticals and chemical products, etc.

Affiliated companies: 145 worldwide

◇ **Astellas Pharma Inc.** (www.astellas.com/jp)

Month/Year of launch: April 2005

Location of the Head Office:

2-5-1 Nihonbashi Honcho, Chuo-ku, Tokyo

Representative: President and Representative Director Yoshihiko Hatanaka

Sales (consolidated): 1,247.3 billion JPY (FY2015:April 1, 2014-March 31,2015)

No. of employees (consolidated): 17,113 (As of March 31, 2015)

Description of business: Manufacturing, marketing and import/export of pharmaceuticals