



5 October 2010

## Press Release

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

### **Micamlo<sup>®</sup> Combination Tablets AP (new product) and Micardis<sup>®</sup> Tablets 80 mg are launched on 7 October**

-Offer new options for effective antihypertensive treatment-

Nippon Boehringer Ingelheim Co., Ltd. (Headquarters: Shinagawa-ku, Tokyo; Chairman & President: Dr. Thomas Heil) and Astellas Pharma Inc. (Headquarters: Chuo-ku, Tokyo; President & CEO: Masafumi Nogimori) have announced that the sale of Micamlo<sup>®</sup> Combination Tablets AP, a combination drug of telmisartan (Brand Name: Micardis<sup>®</sup>), an angiotensin II receptor blocker (ARB) and amlodipine besylate, a calcium channel blocker (CCB) is scheduled to commence on 7 October.

Micamlo<sup>®</sup> Combination Tablets AP is a combination drug of Telmisartan 40 mg Tablets and CCB amlodipine 5 mg whose strong antihypertensive effect last for 24 hours with an equally strong and sustained antihypertensive effect, together offering remarkably strong 24 hour sustained antihypertensive effects.

In a Phase III clinical study conducted in Japan with subjects not having achieved blood pressure control targets with amlodipine 5 mg, Micamlo<sup>®</sup> Combination Tablets AP demonstrated an extremely strong antihypertensive effect, lowering systolic blood pressure by -27 mmHg through administration of Micamlo<sup>®</sup> Combination Tablets AP for 8 weeks after administration of amlodipine 5mg for 6 weeks. The stably sustained 24-hour antihypertensive effect of the drug was confirmed in a overseas clinical trial using ABPM (ambulatory blood pressure monitoring)<sup>1</sup>. Moreover, Micamlo<sup>®</sup> Combination Tablets AP obtained an extremely high responder rate\* of 95.3% in a long-term study in Japan (Week 8 after administration at the end of treatment stage I).

\* Responder rate : Percentage of subjects with a cumulative lowering of systolic blood pressure below 140 mmHg or by 20 mmHg or more

Professor Jitsuo Higaki of the Department of Integrated Medicine and Informatics, Ehime University Graduate School of Medicine, who initiated the Japanese clinical trial of Micamlo<sup>®</sup> Combination Tablets (telmisartan/amlodipine) explains: "Micardis<sup>®</sup> contained in Micamlo<sup>®</sup> Combination Tablets is a second-generation ARB that has a strong AT1 receptor blocker effect and selective PPAR $\gamma$  activation effect. Since it not only demonstrates an excellent antihypertensive effect but also brings about positive effects on metabolism and obesity including insulin resistance improvement, it is called a 'metabolic sartan.' For this reason, Micardis<sup>®</sup> is considered the first choice in blood pressure control for antihypertensive patients also suffering from the metabolic syndrome."

Professor Higaki adds: "The landmark ONTARGET investigation of the ARB published in 2008 demonstrated the excellent preventive effect of Micardis<sup>®</sup> of cardiovascular events. We expect much from Micamlo<sup>®</sup> Combination Tablets, which contains both Micardis and CCB amlodipine, which is the drug most prescribed in the world for its equally strong proven preventive effect of cardiovascular events. Micamlo<sup>®</sup> will offer a new solution to strict blood pressure control for the ultimate goal of preventing cardiovascular events."

In addition, Micardis<sup>®</sup> Tablets 80 mg, a new dosage form of telmisartan is also scheduled to commence on 7 October. With Micamlo<sup>®</sup> and Micardis<sup>®</sup> 80 mg, Micardis<sup>®</sup> family can offer new options for effective antihypertensive treatment. Nippon Boehringer Ingelheim Co., Ltd. and Astellas Pharma Inc. remain committed to continuously maximizing the value of the Micardis<sup>®</sup> family products and contributing to hypertension treatment.

**Micamlo<sup>®</sup> Combination Tablets AP outline:**

- Date of Approval: 23 July 2010
- Date of Drug Price Listing: 17 September 2010
- Date of Sales Commencement: 7 October 2010
- Product Name: Micamlo<sup>®</sup> Combination Tablets AP
- Generic Name: telmisartan/amlodipine besylate
- Ingredients/Content:
  - Micamlo<sup>®</sup> Combination Tablet AP: telmisartan 40 mg and amlodipine besylate 6.93 mg (5 mg as amlodipine)
- Indication: Hypertension
- Use/Dose: Adults - 1 tablet once daily taken orally (as telmisartan/amlodipine 40 mg/5 mg).
  - This drug is not to be used as the first-line drug for antihypertensive treatment.
- Drug Price: Micamlo<sup>®</sup> Combination Tablets AP 143.80 yen

**Micardis<sup>®</sup> 80 mg Tablets outline:**

- Date of Approval: 9 June 2010
- Date of Drug Price Listing: 24 September 2010
- Date of Sales Commencement: 7 October 2010
- Product Name: Micardis® 80 mg Tablets
- Generic Name: telmisartan
- Ingredients/Content:
  - Micardis® 80 mg Tablet: telmisartan 80 mg
- Indication: Hypertension
- Use/Dose: Usually for Adults - 40 mg telmisartan once daily taken orally. Administration should start at 20 mg per day and be titrated upward. Dosage may vary depending on age and symptoms but should not exceed 80 mg per day.
- Drug Price: Micardis® 80 mg Tablets 213.60 yen

**About telmisartan:**

Telmisartan, discovered and developed by Boehringer Ingelheim, is a drug marketed in some 100 countries around the world including Japan, USA and European countries. In Japan, the telmisartan drugs Micardis® Tablets, Micombi® Combination Tablets and Micamlo® Combination Tablets are all manufactured by Boehringer Ingelheim, distributed by Astellas, and co-promoted by the two companies. In Japan, all these drugs are indicated for hypertension.

**Reference:**

1. White WB. et al: Blood Pressure Monitoring 2010; 15: 205-212

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## Company Outlines

◇ **Nippon Boehringer Ingelheim Co., Ltd.**([www.boehringer-ingelheim.co.jp](http://www.boehringer-ingelheim.co.jp))

Established:	June 1961
Headquarters:	ThinkPark Tower, 2-1-1 Osaki, Shinagawa-ku, Tokyo
Representative:	Dr. Thomas Heil, Chairman & President
Sales:	161,482 million yen (January – December 2009)
Number of employees:	1,736 (as of 31 December 2009)
Business activities:	<ul style="list-style-type: none"><li>• Research &amp; development, import, manufacturing, and marketing of pharmaceuticals</li><li>• Import/export and marketing of pharmaceutical active ingredients and intermediates</li></ul>

◇ **Boehringer Ingelheim GmbH** ([www.boehringer-ingelheim.com](http://www.boehringer-ingelheim.com))

Established:	1885
Location:	Ingelheim, Federal Republic of Germany
Representative:	Dr. Andreas Barner, Chairman of the Board
Sales (consolidated)	12,700 million euros (January – December 2009)
Number of employees (consolidated):	Approximately 41,500
Business activities:	Research & development, manufacturing and marketing of prescription medicines, consumer health care products, veterinary medicine, biopharmaceuticals, and chemicals
Affiliated companies:	142 in 50 countries around the world

□ **Astellas Pharma Inc.** ([www.astellas.com/jp](http://www.astellas.com/jp))

Incorporated:	April 2005
Headquarters:	2-3-11 Nihonbashi-Honcho, Chuo-ku, Tokyo
Representative:	Masafumi Nogimori, President & CEO
Sales (consolidated):	974.8 billion yen (for year ending March 2010)
Number of employees (consolidated):	15,161 (as of 31 March 2010)
Business activities:	Manufacturing, marketing and import/export of pharmaceuticals