



17 September 2010

Press Release

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

Micamlo[®] Combination Tablets AP Drug Price Listing **- Strong and sustained antihypertensive treatment with the combination drug of** **long-lasting telmisartan and amlodipine -**

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 the drug price listing of Micamlo[®] Combination Tablets AP, a combination drug of telmisartan (Brand name:「Micardis」), an angiotensin II (AT1)receptor blocker (ARB) and amlodipine besylate, a calcium channel blocker (CCB) on 17 September. The sale of the new drug is scheduled to commence on 7 October.

Hypertension Treatment Guidelines (JSH 2009) indicates strict blood pressure control targets set for the purpose of preventing stroke, myocardial infarction and other cardiovascular diseases. In reality, however, survey results show that some 60% of patients of hypertension have yet to achieve their targets, suggesting the need for even stricter blood pressure control¹.

Micamlo[®] 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 effects².

In a Phase III clinical study conducted in Japan with subjects not having achieved blood pressure control targets with amlodipine 5 mg, Micamlo[®] Combination Tablets AP demonstrated an extremely strong antihypertensive effect, lowering cumulatively systolic blood pressure by -27 mmHg through administration of Micamlo[®] 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)².

Moreover, Micamlo[®] 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

With the existing telmisartan drug, Micardis[®] Tablets, and Micombi[®] Combination Tablets, a combination drug of telmisartan and hydrochlorothiazide (HCTZ) diuretic of the thiazide class, Micamlo[®] Combination Tablets AP constitute Micardis[®] family. As in the previous cases, the new drug will be manufactured by Nippon Boehringer Ingelheim, distributed by Astellas, and co-promoted by the two companies. Both companies remain committed to continuously maximizing the value of the Micardis[®] family products and contributing to hypertension treatment.

Micamlo[®] 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[®] Combination Tablets AP
- Generic Name: telmisartan/amlodipine besylate
- Ingredients/Content:
 - Micamlo[®] 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[®] Combination Tablets AP 143.80 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. Telmisartan demonstrates an excellent antihypertensive effect with its strong AT1 receptor blocker effect³ and selective PPAR γ activation effect⁴. Moreover, it is expected to play an active role in the treatment of hypertension of the metabolic syndrome as a metabolic sartan that brings about positive effects on metabolism including insulin resistance improvement⁵. The landmark ONTARGET trial published in 2008 verified the preventive effect of cardiovascular events of telmisartan as strong as that of ACE inhibitors⁶.

References

- ¹ Obara T, et al: Isolated uncontrolled hypertension at home and in the office among treated hypertensive patients from the J-HOME study: J Hypertens 2005; 23: 1653-1660
- ² White WB. et al: Blood Pressure Monitoring 2010; 15 : 205-212
- ³ Kakuta, H. et al: Int J Clin Pharmacol Res 2005; 25(1): 41-46
- ⁴ Benson SC, et al: Hypertension 2004; 43: 993-1002
- ⁵ 森下 竜一: Pharma Medica 2010; 28(4): 119-125
- ⁶ The ONTARGET Investigators: N Engl J Med 2008; 358: 1547-1559

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Company Outlines

◇ **Nippon Boehringer Ingelheim Co., Ltd.**(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">• Research & development, import, manufacturing, and marketing of pharmaceuticals• Import/export and marketing of pharmaceutical active ingredients and intermediates

◇ **Boehringer Ingelheim GmbH** (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)

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