



23 July 2010

Press Release

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

**Approval for Micamlo Combination Tablets AP Manufacturing and Distribution
- A combination drug of telmisartan, an angiotensin II receptor blocker and
amlodipine besylate, a calcium channel blocker with equally powerful hypertensive
effects lasting for 24 hours -**

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 on (23) they obtained approval for manufacturing and distributing Micamlo Combination Tablets AP, a combination drug of telmisartan (Micardis), an angiotensin II receptor blocker (ARB) and amlodipine besylate, a calcium channel blocker (CCB).

Micamlo Combination Tablets AP is a combination drug of Micardis 40 mg Tablets, whose strong antihypertensive effect lasts for 24 hours, and CCB amlodipine 5 mg, 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 Combination Tablets AP demonstrated an extremely strong antihypertensive effect, lowering systolic blood pressure by -27 mmHg from the baseline (8 weeks post dose). The stably sustained 24-hour antihypertensive effect of the drug was confirmed in a study using ABPM (ambulatory blood pressure monitoring)¹.

Moreover, Micamlo Combination Tablets AP obtained an extremely high responder rate* of 95.3% in a long-term study in Japan (Week 8 at the end of treatment stage I).

*Percentage of subjects with a lowering of systolic blood pressure below 140 mmHg or by 20 mmHg or more from the baseline

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. They remain committed to continuously maximizing the value of the Micardis[®] family products and contributing to hypertension treatment.

The following is a summary of the product:

- Date of Approval: 23/7/2010
- 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 40mg/5mg).

This drug is not to be used as the first-line drug for antihypertensive treatment.

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 effect² and selective PPAR γ activation effect³. 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 improvement⁴. The landmark ONTARGET trial published in 2008 verified the preventive effect of cardiovascular events of telmisartan as strong as that of ACE inhibitors⁵.

References

1. White WB. et al: Blood Pressure Monitoring 2010(in press)
2. Kakuta, H. et al.: Int J Clin Pharmacol Res 2005; 25(1): 41-46
3. Benson SC, et al.: Hypertension 2004; 43: 993-1002
4. Morishita, R: Pharma Medica 2010; 28(4)
5. The ONTARGET Investigators: N Engl J Med 358: 1547-1559, 2008

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Company Outlines

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