22 April 2009

Press Release

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

MICOMBI® Combination Tablets approved for manufacturing and marketing
-Telmisartan and HCTZ combination demonstrates potent hypertension reduction-

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) announced today that on 22 April the approval of manufacture and marketing of Micombi® Combination Tablets was obtained. Micombi® is a combination drug of telmisartan, an angiotensin II receptor blocker (ARB), and hydrochlorothiazide (HCTZ), a diuretic of the thiazide class. Micombi® Combination Tablets will be manufactured by Nippon Boehringer Ingelheim, distributed by Astellas Pharma, and co-promoted by both companies as are the telmisartan drug Micardis® Tablets.

Micombi® Combination Tablets are available in two formulations, "Micombi® Combination Tablets AP," containing telmisartan 40 mg and hydrochlorothiazide 12.5 mg and "Micombi® Combination Tablets BP," containing telmisartan 80mg and hydrochlorothiazide 12.5 mg.

In a Japanese clinical trial, Micombi® Combination Tablets AP demonstrated a very strong antihypertensive effect, lowering systolic blood pressure by -23.3 mmHg from baseline at the end of the trial.[1] Micombi® Combination Tablets offer a very strong antihypertensive effect by a convenient single dose administration which is expected to contribute to improving medication adherence.[2]

The following is a summary of the approved product:

- Date of Approval: 22 April 2009
- Product Name: Micombi® Combination Tablets AP, Micombi® Combination Tablets BP
- Generic Name: telmisartan/hydrochlorothiazide
- Ingredients/Content:

  Micombi® Combination Tablets AP: telmisartan 40 mg and hydrochlorothiazide 12.5 mg.
  Micombi® Combination Tablets BP: telmisartan 80 mg and hydrochlorothiazide 12.5 mg.

- Indication: Hypertension
- Use/Dose: Adults - 1 tablet once daily taken orally (as telmisartan/hydrochlorothiazide either 40 mg/12.5 mg or 80 mg/12.5 mg). This drug is not to be used as the first-line drug for antihypertensive treatment.

About telmisartan

Telmisartan is a member of the angiotensin II receptor blocker (ARB)* class and is undergoing many clinical studies for the verification of its efficacy. A single agent Telmisartan is marketed as Micardis®, while Micombi® is to join the line-up as a combination drug. Landmark clinical trial programmes including ONTARGET®[4] and PRoFESS®[5] have been conducted, enrolling a total of 58,000 subjects or more for investigation of the efficacy of Telmisartan in preventing cardiovascular events. These landmark trials proved the favourable profile of Telmisartan in preventing cardiovascular events.

*Angiotensin II receptor blocker: antihypertensive treatment drug that selectively blocks the angiotensin II AT_1 receptor. The blockade is thought to cause vasodilation and prevent cell proliferation.

Telmisartan was discovered and developed by Boehringer Ingelheim. The company markets telmisartan in nearly 100 countries, including USA, Japan and European countries. Telmisartan drug Micardis® Tablets are manufactured by Nippon Boehringer Ingelheim, distributed by Astellas Pharma, and co-promoted by both companies in Japan. Micombi® Combination Tablets are planned to be introduced to the Japanese market by both companies in the same way. Both Micardis® Tablets and Micombi® Combination Tablets are indicated for hypertension in Japan.

References

1. Data on file
2. Guidelines for the Management of Hypertension JSH2009
3. The ONTARGET Investigators: Telmisartan, Ramipril, or Both in Patients at High Risk for Vascular Events. New Eng J Med: 358 (15): 1547, 2008
4. The PRoFESS group: N Eng J Med 359: 1225-1237, 2008

Contacts

Nippon Boehringer Ingelheim Co., Ltd. External Communications Group, Communications Dept. Tel: +81-3-6417-2145 Fax: +81-3-5435-2926	Astellas Pharma Inc. Corporate Communications Tel: +81-3-3244-3201 Fax: +81-3-5201-7473