



Press Release

3 July 2006

Application for approval of additional indication for type 2 diabetic nephropathy for “Micardis[®]”, Angiotensin II receptor blocker, is filed

Nippon Boehringer Ingelheim Co., Ltd. (Headquarters: Kawanishi, Hyogo; President: Akio Ohsawa) and Astellas Pharma Inc. (Headquarters: Chuo-ku, Tokyo; President: Masafumi Nogimori) announced today that Nippon Boehringer Ingelheim filed on June 30 an application for an approval of additional indication for type 2 diabetic nephropathy for “Micardis[®],” an angiotensin II receptor blocker. Micardis[®], in Japan, is co-promoted by Nippon Boehringer Ingelheim and Astellas, manufactured by Nippon Boehringer Ingelheim and distributed by Astellas.

A clinical study “INNOVATION*”, based on which this application was made, is a large-scale study to evaluate the inhibitory effect of “Micardis[®]” on progression of type 2 diabetic nephropathy. This is the first landmark study to evaluate the efficacy of an angiotensin II receptor blocker only in Japanese patients, including normotensive patients. The study was commenced in January 2003 and completed in November 2005. The study results will be presented or published in 2006.

* INNOVATION: **INcideNt to OVert: Angiotensin II receptor blocker, Telmisartan, Investigation On type II diabetic Nephropathy**

“Micardis[®]” is an antihypertensive drug that provides superior, powerful blood pressure reduction for 24 hours by potently and persistently binding to angiotensin II receptors. It is also expected to be highly effective in renoprotection by resolving intraglomerular hypertension through renin-angiotensin system inhibition as well as Micardis[®] specific features such as selective PPAR-gamma activation and superior tissue penetration¹⁻⁵.

Since Micardis[®] was launched in the Japanese market in December 2002, its features have been highly appraised, resulting in a remarkable sales expansion to approximately 42 billion yen (on the basis of NHI drug price) in fiscal 2005.

INNOVATION Study

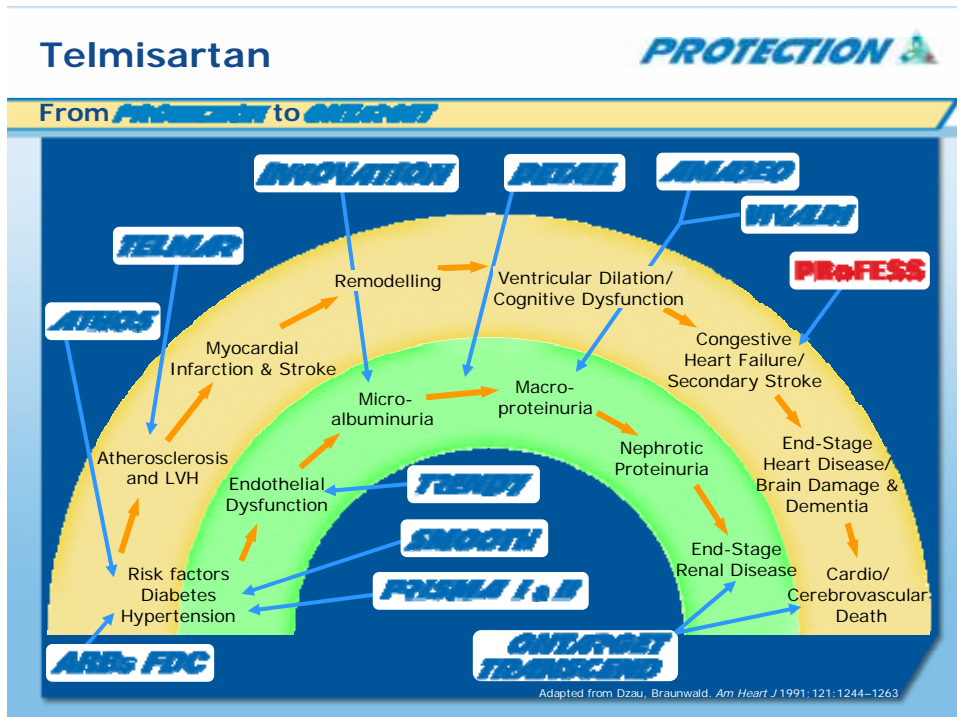
The INNOVATION study is to evaluate the inhibitory effect of Micardis® on progression of type 2 diabetic incipient nephropathy (symptoms of microalbuminuria) to overt nephropathy. This double-blind placebo-controlled comparative study involved not only hypertensive patients, but also normotensive patients. A total of 1,855 patients were recruited at 160 medical institutions in Japan and, using microalbuminuria levels as the main screening parameter, 527 subjects were assigned to 3 treatment groups (40 mg Micardis®, 80 mg Micardis®, and placebo).

This study is part of the PROTECTION™ trail programme conducted by Boehringer Ingelheim on a global basis to evaluate the various organ-protective effects of “Micardis®”. In addition to this study, the ONTARGET™ trial programme, the largest-ever programme for an angiotensin II receptor blocker, as well as the PROfESS® trial to evaluate the stroke preventive effect, are currently underway. These studies involve over 54,000 subjects in total, enabling a comprehensive evaluation of the effects of “Micardis®” on cerebrovascular and cardiovascular systems.

About The PROTECTION™ Trial Programme

In 2001, Boehringer Ingelheim announced ten additional studies as part of the company's comprehensive cardio- and cerebrovascular trial programme involving Micardis®. The PROTECTION™ trial programme includes over 6,500 patients in addition to the 29,400 patients included in the ONTARGET™ / TRANSCEND™ trial and will be conducted throughout Europe, in South Africa, North America and Japan.

PROTECTION (Program of Research to shOW Telmisartan Endorgan proteCTIOon poteNtial) is aimed at showing the potential of telmisartan (Micardis®) to protect against end-organ damage caused by hypertension and will examine the efficacy of telmisartan in many stages of the cardiovascular continuum.



References

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4. Clasen R, Schupp M *et al.* PPAR-gamma-Activating Angiotensin Type-1 Receptor Blockers Induce Adiponectin. *Hypertension*. 2005;46:137-143.
5. Rosiglitazone improves glomerular hyperfiltration, renal endothelial dysfunction, and microalbuminuria of incipient diabetic nephropathy in patients. *Diabetes*. 2005 Jul; 54 (7):2206-11

Contacts:

Nippon Boehringer Ingelheim Co., Ltd.
Communications Dept.
Tel: +81-3-5280-7147 Fax: +81-3-5280-1133

Astellas Pharma Inc.
Corporate Communications
Tel: +81-3-3244-3201 Fax: +81-3-5201-7473

Company Profiles

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

Establishment:	June 1961
Head Office:	3-10-1, Kawanishi-shi, Hyogo, Japan
President:	Akio Ohsawa
Net Sales*:	83,867 million yen (Apr.2005 - Dec.2005)
Number of Employees:	1,678 (as of 1 st January 2006)
Major Business:	<ul style="list-style-type: none">• Research & development, import, manufacturing, and marketing of pharmaceuticals• Import/export and marketing of pharmaceutical active ingredients and intermediates

* The fiscal year end was changed from March 31 to December 31; therefore, the current fiscal term is a nine-month period.

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

Establishment:	1885
Head Office:	Ingelheim, Germany
Representative:	Dr. Alessandro Banchi (Chairman of the Board)
Consolidated Net Sales:	EUR 9,535 million (as of December 2005) / about 1,305 billion yen
Consolidated Number of Employees:	About 37,500
Major Business:	Research & Development, manufacturing, and marketing of prescription medicine, consumer healthcare products, animal health product, bio-pharmaceuticals, and chemicals
Operation Sites:	143 sites around the world

Astellas Pharma Inc.(www.astellas.com)

Establishment:	April 2005
Head Office:	3-11, Nihonbashi-Honcho 2-chome, Chuo-ku, Tokyo, Japan
President:	Masafumi Nogimori
Consolidated Net Sales:	879.3 billion yen (as of March 2006)
Consolidated Number of Employees:	About 15,000 (as of March 2006)
Major Business:	Manufacture and Marketing of Pharmaceuticals, Quasi Drugs, Food, and Medical Devices.