Press Release

21 December 2005

Study design and patient background of a large-scale clinical study, INNOVATION, of the angiotensin II receptor blocker MICARDIS® was published in medical journal

- The first study in the world to evaluate the inhibitory effect of ARBs on nephropathy progression in normotensive type 2 diabetic patients -

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The study design and patient background of the large-scale clinical trial INNOVATION* of MICARDIS®, an angiotensin II receptor blocker (ARBs), has recently been published on the website of the medical journal "*The Journal of International Medical Research*"[*1]. INNOVATION is the first stand alone study to evaluate the inhibitory effect of MICARDIS® on type II diabetic nephropathy progression involving only Japanese subject. This study is innovative in its design to evaluate the inhibitory effect of ARBs on nephropathy progression in normotensive type II diabetic patients for the first time in the world. MICARDIS® demonstrates continuous potent antihypertensive effect for 24 hours due to its strong and persistent binding to angiotensin II receptors. MICARDIS® also improves glomular hypertension, and is expected to provide a significant renoprotective effect. Because of such characters of MICARDIS®, Boehringer Ingelheim is conducting globally the trials to evaluate the various organ protective effects of it, including the INNOVATION study.

* INNOVATION : **IN**cide**N**t to **OV**ert: **A**ngiotensin II receptor blocker, **T**elmisartan, **I**nvestigation **O**n type 2 diabetic **N**ephropathy

The INNOVATION study evaluated the inhibitory effect of Micardis® on progression of early type 2 diabetic 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 enrolled from 160 study centers in Japan and, using microalbuminuria levels as the main screening parameter, 527 patiants were assigned to 3 treatment groups (40-mg Micardis®, 80-mg Micardis®, and placebo). The study was commenced in January 2003 and was completed at the end of October 2005.

Diabetic nephropathy progresses from incipient nephropathy associated with microalbuminuria through overt nephropathy with persistent proteinuria to renal failure. Microalbuminuria is both an appropriate marker for early detection of nephropathy and also a marker for type 1 diabetes, type 2 diabetes, and cardiovascular events in the general population.[*2] It is known that disease progression after the transition from incipient nephropathy to overt nephropathy is often irreversible and that it is difficult to inhibit further progression. In patients whose disease has already progressed from overt nephropathy to renal failure, cerebrovascular events are more likely and the number of deaths due to cerebrovascular events is 5-fold higher than that in patients in pre-renal failure stages. Therefore, given this difficulty in slowing down the progression to end-stage renal disease once it has progressed to overt nephropathy, it is extremely important to treat patients at the microalbuminuria stage.

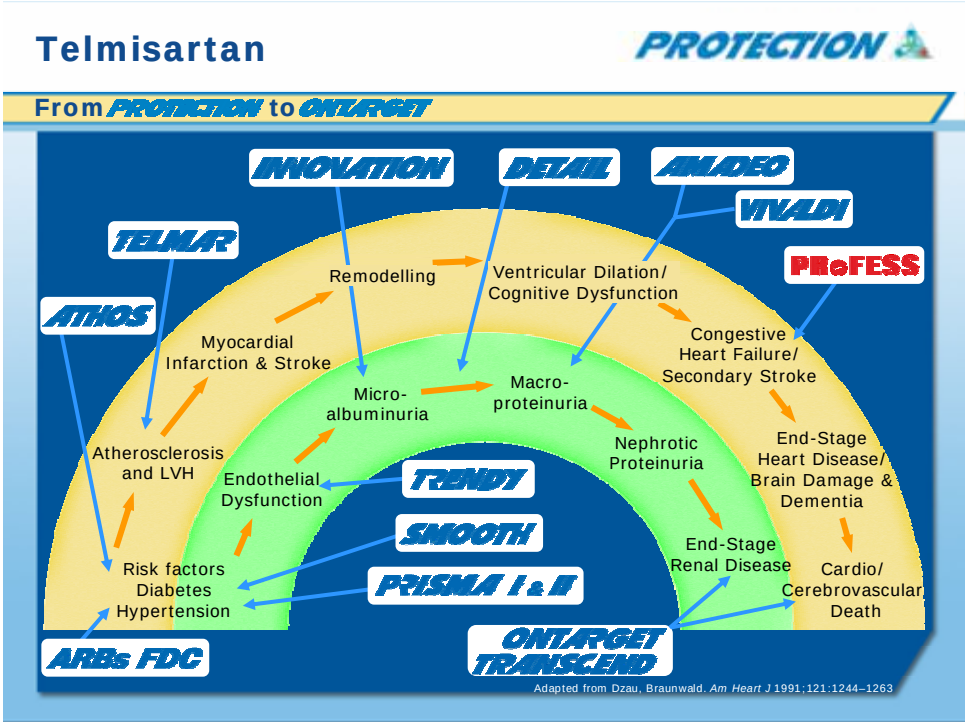
Angiotensin II is profoundly involved in the disease progression of diabetic nephropathy mainly through increasing intraglomerular pressure. ARBs are expected to inhibit nephropathy progression by blocking the action of angiotensin II at the receptor level, suppressing the increase in intraglomerular pressure, and other mechanisms.

The INNOVATION study forms the PROTECTION™ Programme that is being conducted globally by Boehringer Ingelheim to evaluate the various organ protective effects of MICARDIS®. Along with this study, the largest-ever ONTARGET™ trial programme with an ARB and the PRoFESS® trial for evaluation of stroke prevention are also being conducted. These studies involve over 54,000 subjects in total to evaluate the organ protective effects of MICARDIS® on the cardiovascular and cerebrovascular system including the end organs comprehensively.

About The PROTECTION™ 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 Programme includes over 6,500 patients in addition to the 29,400 patients included in the ONTARGET/TRANSCEND Trial Programme and will be conducted throughout Europe, in South Africa, North America and Japan.

PROTECTION (**P**rogram of **R**esearch to sh**O**w **T**elmisartan **E**ndorgan prote**CTIO**n pote**N**tial) 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:

1. The Journal of International Medical Research：http://www.jimronline.net/default.asp
2. Pharma Medica 21（10）：61-70, 2003

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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:	About 85.1 billion yen (as of December2004)
Number of Employees:	1,699 (as of 1st January 2005)
Major Business:	• 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)

Establishment:	1885
Head Office:	Ingelheim, Germany
Representative:	Dr. Alessandro Banchi (Chairman of the Board)
Consolidated Net Sales:	EUR 8.157 billion (as of December 2004) / about 1,100 billion yen
Consolidated Number of Employees:	About 36,000
Major Business:	Research & Development, manufacturing, and marketing of prescription medicine, consumer healthcare products, animal health product, bio-pharmaceuticals, and chemicals
Operation Sites:	About 150 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:	Toichi Takenaka,Ph.D.
Consolidated Net Sales:	862.1 billion yen (as of March 2004)
Consolidated Number of Employees:	About 15,500 (as of March 2005)
Major Business:	Manufacture and Marketing of Pharmaceuticals, Quasi Drugs, Food, and Medical Devices.