

26 February, 2010

Withdrawn application for approval of additional indication for type 2 diabetic incipient nephropathy for “Micardis®Tablets”, Angiotensin II receptor blocker

Japan, February 26, 2010 - Astellas Pharma Inc. (“Astellas” Headquarters: Chuo-ku, Tokyo; President & CEO: Masafumi Nogimori) announced today the withdrawal of the application for approval of additional indication for type 2 diabetic incipient nephropathy for “Micardis®Tablets”(generic name: telmisartan), angiotensin II receptor blocker which is co-promoted with Nippon Boehringer Ingelheim (“Nippon Boehringer Ingelheim” Headquarters: Shinagawa-ku, Tokyo; Chairman & President: Dr. Thomas Heil) on 26 February 2010.

The application for approval of additional indication for type 2 diabetic incipient nephropathy for Micardis Tablets was submitted by Nippon Boehringer Ingelheim on June 2006. The decision for the withdrawal of application was made because currently submitted data is insufficient to establish an evidence that is necessary to attain the approval, as a result of discussion with Pharmaceuticals and Medical Devices Agency.

The inhibitory effect of Micardis Tablets on progression of early type 2 diabetic incipient nephropathy to overt nephropathy was evaluated by the result of *INNOVATION study, which was used as the evidence of the application for additional indication.

Micardis Tablets is an antihypertensive drug developed by Boehringer Ingelheim GmbH launched in December 2002 in Japan. Micardis Tablets are manufactured by Nippon Boehringer Ingelheim and distributed by Astellas, and co-promoted by both companies in accordance with Sales Agreement and Co-Promotion Agreement which were signed on September 2002. Micombi® Combination Tablets, a combination drug of telmisartan and hydrochlorothiazide was launched on June 2009.

Astellas expects to further contribute to hypertension treatment through the promotion of Micardis Tablets and Micombi Combination Tablets.

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

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