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News Release

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The results of CASE-J study, the first large-scale clinical study of high-risk hypertensive patients in Japan, were presented

- CASE-J demonstrated Blopress®'s organ-protective effects -

During the scientific meeting of the 21st International Society of Hypertension, Oct. 15th -19th, held in Fukuoka Japan, the results of the CASE-J study* were finally presented.
* CASE-J: Candesartan Antihypertensive Survival Evaluation in Japan

This is the first large-scale outcome study in Japan comparing Blopress®, (generic name: candesartan cilexetil), angiotensin receptor blocker and Amlodipine, a calcium antagonist, both of which are the most frequently prescribed medicines in Japan in each class. In the study, the incidences of cardiovascular (CV) events in 4,728 Japanese patients with high-risk hypertension were compared in the two treatment groups for 3 years or longer.

The following three main findings were obtained in the CASE-J study.

- Blopress and Amlodipine equally reduced CV events high-risk hypertensive patients (incidence with each drug: 5.7%). <Primary endpoint>
- Blopress reduced all-cause mortality by 15% compared with Amlodipine, although this difference was not statistically significant. In obese patients with hypertension, in particular, Blopress significantly reduced all-cause mortality by 49% compared to Amlodipine (p=0.045). <Secondary endpoint>
- Blopress significantly reduced new onset of diabetes by 36% compared to Amlodipine (p=0.030). Stratified analysis revealed that this effect was conspicuous, particularly in obese patients with higher body mass index.

Dr. Toshio Ogihara, Chairman of the CASE-J Steering Committee, Director of Osaka University Hospital, and Professor, Department of Geriatric Medicine and Nephrology, Osaka University Graduate School of Medicine, stated the following on the basis of the study results: “Although there was no significant difference in the incidence of cardiovascular events between the two treatment groups, Blopress was proven to be significantly superior to Amlodipine in the prevention of new onset of diabetes mellitus and induction of regression of left ventricular hypertrophy. In addition, several stratified analyses indicate that Blopress can be an ideal anti-hypertensive drug that meets the current needs based on the increasing concerns about metabolic syndrome in general society.”

Dr. Kazuwa Nakao, Director of the EBM Collaborative Research Center, Chairman of Internal Medicine, Board of Chairs, and Professor, Department of Medicine and Clinical Science, Kyoto University Graduate School of Medicine, also commented as follows: “Almost all of Japanese patients with obesity, even those with only slight obesity, are hypertensive,. This is different from the U.S. and European countries, and is a feature of the metabolic syndrome in Japan. In the CASE-J study, Blopress was confirmed to improve the life expectancy of patients with hypertension complicated by obesity, and to reduce new onset of diabetes to half compared with amlodipine. The drastic increase in metabolic syndrome is now a global concern, therefore, the findings that the higher efficacy of Blopress in higher body mass index patient population will extensively affect the future guidelines for anti-hypertensive therapy not only in Japan but also in Asia and Western countries.”

Outline of CASE-J study

Patients: A total of 4,728 Japanese patients with high-risk hypertension*
Follow-up period: 3 years or longer
Study design: Open-label randomized controlled trial
Primary endpoint: Composite of cardiovascular mortality and morbidity**
Secondary endpoints: All-cause mortality, regression of LVMI, etc.
Pre-specified analysis: New onset of diabetes

*At least one of the following risk factors:
Severe high blood pressure (≥180 and/or 110mmHg), Type 2 diabetes, Cerebrovascular risk, cardiac risk, renal risk, vascular risk

**Sudden death, cerebrovascular events, cardiac events, renal events, vascular events

CASE-J study is the first large-scale clinical study led by the CASE-J Study Group, and was supported by the Japanese Society of Hypertension. The study was conducted from September 2001 to December 2005 with more than 600 physicians all over Japan, with the EBM Collaborative Research Center of Kyoto University Graduate School of Medicine as central secretariat.

Candesartan was discovered and originally synthesized by Takeda Pharmaceutical Company Limited, and was jointly developed with AstraZeneca. Candesartan is currently marketed in about 90 countries worldwide under the brand names of Blopress®, Amias® and Kenzen® by Takeda, and Atacand® by AstraZeneca.

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