July 16, 2008

Press Release

Ajinomoto Co., Inc.
Eisai Co., Ltd.
Takeda Pharmaceutical Company Limited

Antiosteoporotic drugs "Actonel® 17.5 mg tablets" and "Benet® 17.5 mg tablets" received approval for additional indication in patients with Paget's disease of bone: Both come in new packages.

Ajinomoto Co., Inc. ("Ajinomoto", President and CEO: Norio Yamaguchi, Headquarters: Tokyo) and Takeda Pharmaceutical Company Limited ("Takeda", President: Yasuchika Hasegawa, Headquarters: Osaka) are pleased to announce that the Ministry of Health, Labour and Welfare (MHLW) has approved the additional indication of "Actonel® 17.5 mg tablets" and "Benet® 17.5 mg tablets" (generic name: risedronate sodium hydrate) for Paget's disease of bone.

"Actonel® 17.5 mg tablets" will be distributed by Eisai Co., Ltd. ("Eisai", President and CEO: Haruo Naitou, Headquarters: Tokyo) supplied by Ajinomoto, and "Benet® 17.5 mg tablets" will be distributed by Takeda.

Paget's disease of bone is a metabolic disorder of bone. Its etiology is unknown. The prevalence of this disease is very low in Japan: estimated at 200-300 patients. Paget's disease of bone causes deformity and thickening of the bone due to excessive bone metabolism, which may lead to pain, bone fracture and osteosarcoma. There surely are unmet needs for the effective treatment for this disease. Ajinomoto and Takeda have jointly developed the antiosteoporotic agent—risedronate sodium hydrate—to obtain approval for indication in patients with Paget's disease of bone. Given the orphan drug designation by the MHLW, the new drug application for Paget's disease of bone was subject to a shortened exanimation with priority review by the authorities. This enabled "Actonel® 17.5 mg tablets" and "Benet® 17.5 mg tablets" to be launched for patients suffering from the incurable disease earlier than usual. With purpose to ensure effective and safe use, treatment outcome researches will be conducted in all patients who receive the drugs (the all-case research) for a predetermined period after the launch.

Risedronate sodium hydrate is a bisphosphonate agent, which was originally synthesized by Procter & Gamble Pharmaceuticals, Inc. in the United States. In Japan, a once-daily formulation of this agent was launched in May 2002 and a once-weekly formulation was launched in June 2007 for the treatment of osteoporosis. Risedronate sodium hydrate has contributed to treatment of a number of osteoporosis patients.

For the newly approved additional indication in patients with Paget's disease of bone, "Actonel® 17.5 mg tablets" and "Benet® 17.5 mg tablets" will come in special packages designed to be highly distinguishable from the existing products indicated for osteoporosis for prevention of misuse by patients and medical staff.

The following is a product outline of "Actonel® 17.5 mg tablets" and "Benet® 17.5 mg tablets" for reference.

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<Reference>

Product outline of "Actonel® 17.5 mg tablets" and "Benet® 17.5 mg tablets"

【Brand Name】
"Actonel® 17.5 mg tablets", "Benet® 17.5 mg tablets"

【Generic Name】
Risedronate sodium hydrate

【Indication】(The underlined one is the new indication approved this time.)
Osteoporosis, Paget's disease of bone

【Dosage and Administration】(The underlines mean the parts changed or added this time.)

・For osteoporosis
The usual dosage in adults is 17.5 mg of risedronate sodium to be taken orally once a week on awakening with an adequate amount of water (about 180 mL). Patients should not lie down at least for 30 minutes after taking the medication and avoid eating, drinking except for water and taking any other oral drugs.

・For Paget's disease of bone
The usual dosage in adults is 17.5 mg of risedronate sodium to be taken orally once daily on awakening with an adequate amount of water (about 180 mL) consecutively for eight weeks. Patients should not lie down at least for 30 minutes after taking the medication and avoid eating, drinking except for water and taking any other oral drugs.

【Approval date of additional indication for Paget's disease of bone】
July 16, 2008