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 A1(e)0 Tc 0 Tw

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, <u>Paget's disease of bone</u>

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