Press Release

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

A ONCE-WEEKLY FORMULATION OF RISEDRONATE SODIUM HYDRATE, AN ANTIOSTEOPOROTIC AGENT, WAS APPROVED.

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 approved today "Actonel® 17.5 mg tablets" and "Benet® 17.5 mg tablets", a once-weekly formulation of risedronate sodium hydrate (generic name) for the treatment of osteoporosis.

Both Ajinomoto and Takeda own the drug manufacturing approval of above products while Eisai Co., Ltd. ("Eisai", President and CEO: Haruo Naito, Headquarters: Tokyo) will distribute "Actonel[®] 17.5 mg tablets" supplied by Ajinomoto, and Takeda will distribute "Benet[®] 17.5 mg tablets" respectively.

Risedronate sodium hydrate is a bisphosphonate antiosteoporotic agent, which was originally synthesized by Norwich Eaton Pharmaceuticals, Inc. in the United States (then a subsidiary of The Procter & Gamble Company and now Procter & Gamble Pharmaceuticals, Inc.). This agent has two distinctive features from other antiosteoporotics:

In the additional analysis of large clinical trials, vertebral and non-vertebral bone fractures suppressing effects of this agent showed statistically significant difference as compared to placebo as early as 6 months after starting administration.

In large clinical trials with the primary endpoint of the reduction of frequency of hip fractures, this agent showed statistically significant difference as compared to placebo.

The once-weekly formulation of risedronate sodium hydrate was approved in 2002 in the United States and now are being approved in more than 80 countries around the world.

In Japan, a once-daily formulation of this agent was launched in May 2002 under the brand names of "Actonel[®] 2.5 mg tablets" (supplied by Ajinomoto) by Eisai and "Benet[®] 2.5 mg tablets" by Takeda. These products have contributed to the treatment of a great number of osteoporosis patients.

The once-weekly formulation approved today was confirmed as safe and effective as the once-daily formulation in the phase III double-bind comparative studies conducted in Japan. In addition, the less frequent doses from once-daily to once-weekly enhance the convenience for patients and, eventually, can improve their quality of life.

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]

Osteoporosis

[Dosage and Administration]

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.