

December 25, 2012

Press Release

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

**Approval of a Once-Monthly Formulation of Risedronate Sodium Hydrate,
an Antiosteoporotic Agent in Japan**

Ajinomoto Pharmaceuticals Co., Ltd. (Tokyo, President: Tomoyasu Toyoda, “Ajinomoto Pharmaceuticals”) and Takeda Pharmaceutical Company Limited (Osaka, President & CEO: Yasuchika Hasegawa, “Takeda”) jointly announced today that “Actonel[®] 75 mg tablets” and “Benet[®] 75 mg tablets”, a once-monthly formulation of risedronate sodium hydrate (generic name) for the treatment of osteoporosis has been approved by the Ministry of Health, Labour and Welfare in Japan.

Both Ajinomoto and Takeda own the drug marketing approval of above products. “Actonel[®] 75 mg tablets” will be manufactured by Ajinomoto Pharmaceuticals and distributed by Eisai Co., Ltd. (Tokyo, President & CEO: Haruo Naito). “Benet[®] 75 mg tablets” will be manufactured and distributed by Takeda.

Risedronate sodium hydrate is a bisphosphonate agent*, which is currently approved and marketed for the treatment of osteoporosis in about 100 countries. In Japan, once-daily and once-weekly formulations were launched in 2002 and 2007, respectively. A once-monthly formulation was already approved and has been marketed since 2008 in many countries outside Japan.

With less frequent administration than a once-daily or a once-weekly formulation, the once-monthly formulation is expected to improve adherence** in patients. Risedronate sodium hydrate will become the only bisphosphonate agent with three oral formulations, once-daily, once-weekly and once-monthly, in Japan. A variety of formulations will provide a wide range of choices for healthcare providers and enable them to select the formulation that best suits patients’ lifestyles.

* Bisphosphonate agent is expected to increase bone density and bone strength by inhibiting osteoclastic bone resorption.

** Patients actively participate in the decision-making of treatment courses or policies, and the treatment is implemented and continued accordingly.

<Reference>

Brand Name	“Actonel [®] 75 mg tablets”, “Benet [®] 75 mg tablets”
Generic Name	Risedronate sodium hydrate
Indication	Osteoporosis
Dosage and Administration	The usual dosage in adults is 75 mg of risedronate sodium to be taken orally once a month 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.

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