Ajinomoto Pharmaceuticals Co., Ltd. Eisai Co., Ltd.

Ajinomoto Pharmaceuticals and Eisai Announce Japan Launch of Antiosteoporotic Agent Once-Monthly Formulation Actonel® 75 mg Tablets

Ajinomoto Pharmaceuticals Co., Ltd. (Tokyo, President: Tomoyasu Toyoda, "Ajinomoto Pharmaceuticals") and Eisai Co., Ltd. (Tokyo, President & CEO: Haruo Naito, "Eisai") jointly announced today the Japan launch of antiosteoporotic agent once-monthly formulation "Actonel[®] 75 mg tablets" (risedronate sodium hydrate) following its listing on the National Health Insurance (NHI) Drug Price List on February 22. The formulation will be manufactured by Ajinomoto Pharmaceuticals and distributed by Eisai.

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

In a Phase III study conducted in Japan, "Actonel 75 mg tablets" was confirmed to be as safe and effective as "Actonel 2.5 mg tablets," the once-daily formulation. With administration less frequent than both the once-daily and once-weekly formulations, the once-monthly formulation is expected to improve patient adherence**. In addition, having adopted the same packaging design as the once-weekly formulation, the once-monthly formulation utilizes a blister card packaging containing patient-friendly instructions and space provided to fill in the date for the tablet to be taken. Given the launch of "Actonel 75 mg tablets" in Japan, Actonel is the first bisphosphonate agent to be available in three different oral formulations in the country: once-daily, once-weekly and once-monthly. This variety of formulations is expected to provide a wider range of choice for healthcare providers, enabling them to select the formulation that best suits patients' lifestyles.

By making all three Actonel formulations available for the Japanese market, Ajinomoto Pharmaceuticals and Eisai seek to make further contributions to improving patient quality of life.

- * Bisphosphonate agents are expected to increase bone density and bone strength by inhibiting osteoclastic bone resorption.
- ** Patients actively participate in the decision-making of treatment courses and policies and treatment is implemented and continued accordingly.

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[Note to editors]

Actonel® 75 mg Tablets Product Outline

Product Name	Actonel [®] 75 mg tablets
Generic Name	Risedronate sodium hydrate
Indication	Osteoporosis
Dosage and Administration	The usual adult dose is 75 mg of risedronate sodium taken orally once a month on awakening, with an adequate amount of water (about 180 mL). Patients should not lie down for at least 30 minutes after taking the medication and should avoid eating and drinking except for water and administration of any other oral drugs.
Date of Approval	December 25, 2012
Listed Price	2,945.50 yen per tablet (date of NHI Drug Price List registration: February 22, 2013)
Date of Launch	February 28, 2013

