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Japan approves generic drug for osteoporosis

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Singapore: Actonel 75 mg tablets and Benet 75 mg tablets, a once-monthly formulation of risedronate sodium hydrate (generic name) for the treatment of osteoporosis by Ajinomoto Pharmaceuticals and Takeda Pharmaceutical 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 and 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.