Steovess® accepted for national approvals in European Union

Zurich, Switzerland, December 20, 2011 - Takeda Pharmaceuticals International GmbH ("Takeda") today announced that the European decentralised procedure (DCP) was positively concluded for Steovess® (formerly known as EX101), a once-a-week 70mg buffered effervescent alendronate for the treatment of post-menopausal osteoporosis.

The Company submitted its application for marketing authorization in multiple countries through the DCP on 17 September 2010, with the United Kingdom (MHRA) serving as its Reference Member State (RMS). Following its evaluation, the RMS and all Concerned Member States (CMS) reached consensus that Steovess® is approvable. The regulatory process will enter now into the national phase in which each of the member states shall adopt a national decision and grant national marketing authorizations. Pending those decisions, Takeda anticipates first launches in the second half of 2012. European approval will be used as the basis for submissions in key emerging markets.

Trevor Smith, Head of Europe and Canada said: “Osteoporosis affects more than 200 million people globally and its prevalence is expected to increase rapidly as the global population ages. Steovess® represents an important new treatment option for these patients, who often stop taking their medications because of the inconvenience associated with existing tablet forms of alendronate. Steovess® complements our existing osteoporosis offering and we believe it will be an important new treatment for patients with this debilitating disease in Europe and other key markets”.

Alendronate is a bisphosphonate which reduces the risk of vertebral and hip fractures in women suffering from post-menopausal osteoporosis. Steovess® is a unique once-weekly effervescent tablet, which, after being dissolved in water, delivers alendronate to the stomach in a proprietary buffered strawberry flavoured solution. With no tablet to swallow, a reduced volume to drink and no risk of a tablet getting stuck in the oesophagus, Steovess® aims to offer patients a more convenient dosage form, thereby improving compliance and adherence.

Steovess®, which will also be known as Avalent® or Binosto® in some countries, has been licensed from EffRx Pharmaceuticals SA of Lausanne, Switzerland. Under the agreement with EffRx, Takeda holds exclusive rights to develop, manufacture and commercialise the effervescent formulation of alendronate for the treatment of osteoporosis in all territories in the world except USA, Canada, and Japan.

Takeda has an established presence in the osteoporosis market through its existing portfolio. This includes Preotact® (full-length parathyroid hormone [PTH (1-84)]) for treatment of osteoporosis in post-menopausal women at high risk of fractures, and its broad Calcium D3 product range for those individuals who are unable to get enough calcium and vitamin D to ensure bone health and as a required adjunct to all osteoporosis treatments.
About Takeda Pharmaceuticals International GmbH

Takeda Pharmaceuticals International GmbH, headquartered in Zurich, is a wholly owned subsidiary of Takeda Pharmaceutical Company Limited. As the largest pharmaceutical company in Japan and a leader in the global industry, Takeda’s mission is to strive toward better health for patients worldwide through leading innovation in medicine. It has a commercial presence covering more than 70 countries, with particular strength in Asia, North America, Europe and fast-growing emerging markets including Latin America, Russia-CIS and China. Takeda is ranked 12th by global Rx sales, 14th in the BRIC countries and 18th in Europe. Takeda is mainly focused on the therapeutic areas of metabolic diseases, gastroenterology, oncology, cardiovascular health, CNS diseases, inflammatory and immune disorders, respiratory diseases and pain management.


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