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ASIA EDITION

Will Keryx's ferric citrate NDA get nod in Japan?

08 January 2013 | News | By BioSpectrum Bureau

Singapore: Keryx Biopharmaceuticals announced that its Japanese partner, Japan Tobacco (JT), has filed a New Drug Application (NDA) with the Japanese Ministry of Health, Labour and Welfare for marketing approval of ferric citrate in Japan for the treatment of hyperphosphatemia in patients with chronic kidney disease (CKD).

Under the license agreement with JT and its subsidiary Torii Pharmaceutical, Keryx will receive a non-refundable payment of $7 million for the achievement of the NDA filing milestone within 30 days. The NDA filing is supported by efficacy and safety data from several successfully completed phase III studies in CKD patients with hyperphosphatemia in Japan.

In September 2007, Keryx sublicensed to JT and Torii the exclusive rights for the development and commercialization of its hyperphosphatemia drug, Zerenex (ferric citrate), in Japan. The licensing arrangement calls for JT and Torii to pay to Keryx up to $100 million in up-front license fees and payments upon the achievement of specified milestones, of which $35 million has been received by Keryx to date (including the milestone achieved today). In addition, upon commercialization, JT and Torii will make royalty payments to Keryx on net sales of the drug in Japan. JT and Torii are responsible for all development and commercialization costs in Japan.

Zerenex (ferric citrate), a ferric iron-based phosphate binder, has recently completed a long-term phase III study, under Special Protocol Assessment, as a treatment for end-stage renal disease patients with hyperphosphatemia on dialysis, and the top-line data from this phase III study is expected to be announced imminently. Zerenex is also being explored in a phase II study in managing serum phosphorus and iron deficiency in anemic patients with stage III-to-V CKD not on dialysis.

Mr Ron Bentsur, chief executive officer of Keryx, commented, "We eagerly await our top-line results from our US long-term phase III study in dialysis patients and the anticipated US NDA and European MAA filings, which will follow suit."