BioSpectrum the business of Bio & Health Sciences ASIA EDITION

Eisai gets 6 months US exclusivity for Aciphex

12 December 2012 | Regulatory | By BioSpectrum Bureau

Singapore: Eisai has been able to meet the US FDA's written request requirements for pediatric exclusivity for Aciphex (rabreprazole sodium). As a result, Eisai has now gained an additional six months of market exclusivity for Aciphex in the US, which will expire on November 8, 2013.

The granting of pediatric exclusivity does not mean that Aciphex is approved for use in pediatric patients. Eisai has a new drug application (NDA) pending before the FDA for the delayed-release sprinkle capsules 5mg and 10mg of the drug.

These are proposed indication of healing of gastroesophageal reflux disease (GERD), maintenance of healing of GERD and improvement of symptoms of GERD in children between one-to-11 years of age. The FDA assigned a prescription drug user fee act (PDUFA) date of March 27, 2013.

Indications for currently approved Aciphex 20mg
In adults (greater than or equal to 18 years of age), one Aciphex 20mg tablet daily is used for the treatment of day time and night time heartburn and other symptoms associated with acid reflux disease. Aciphex is also used for the short-term (four-to-eight weeks) treatment in the healing and symptom relief of damaging (erosive) acid reflux disease (gastroesophageal reflux disease) and to maintain healing of damage (erosion) and relief of heartburn symptoms that happen with acid reflux disease.

Aciphex has not been studied for treatment lasting longer than 12 months. In adolescents (greater than or equal to 12 years of age), one Aciphex 20mg tablet daily is used for the treatment of day time and night time heartburn and other symptoms associated with acid reflux disease.