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TWi Pharma gets FDA nod for ADHD drug

15 May 2013 | News | By BioSpectrum Bureau

Singapore: Taiwan-based TWi Pharmaceuticals has received tentative approval for its Abbreviated New Drug Application (ANDA) for Guanfacine Hydrochloride extended release tablets 1mg, 2mg, 3mg and 4mg from the US FDA.

Guanfacine Hydrochloride is a central alpha2A-adrenergic receptor agonist indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) as monotherapy and as adjunctive therapy to stimulant medications.

"We are pleased to receive the tentative approval from US FDA for our Guanfacine Hydrochloride product," said Dr Calvin C Chen, president, TWi Pharmaceuticals. "TWi had already reached a settlement agreement with the branded product manufacturer and intends to begin shipping its Guanfacine Hydrochloride product upon receiving the final approval from US FDA."

According to IMS Health, a market research firm, the total annual sales of the branded product, Intuniv, marketed by Shire in the US were approximately $448 million in 2012.