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FDA not in favour of Otsuka's kidney drug Tolvaptan

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Singapore: The US FDA Cardiovascular and Renal Drugs Advisory Committee has disapproved Japan-based Otsuka Pharmaceutical's tolvaptan for the treatment of Autosomal Dominant Polycystic Kidney Disease (ADPKD).

"While we are disappointed in the Committee's recommendation, we remain committed to providing patients and physicians with a novel treatment for ADPKD, a rare genetic disease. We are looking forward to continuing discussions with the FDA to address the panel's concerns," said Dr Robert McQuade, executive VP and chief strategic officer, development and commercialization, Otsuka.

ADPKD is characterized predominantly by the formation of cysts in both kidneys that cause progressive kidney enlargement, and it is associated with pain, hypertension, decreased kidney function and ultimately, kidney failure.

The FDA accepted Otsuka's new drug application (NDA) for tolvaptan earlier this year, granting the drug a priority review status and assigning a Prescription Drug User Fee Act (PDUFA) goal date of September 1, 2013.

Tolvaptan is currently under review as a treatment to slow the progression of kidney disease for patients at risk of rapidly progressing ADPKD. Tolvaptan was studied in patients with enlarged kidneys who were in chronic kidney disease (CKD) stages 1-3 at initiation of treatment.