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FDA to further review Otsuka kidney drug

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Singapore: Otsuka Pharmaceutical received a Complete Response Letter (CRL) from the US FDA regarding the new drug application (NDA) for tolvaptan for the treatment of adult patients with rapidly progressing autosomal dominant polycystic kidney disease (ADPKD). The US FDA Cardiovascular and Renal Drugs Advisory Committee had recently disapproved Otsuka's tolvaptan.

The FDA issued CRLs to convey that Otsuka's initial review of the application is complete. The FDA, however, said that it cannot approve the application in its present form and requested additional information.

In its letter to Otsuka, the FDA requested Otsuka to provide additional data to further evaluate the efficacy and safety of tolvaptan in patients with ADPKD.

"Otsuka is evaluating the content of the FDA's response and will work closely with the Agency to determine if there are viable paths forward to address its outstanding questions," said Mr Robert McQuade, executive VP and chief strategic officer, Otsuka Pharmaceutica.

He further added, "Otsuka remains committed to patients with ADPKD and their healthcare providers."