

FDA stamps Merck's Hep C drug as breakthrough therapy

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Singapore: Merck's grazoprevir/elbasvir, an investigational single tablet regimen for the treatment of chronic hepatitis C virus (HCV) infection, has received breakthrough therapy designations from US Food and Drug Administration (FDA).

Grazoprevir is indicated for the treatment of patients with chronic HCV genotype 4 (GT4) infection, and for the treatment of chronic HCV genotype 1 (GT1) infection in patients with end stage renal disease on hemodialysis.

"HCV remains a global public health epidemic. At Merck, we are focused on the development of an efficacious, well-tolerated, once-daily therapy that can be used to treat multiple genotypes and a diverse population of chronic HCV patients," said Dr Eliav Barr, vice president, infectious diseases, Merck Research Laboratories. "Our clinical program is among the largest and most comprehensive, with studies dedicated to patient populations where significant unmet medical need still exists, such as prior treatment failures, as well as those living with co-morbid conditions, including HIV infection, chronic kidney disease and individuals on opiate substitution therapy."