Merck’s Hepatitis C Therapy Regains FDA ’Breakthrough’ Status

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Merck’s fixed-dose hepatitis C virus (HCV) combination tablet, grazoprevir/elbasvir, has received two “breakthrough therapy” designations from the U.S. Food and Drug Administration (FDA). The nods are for the treatment of those with genotype 4 of the virus as well as people with genotype 1 who have end-stage kidney disease and are on dialysis.

In October 2013, the FDA granted grazoprevir/elbasvir breakthrough status for the treatment of genotype 1, only to notify Merck of its intention to rescind the designation in January 2015. By then Gilead’s highly effective Harvoni (ledipasvir/sofosbuvir) and AbbVie’s similarly effective Viekira Pak (ombitasvir/paritaprevir/ritonavir; dasabuvir) had both been approved to treat genotype 1.

The FDA grants breakthrough status to an investigatory drug intended to treat a life-threatening condition if research suggests it offers an advancement over existing therapies. The benefit is an expedited review process.

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