Merck Seeks FDA Approval of Hep C Tablet Grazoprevir/Elbasvir

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Merck has filed a new drug application with the U.S. Food and Drug Administration (FDA) for approval of its single-tablet hepatitis C virus (HCV) treatment, BioPharmaDIVE reports. The once-daily combination of the NS3/4A protease inhibitor grazoprevir and the NS5A replication complex inhibitor elbasvir would treat those with genotypes 1, 4 and 6 of the virus. The FDA previously granted breakthrough status to the combination tablet for the treatment of those with genotype 1 who have end-stage kidney disease and are on dialysis, and for those with genotype 4.

Breakthrough status provides an expedited review process and is granted to treatments for a serious or life-threatening disease or condition that may offer a substantial improvement over existing drug regimens.

Merck's application is based in part on data from the C-EDGE, C-SURFER and C-SALVAGE clinical trials, which studied grazoprevir/elbasvir with and without ribavirin. The trials researched the therapy among people with multiple genotypes of the virus and in those with HIV coinfection, advanced chronic kidney disease, inherited blood disorders and liver disorders, and those taking opiate substitution therapy.

To read the BioPharmaDIVE article, click here.

To read a press release on the FDA application, click here.

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