



# Gilead Applies for FDA Approval of Sofosbuvir, First Interferon-Free Hep C Regimen

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Setting the stage for a major step forward in the treatment of hepatitis C virus (HCV), Gilead Sciences has submitted its once-daily oral nucleotide analogue sofosbuvir to the U.S. Food and Drug Administration (FDA) for approval. Sofosbuvir stands to become a part of the first interferon-free, all-oral therapy available for at least some people with hep C. Gilead is seeking approval for the drug to be used with ribavirin for those with genotypes 2 or 3 of the virus, and to be used with ribavirin and pegylated interferon for treatment-naive people with genotypes 1, 4, 5 and 6.

Although sofosbuvir may not allow all genotypes to eliminate interferon and its onerous, flu-like side effects, the drug would dramatically shorten the standard length of hep C therapy—which is currently between 24 to 48 weeks—to just 12 to 16 weeks.

“Current therapies are not suitable for large numbers of patients with HCV infection and are challenging to take and tolerate,” John C. Martin, PhD, chairman and chief executive officer of Gilead Sciences, said in a release. “Sofosbuvir’s antiviral potency safety profile and once-daily administration have the potential to improve cure rates by simplifying and shortening therapy for patients with this disease.”

Data from four Phase III studies—NEUTRINO, FISSION, POSITRON and [FUSION](#)—composed the bulk of the data submitted for this New Drug Application. In these studies, sofosbuvir-based regimens were given for 12 to 16 weeks and were found superior or essentially equivalent to either the currently available hep C treatments or to historical controls based on the proportion of participants who reached a sustained virologic response (SVR, considered a cure) 12 weeks after completing therapy.

To read the Gilead release, [click here](#).

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