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NIH: Gilead's sofosbuvir + ribavirin cures hepatitis C

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Singapore: Phase II clinical trials by scientists from the National Institute of Allergy and Infectious Diseases (NIAID) and the National Institute of Health (NIH) Clinical Center have found that majority of volunteers with liver damage due to hepatitis C virus (HCV) infection were cured following a six-month course of therapy that combined experimental drug, sofosbuvir, with the licensed antiviral drug ribavirin. The findings appear in the August. 28 issue of the Journal of the American Medical Association (JAMA).

The current study involved 60 volunteers with genotype-1 HCV, which tends to be less responsive to interferon-based treatment. Fifty of the 60 participants were African-American. The new study differs from many previous trials because it enrolled people with severe liver damage as well as those with mild or moderately scarred livers. Sofosbuvir for the study was supplied by its manufacturer, Gilead Sciences.

"There is a pressing need for hepatitis C virus treatments that are less burdensome to the patient, have fewer side effects and take less time to complete. Building on previous work, this trial provides compelling evidence that interferon-free regimens can be safe and effective," said NIAID director and study co-author, Dr Anthony S Fauci.

"While African-Americans make up about 13 percent of the US population, they represent more than 22 percent of people with chronic HCV infection and, compared to whites, have lower cure rates with traditional HCV therapy. Several recently completed trials testing interferon-free regimens have yielded promising results, but most volunteers in those studies were white," said NIAID researcher and principal investigator of the trial, Dr Shyam Kottilil.

The study was divided into two parts. The first part enrolled 10 people with mild or moderate liver fibrosis. Volunteers received oral ribavirin at a dosage based on their weight along with the experimental drug sofosbuvir, also in pill form, taken daily for six months. The second part of the trial enrolled 50 volunteers, 13 of whom had liver damage rated as serious. Twenty-five received ribavirin based on their weight, and 25 received a low dose (600 milligrams per day). All received sofosbuvir.

Dr Kottilil said, "Because ribavirin can cause serious side effects, including anemia, we wanted to compare response rates in patients taking low-dose ribavirin with results from patients on a weight-based dosage. We saw an overall cure rate of about

70 percent using regimens that did not include interferon. This is an encouraging result, especially considering the proportion of volunteers who had characteristics, such as being male, having HCV genotype-1 infection, being African-American and having advanced liver damage, that are recognized as predictors of poor response to treatment."

Additional trials are underway to further determine if regimens without interferon or ribavirin can help people with chronic HCV infection, particularly those who have both HIV and HCV infections, said Dr Kottilil. These trials include two studies in which volunteers with or without HIV infection take a combination of HCV drugs (but no interferon or ribavirin) for periods of three months or less.