

PRESS RELEASE

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Story Idea for
World Hepatitis Day
July 28, 2014



New pill regimens published in *The Lancet* cure hardest-to-treat hepatitis C patients

San Antonio researcher leads national study that included hard-to-treat patients

SAN ANTONIO (July 28, 2014) — Researchers from The University of Texas Health Science Center at San Antonio, the Texas Liver Institute and other institutions have identified a combination of pills that cures 9 of 10 hepatitis C patients.

The combination of the drugs sofosbuvir and simeprevir, with or without ribavirin, cured 93 percent of patients in 12 weeks, and was well tolerated by patients, according to the study published today in *The Lancet*.

Eric Lawitz, M.D., clinical professor in the School of Medicine at the UT Health Science Center and vice president of research and scientific development at the Texas Liver Institute, led the clinical trial conducted in the United States.

News of this study is important because encouraging people to take a simple blood test to diagnose hepatitis C could result in their being treated with an oral regimen that could prevent serious liver diseases such as cancer, cirrhosis or liver failure. Hepatitis C is the leading cause of liver transplants in the U.S. today.

It is estimated that 3.2 million people in the U.S. have hepatitis C and most do not know they are infected. Historically, cure rates for hepatitis C patients with cirrhosis have been lower than 50 percent and the treatment has had numerous adverse effects. The previous standard of care with interferon involved a complicated regimen of shots and up to 18 tablets a day for up to 48 weeks, and subsequent six months of follow-up care to determine if the therapy was successful. There were also major side effects with the treatment, including rash, anemia and depression.

“We are now in the midst of a paradigm shift of moving away from complicated injection regimens that included interferon and often caused significant side effects with modest success rates,” Dr. Lawitz said. “This trial provides a glimpse into the outcomes of sofosbuvir and simeprevir for treatment of hepatitis C. Both drugs are approved by the FDA but are not yet approved together for this treatment,” he said.

More

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All-oral regimens hold promise for a hepatitis C cure rate of more than 90 percent of patients, including those with liver cirrhosis (liver scarring). Participants in the study had the most common form of hepatitis C (genotype 1) and were difficult to treat due to either failing a previous course of interferon and ribavirin, or having cirrhosis.

More than 150 million people worldwide have chronic hepatitis C, a major cause of liver cirrhosis and liver cancer, with 350,000 to 500,000 deaths reported annually.

According to the U.S. Centers for Disease Control and Prevention, 75 percent of U.S. residents with chronic hepatitis C were born from 1945 through 1965. For this reason, the CDC recommends people born during these years have a one-time test for hepatitis C to prevent the risk of more serious health problems.

The study was funded by Janssen.

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The study embargo lifts at 12:01am [UK time] Monday 28 July, which corresponds to 6:30pm [EDT] Sunday 27 July to allow for potential evening broadcast coverage in the US.

Attached is the embargoed final proof of the paper, which is provided for media use only and must not be copied, forwarded, or otherwise circulated.

The following live link can be used to link to the Lancet paper, which will go live when the embargo lifts on July 27, 2014 at 6:30 PM EDT:

[http://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(14\)61036-9/abstract](http://www.thelancet.com/journals/lancet/article/PIIS0140-6736(14)61036-9/abstract)

Dr. Eric Lawitz is available for interviews on World Hepatitis Day on July 28 between 5:00 am to 8 am, 10:30 am to 1 pm CDT and after 4:00 pm.

A patient from the trial, who has been cured, is available for interviews.

Dr. Julio Gutierrez, with the Texas Liver Institute, is available for Spanish language interviews.

TLI media resources: <http://test.txliver.com/about/news/press-releases/media-resources/>

About Hepatitis and World Hepatitis Day:

<http://www.worldhepatitisalliance.org/en/about-viral-hepatitis.html>

<http://www.worldhepatitisalliance.org/en/who-what-where-when-and-how.html>

The University of Texas Health Science Center at San Antonio, one of the country's leading health sciences universities, ranks in the top 3 percent of all institutions worldwide receiving National Institutes of Health funding. The university's schools of medicine, nursing, dentistry, health professions and graduate biomedical sciences have produced more than 29,000 graduates. The \$765 million operating budget supports eight campuses in San Antonio, Laredo, Harlingen and Edinburg. For more information on the many ways "We make lives better," visit www.uthscsa.edu.

The Texas Liver Institute, based in San Antonio, is globally renowned as a multi-disciplinary center for the research and treatment of liver disease. In affiliation with the University of Texas Health Science Center at San Antonio, phase 1-3 clinical trials and studies are performed at The Texas Liver Institute supporting ground-breaking research and state of the art clinical care for treatment of viral hepatitis, liver cancer, cirrhosis and fatty liver disease. For more information, visit www.txliver.com.

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