FDA expedites development of hepatitis C drugs

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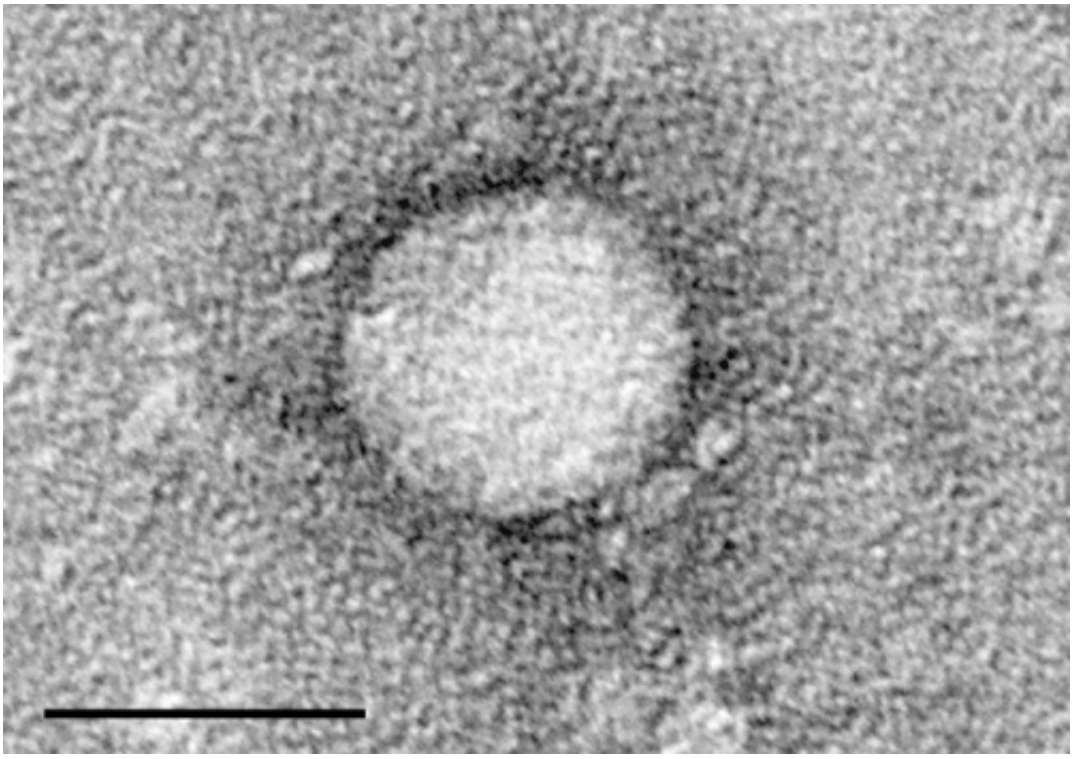

Electron micrographs of hepatitis C virus purified from cell culture. Scale bar is 50 nanometers. Credit: Center for the Study of Hepatitis C, The Rockefeller University.

The U.S. Food and Drug Administration has granted amended Breakthrough Therapy Designation for an investigational combination of drugs that show great promise for treating the sickest hepatitis C patients—those with advanced cirrhosis and those who have had a liver

transplant but the virus has returned.

The designation clears the way for expedited drug development and review by the FDA based on early clinical trial results for this serious, life-threatening disease. Fred Poordad, M.D., from The University of Texas Health Science Center at San Antonio, presented the results of the ALLY-1 clinical trial at The International Liver Congress 2015, part of the annual meeting of the European Association for the Study of the Liver.

Dr. Poordad, the principal investigator of the study, is a clinical professor of medicine at the UT Health Science Center and vice president of academic and clinical affairs at the Texas Liver Institute.

"I have been researching cures for hepatitis C for 20 years," Dr. Poordad said. "We have had a lot of success recently with new oral medications for various groups of patients, but it's exciting to see a cure in sight for patients who have the bleakest outlook. We are refining treatments for different groups and I would say that in the next few years we should be able to treat most genotypes very successfully. This is a very promising time for hepatitis C patients."

The Phase III study evaluated a 12-week oral regimen of daclatasvir and sofosbuvir taken once a day with ribavirin for the treatment of patients with the genotype 1 strain of hepatitis C. The patients in the study either had advanced cirrhosis (scarring of the liver) or have had a liver transplant but hepatitis C has returned.

Study results showed an overall cure rate of 94 percent for patients with a liver transplant and returning hepatitis C, and 83 percent for patients with advanced cirrhosis.

The study's primary endpoints also were reached, with 95 percent of post-

transplant genotype 1 patients and 82 percent of genotype 1 patients with advanced cirrhosis being cured 12 weeks after treatment.

Genotypes are subgroups or strains of a disease, such as hepatitis C. There are many subtypes of the hepatitis C virus based on the geographic regions where the strain is most prevalent. Over time, each strain evolved differently so that treatments are based on the genotype of the disease. Genotype 1 is the hepatitis C strain most common in the United States and is the most difficult to treat.

Douglas Manion, M.D., head of specialty development at Bristol-Myers Squibb, which sponsored the clinical trial, said, "Our daclatasvir clinical development program focuses on addressing high unmet medical needs still encountered in the treatment of hepatitis C despite the advent of new therapies. This designation recognizes the importance of developing a new treatment option for post-liver transplant and cirrhotic patients who are among the most challenging patient populations to treat with currently available regimens."

Earlier this year, the FDA had planned to withdraw Breakthrough-Therapy Designation for the daclatasvir-sofosbuvir regimen because of the availability of other medicines that were more successful for other genotypes. However, based on the early data from the ALLY-1 trial, the FDA amended its original decision and opted to continue expedited development of this treatment for the subgroup of patients studied in ALLY-1.

The FDA is continuing its new drug application review of the daclatasvir-sofosbuvir regimen for the treatment of genotype 3 hepatitis C patients.

Provided by University of Texas Health Science Center at San Antonio