Achillion’s Hep C Med ACH-3102 Approved for Fast Track Status

May 16, 2012

ACH-3102, a hepatitis C drug under development by Achillion Pharmaceuticals, has received Fast Track status from the U.S. Food and Drug Administration (FDA), according to an Achillion statement. ACH-3102 is currently undergoing a Phase I clinical trial.

The drug targets NS5A, a protein found in the most common strains of the hepatitis C virus (genotypes 1 through 6). Testing shows the drug to be effective against drug-resistant strains that have arisen during studies of first-generation drugs in its class. Achillion hopes to use it as part of a combination therapy with ACH-1625, a protease inhibitor currently being evaluated in a Phase II clinical trial. A trial of the combination therapy is planned for late 2012.

Achillion applied for Fast Track status on the grounds that ACH-3102 offered several benefits over existing therapies, such as a lower risk of adverse effects, fewer interactions with other medications (such as liver transplant immunosuppressants or treatment for hepatitis B or HIV coinfection), and the potential to combine ACH-3102 with other hepatitis C medications and create single-tablet regimens.

Fast Track designation allows manufacturers to file parts of their New Drug Application on a rolling basis as research data comes in, rather than waiting until all data is in before filing the entire application. This allows the FDA to review parts of the application as they come in rather than waiting for completion. The Fast Track designation also provides more opportunity for the researchers to interact with the FDA, and it offers the potential for a priority review with a deadline of six months instead of the usual 10.

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