Intercept NASH Drug OCA Gets FDA Fast-Track Status

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Intercept Pharmaceuticals' new investigational treatment for non-alcoholic steatohepatitis—a.k.a. NASH—has received a Breakthrough Therapy Designation status from the U.S. Food and Drug Administration (FDA), Fierce Biotech reports.

The new drug is called obeticholic acid (OCA), a semi-synthetic bile acid analog that has been shown to help reduce markers of liver inflammation and fibrosis, as well as increase insulin sensitivity in liver disease patients.

OCA's fast-track status will give Intercept quicker access to and better feedback from the FDA in designing Phase III human trials for the drug. The FDA's decision was based on promising results from two recent placebo-controlled Phase II studies.

NASH, an advanced form of fatty liver disease, is a chronic condition characterized by liver inflammation that mostly affects people who are overweight or obese. NASH can lead to progressive fibrosis, cirrhosis and possible liver failure if left untreated. There are no FDA-approved drugs for NASH on the market.

Health officials also estimate that between 10 and 30 percent of the U.S. population currently has fatty liver disease and that as many as half of all Americans could develop it by 2030. Because of this, many liver disease experts are now calling NASH "the next hepatitis C."