FDA Fast Tracks Treatment for Non-alcoholic Steatohepatitis

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The U.S. Food and Drug Administration (FDA) has granted fast-track status to Galmed Pharmaceuticals' aramchol, an investigatory treatment for non-alcoholic steatohepatitis (NASH), Globes.co.il reports. The Israeli biotech firm plans to start a Phase IIb trial of the drug by year's end in 240 people with NASH who are also obese and have insulin resistance.

NASH, which is a chronic liver condition similar in effects to alcoholic liver disease, occurs in an estimated 2 to 5 percent of Americans. The condition, like hepatitis C, can lead to cirrhosis. The prevalence of NASH is expected to expand along with American waistlines and increasing diabetes rates.

"The fast-track designation of aramchol will allow for continued contact between Galmed and the FDA to optimally design aramchol's future studies, including clinical trials in the United States, and may enable Galmed to accelerate its development, FDA approval and the time to market," Allen Baharaff, chief executive officer of Galmed, said in a release.

To read the Globes report, click here.

To read the press release, click here.

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