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Letter to Editor

Food and drug administration gives breakthrough: sanctioning of Rezdiffra for non-alcoholic steatohepatitis

Sir,

On March 14,2024, FDA i.e., the US food and drug administration, approved Rezdiffra (resmetirom) for treating noncirrhotic non-alcoholic steatohepatitis (NASH) in adults who may have moderate to advanced degrees of liver fibrosis. This is a game-changing moment for patients who until now had only diet and exercise as their options.[1]

The liver disease epidemic of the twenty-first century is non-alcoholic fatty liver disease (NAFLD), whose incidence rates vary by area ranging from 23% to 32% and are expected to climb further. NAFLD is a broad category of pathologies that includes non-alcoholic fatty liver (NAFL), which is characterized by simple steatosis without inflammation, and NASH, which is characterized by hepatocyte ballooning, inflammation, and liver steatosis. Advanced fibrosis, cirrhosis, and hepatocellular carcinoma can result from these pathologies. Current worldwide guidelines until now only had a limited number of pharmacological treatments related to NAFLD, such as pioglitazone and vitamin E, in addition to lifestyle adjustments like weight loss, a Mediterranean diet, and physical activity.[2]

Thyroid hormones are important modulators of hepatic lipid metabolism, including FT4 and free triiodothyronine (FT3). The primary form of the thyroid hormone receptor in the liver is called thyroid hormone receptor-beta (THR-β), and by stimulating this receptor, Resmeritom lowers intrahepatic triglycerides-increasing lipophagy and hepatic fatty acid β-oxidation.[3]

A once-daily oral THR-β agonist, Rezdiffra is intended to address important underlying causes of NASH. Rezdiffra's expedited approval was granted based on the phase 3 MAESTRO-NASH trial's results, which were just released in the New England Journal of Medicine. 1,759 patients with biopsy-confirmed NASH were included in the pivotal, multi-center, randomized, double-blind, placebo-controlled MAESTRO-NASH trial, which is still ongoing. After 52 weeks of treatment, both the 100 mg (for people >or equal to 100 kg) and 80 mg (<100 kg) doses of Rezdiffra showed statistically significant improvement over placebo on two primary endpoints: improvement in fibrosis by at least one stage and resolution of NASH i.e. reduction in hepatic fat and inflammation (including a reduction in the NAFLD activity score by ≥2 points) without worsening of fibrosis. Improvement in fibrosis was seen irrespective of gender, age, type 2 diabetes status and fibrosis level.[4]

Mild side effects of Rezdiffra can include abdominal pain, constipation, diarrhoea, dizziness, itching, nausea and vomiting. Serious side effects of the medications include hepatotoxicity, cholecystitis, and cholelithiasis. In rare cases, allergic reactions to the drug may be seen.[5]

Therefore, to conclude, Rezdiffra is a ground-breaking discovery by Madrigal Pharmaceuticals which will change the way we look at NASH. Continued approval of this drug depends upon the verifications which will be received through the ongoing confirmatory trials.

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