Incorrect Dosing Leads to Death with Ocaliva

On September 21, 2017, the Food and Drug Administration (FDA) alerted healthcare professionals about severe and/or fatal events resulting from incorrect Ocaliva (obeticholic acid) dosing. Ocaliva is an orphan drug used as monotherapy or adjunct therapy to ursodeoxycholic acid to treat primary biliary cholangitis. Primary biliary cholangitis, formally known as primary biliary cirrhosis (PBC), is a chronic disease that affects mostly women over the age of 35. This assumed autoimmune disease destroys the cholangiocytes leading to cholestasis and ultimately, hepatic destruction.

Since Ocaliva's approval on May 27, 2016, nineteen deaths have been reported to the FDA. Only eight cases reported contained information regarding the patient's cause of death. Seven of the eight cases included patients with moderate to severe hepatic dysfunction (Child-Pugh B & C). These patients were taking almost two times the maximum weekly dose recommended for this population. Eleven cases of serious hepatic injury also have been reported. Five of these cases were in patients without a history of hepatic dysfunction.

The current recommended starting dose for patients with moderate to severe hepatic impairment is 5 mg once weekly. Daily dosing was being used in all the cases described above. Liver function tests should be performed before initiation of Ocaliva and regularly throughout treatment. Dosing is determined and adjusted based on the patient's degree of liver impairment. A dose of 10 mg twice weekly should not be exceeded in patients with moderate to severe hepatic impairment. Ocaliva should be discontinued if hepatic injury is suspected. Intercept Pharmaceuticals, Inc and the FDA encourage providers to report all adverse events and contact them for more information or questions.

References:

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Beka McCutcheon, Pharm.D. Candidate