ALEXANDRIA, Va., Sept. 30, 2013 /PRNewswire/ -- Food and Drug Administration (FDA) announced the requirement of a Boxed Warning for the anti-cancer immunosuppressive drugs Arzerra (ofatumumab) and Rituxan (rituximab). The Boxed Warning is specific to the risk of reactivating hepatitis B virus (HBV) in patients who were previously infected with the virus. Use of these drugs in patients with prior HBV infection can result in severe liver damage if the virus is reactivated.

The American Association for the Study of Liver Diseases represents the hepatology community, which has recognized for more than a decade that treatment of cancer with chemotherapy sometimes results in reactivation of HBV. The risk of HBV reactivation is already described in the *Warnings and Precautions* section of the labels for both drugs; however, the FDA's monitoring system had continued to detect cases of HBV reactivation with these agents and independently came to appreciate the problem's persistence.

AASLD convened a conference on the subject of HBV reactivation during chemotherapy in Mar ch 2013
, and representatives of the FDA were present at the meeting and engaged in discussions. Those discussions between AASLD and the FDA were continued through the summer. According to AASLD President-Elect Adrian Di Bisceglie, MD, "AASLD members were recognized as experts and our persistence as an organization in this area helped FDA make up its mind to notify prescribing physicians of this problem."

The FDA also released new recommendations to decrease the risk of HBV reactivation when these drugs are used. Addressing this risk of hepatitis B reactivation, the full FDA communication states: "The revised labels will include additional recommendations for screening, monitoring, and managing these patients on these drugs to decrease this risk."

The *Warnings and Precautions* section is being revised for each drug to express new

recommendations for health care professionals. Dr. Di Bisceglie added, "We still believe there are other agents and treatment regimens that pose similar risks of HBV reactivation, and AASLD will call for further study and awareness of this and other agents may perhaps need similar box warnings."

Please follow this link for the FDA press release and additional information on HBV reactivation: http://www.fda.gov/Drugs/DrugSafety/ucm366406.htm .

AASLD is the leading organization of scientists and healthcare professionals committed to preventing and curing liver disease. AASLD was founded in 1950 by a small group of leading liver specialists and has grown to an international society responsible for all aspects of hepatology.

Press releases and additional information about AASLD are available online at www.aasld.org .

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