Bosentan Label Changes Address Hepatotoxicity

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Reported cases of hepatotoxicity associated with bosentan therapy have prompted changes to the pulmonary arterial hypertension drug's prescribing information.

Actelion Pharmaceuticals US Inc., which manufactures bosentan (Tracleer), made the changes to highlight the importance of monthly liver function monitoring for the duration of bosentan treatments and the need to adhere to the new dosage adjustment and monitoring guidelines. The new recommendations include:

► For alanine aminotransferase/aspartate aminotransferase (ALT/AST) levels greater than three and up to five times the upper limit of normal, confirm by another aminotransferase test. If confirmed, reduce the daily dose or interrupt treatment and monitor aminotransferase levels at least every 2 weeks. If the aminotransferase levels return to pretreatment values, continue or reintroduce the treatment as appropriate.

► For ALT/AST levels greater than five and up to eight times the upper limit of normal, confirm by another aminotransferase test. If confirmed, stop treatment and monitor aminotransferase levels at least every 2 weeks. Once the aminotransferase levels return to pretreatment values, consider reintroduction of the treatment.

► For ALT/AST levels greater than eight times the upper limit of normal, treatment should be stopped and reintroduction of the drug should not be considered. There is no experience with reintroduction of the drug in these circumstances.

For more information, contact the company by calling 888-835-5445. Report any serious adverse events that occur with the use of bosentan to the Food and Drug Administration's MedWatch Adverse Event Reporting program by calling 800-332-1088 or online at www.fda.gov/medwatch/report.htm. ■