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Canada Links Merck Drugs To Male Breast Cancer

By **Greg Ryan**

Law360, New York (August 5, 2011) -- Canada's health department warned Thursday that use of Merck & Co. Inc.'s Propecia and Proscar could amplify the risk of male breast cancer, less than two months after U.S. officials said the drugs could increase the likelihood of prostate cancer.

Health Canada said a small number of men taking finasteride, sold by Merck under the brand name Propecia for the treatment of male-pattern hair loss and under the name Proscar for treatment of benign prostatic hyperplasia, had developed breast cancer.

The labeling on finasteride-based medications, which are also sold generically, will now feature a warning about the potential breast cancer risk in Canada, the department said.

In June, the U.S. Food and Drug Administration announced that Proscar and Propecia and GlaxoSmithKline PLC's Avodart and Jalyn may increase the risk of contracting high-grade prostate cancer, which spreads faster than other forms of prostate cancer.

Health Canada said Thursday that breast cancer was found in patients taking both 1-milligram and 5-milligram versions of finasteride, though those taking the 5-milligram dose made up the majority. Propecia is sold in 1-milligram tablets, while Proscar is sold in 5-milligram doses.

"Based on the currently available evidence, it is not known with certainty whether finasteride can cause breast cancer, nor can this possibility be ruled out at this point in time," the department said in a statement.

Propecia and Proscar users should tell their doctors if they notice their breasts have grown larger or if their breasts have any lumps, tenderness, pain or nipple discharge, according to Health Canada.

The U.K.'s Medicines and Healthcare Products Regulatory Agency announced a similar finding in December 2009, saying it could not rule out that the use of finasteride increases the risk of male breast cancer.

Benign prostatic hyperplasia, a common condition in men older than 40, causes frequent urination and difficulty emptying the bladder, along with an enlarged prostate gland.

The FDA's June warning impacted the 5-alpha-reductase inhibitor class of drugs, primarily used to treat the symptoms of BPH.

Drugs in the class include finasteride and dutasteride, the latter of which is marketed as Avodart. Jalyn is included in the drug class because it contains dutasteride.

After conducting two multiyear trials, the FDA found the drugs helped reduce the risk of low-grade prostate cancer, but simultaneously increased the chance of contracting a more serious form of prostate cancer.

While Propecia was not included in either of the studies, the agency said at the time that the drug's warning label would be modified because it contains 1 milligram of finasteride.

--Additional reporting by Bibeka Shrestha. Editing by John Williams.