Actos And Avandia Use Associated With Diabetic Macular Edema, Which Can Lead To Blindness

New UK Study Found Three To Six Times Increased Risk Of Developing This Retinal Eye Disease Side Effect

(Posted by Tom Lamb at www.DrugInjuryWatch.com on June 27, 2011; see http://bit.ly/m09upO)

A study presented at the American Diabetes Association's annual meeting in San Diego on June 26, 2011 finds taking the diabetes treatments Actos (pioglitazone) and Avanidia (rosiglitazone) -- both in the Thiazolidinediones (TZDs) class of drugs -- have a three to six times increased risk of developing diabetic macular edema (DME), an eye disease in which the retina thickens and swells, possibly leading to blindness.

Takeda Pharmaceutical Co. markets Actos, the world's best-selling diabetes treatment, and GlaxoSmithKline Plc. (Glaxo or GSK) markets Avandia.

According to a June 24, 2011 *Bloomberg* news article, "Takeda, Glaxo Diabetes Treatments Raise Risk of Eye Disease, Study Finds":

> Diabetic eye disease is the most common cause of blindness in working-age Americans, according to the National Eye Institute. Macular edema damages the retina and can eventually cause blindness. The best way to prevent the side-effect of diabetes is to keep blood sugar under control, according to the National Eye Institute.
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> "Patients at high risk of sight-threatening DME should avoid" the class of drugs including Actos and Avandia, the study authors, led by Richard Donnelly at the University of Nottingham, wrote in their study abstract. High-risk patients include those who have poor control of their blood sugar and those with a previous history of macular edema.

For more about this new study finding a significant (3 to 6 times) increased risk of developing diabetic macular edema (DME) when using Avandia or Actos, we look to this June 27, 2011 *Medical Economics eConsult*, "TZDs, GLP-1 agonist may worsen diabetic retinal disease":

> In the TZD [Avanida and Actos] study, Iskandar Idris, MD, and colleagues at Sherwood Hospital Foundation Trust and the Universities of Sheffield and Nottingham, UK, retrospectively reviewed data from a cohort of 103,368 patients in more than 400 general practices in England and Wales. The patients all had type 2 diabetes, and only patients with no prior exposure to TZDs were included. Follow-ups were conducted at 1 and 10 years after the study index date.
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> In an unadjusted analysis, the 1-year incidence rate of DME in patients taking a TZD was 1.3%, compared with 0.2% for patients with no TZD exposure (odds ratio [OR] 5.7, 95% confidence interval [CI] 4.1–7.9, P<.001).
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> In adjusted analyses controlling for mean HbA1c and blood pressure during follow-up, weight, body mass index (BMI), lipids, insulin treatment, oral antidiabetic agents, and other parameters, the hazard ratio (HR) for DME with a

> TZD with no insulin was 3.29 (95% CI 2.21–4.91, P<.0001). The HR for a TZD with insulin was 8.44 (95% CI, 4.23–16.85, P<.0001).
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> "The increased risk of DME was observed after 1 year of exposure and continued to accrue over the 10-year follow-up of the study even when adjusting for confounding factors," Idris said.

Returning to the June 24 *Bloomberg* news report:

> Actos may raise the risk of bladder cancer in patients who take the medicine more than a year, the U.S. Food and Drug Administration said in a June 16 safety announcement. The medicine has sales of 387.9 billion yen ($4.8 billion) in the fiscal year ended in March, according to Bloomberg data.

We wrote about the Actos bladder cancer safety issue earlier this month in our "Actos-Related Bladder Cancer: June 2011 Review Of Regulatory Actions And Safety Warnings" post.

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Attorney Tom Lamb represents people in personal injury and wrongful death cases involving unsafe prescription drugs or medication errors. The above article was posted originally on his blog, **Drug Injury Watch** – with live links and readers' Comments.
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