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### **RISK OF BIRTH DEFECTS WITH PAROXETINE USE IN PREGNANCY**

**Ottawa – October 1, 2005** - A recent study conducted by GlaxoSmithKline, the makers of the antidepressant Paxil® (paroxetine), has found a potential association between the use of the product in the first trimester of pregnancy, and the risk of birth defects. The study of over 3,500 pregnant women who were exposed to the drug during their 1<sup>st</sup> trimester found the overall rate of birth defects to be about 4%, and the rate of heart defects to be 2%. The average rate of birth defects in the general population is approximately 3% and the rate of heart defects about 1%.

To put this into perspective, with a 1% difference in absolute risk, it means approximately 100 women would have to take the drug in their 1<sup>st</sup> trimester to lead to one additional birth defect.

Earlier studies conducted on Selective Serotonin Receptor Antagonists (SSRI), the class of medications that Paxil® is in, have shown conflicting results on the risk of malformations. The largest study that analyzed the risk in over 150,000 women found there to be a slight increase in risk in birth defects when exposure to an SSRI occurred between one week before conception and the end of the first trimester. At the same time, smaller studies have found no increase in risk of birth defects associated with SSRI use.

It is important to consider that untreated depression can lead to severe negative outcomes to both the mother and fetus. As stated in the product monograph, paroxetine should be used in pregnancy only when the potential benefits outweigh the risk to the fetus. The decision as to whether or not to continue treatment must take into consideration the risk associated with not treating depression. If it is decided that the agent should be discontinued, abrupt discontinuation may lead to withdrawal-like reactions. In this situation, tapering should be considered, especially if the patient is on a high daily maintenance dose.