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SWOG statement on FDA ODAC review of finasteride for prostate cancer prevention

ANN ARBOR, MICH., NOV 30, 2010 – SWOG is pleased to have the data and analysis from our Prostate Cancer Prevention Trial (PCPT) presented before the FDA's Oncologic Drugs Advisory Committee (see http://www.fda.gov/AdvisoryCommittees/Calendar/ucm230653.htm).

We believe the PCPT trial results and the subsequent analyses done on PCPT data have demonstrated for the first time a proof of principle that a drug can reduce the risk of prostate cancer by a significant amount.

Based on independent studies published in peer-reviewed journals by our investigators and others, SWOG is convinced that finasteride is a safe, effective compound that can reduce the incidence of prostate cancer by roughly 25 percent. After carefully analyzing the data and the concerns expressed after initial publication of the PCPT results, we judge that the chemoprevention benefit of the drug greatly outweighs the risk of side effects from it.

That the drug's prevention benefit was greater in men with lower Gleason scores does not detract from the fact that prostate cancer risk reduction for the more than 18,000 men who took part in PCPT was real and was significant.

We agree that the impact of finasteride on overall survival is still unknown at this point. But given that the data to answer that question won't be available for another decade or more, we believe that in the interim it is reasonable to think that lowering the prostate cancer rate is desirable -- that *not* having prostate cancer is better than having it.

In our judgment the argument that finasteride slightly increased the risk of high-grade prostate cancer for the men taking it has been disproved in peer-reviewed journal articles, most notably in the August 2008 issue of *Cancer Prevention Research*.

We note that a joint panel of the American Society for Clinical Oncology (ASCO) and the American Urological Association (AUA) has endorsed the concept of chemoprevention of prostate cancer. In its 2009 article in the *Journal of Clinical Oncology*, the panel said "The goal of developing a chemopreventive agent that can reduce the risk of prostate cancer has been achieved."

We also note that finasteride is a drug that has been used for years by many men to reduce the size of the prostate in the condition benign prostatic hyperplasia (BPH).

A similar drug, dutasteride (Avodart), is in the same class of compound as finasteride, although it is not available in generic form. It has undergone its own clinical trials that should be considered by the FDA separately from finasteride.

SWOG is a publicly funded clinical trials cooperative group with no financial interest in Merck or finasteride. The SWOG leadership, including the principal investigator for the PCPT study, Dr. Ian Thompson, likewise has no financial interest in Merck or finasteride.

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