



Memorandum

Date: February 2, 2005
To: Oncologic Drugs Advisory Committee Members and Guests
From: Richard Pazdur, M.D.
Director, Division of Oncology Drug Products, CDER, FDA
Subject: FDA Background Package for afternoon of March 3, 2005 Meeting

This memo outlines the purpose of the afternoon session of the March 3, 2005 meeting of ODAC and describes the content of this briefing package.

The Food and Drug Administration has undertaken a project to evaluate potential endpoints for cancer drug approval. Endpoints will be examined for the most common cancers, such as lung cancer, colon cancer, etc. For each cancer, FDA will hold public workshops to identify important issues, and these issues will be discussed in meetings of the Oncologic Drugs Advisory Committee (ODAC). Subsequently, guidance documents will be published describing FDA's current thinking on endpoints for cancer drug approval.

The afternoon session of March 3, 2005 will focus on endpoints in prostate cancer. This session will include presentations from participants in the prostate cancer endpoint workshop held June 21-22, 2004. ODAC discussions will center on FDA written questions.

In previous ODAC meetings where clinical trial endpoints were discussed, the ODAC members came to some definitive conclusions. For the prostate cancer trial endpoints, however, there remain many uncertainties. The goal of this meeting is to discuss the merit of several prostate cancer endpoints and to propose next steps in evaluating and validating these endpoints. This will likely be one of several ODAC meetings to discuss endpoints in prostate cancer.

Documents in this background package include:

General background document:

TAB 1 Endpoints that have supported cancer drug approval (JCO article)

Prostate Cancer Endpoints Workshop Summary

- TAB 2 Monday Morning
Introductory Overview: Endpoints to Measure Therapeutic Efficacy in Prostate Cancer
- TAB 3 Monday Afternoon
Primary Treatment (Neoadjuvant and Adjuvant) and Hormone-Sensitive Prostate Cancer
- TAB 4 Tuesday Morning
Hormone-Refractory Prostate Cancer

Prostate Cancer Endpoint Proposal

- TAB 5 ASCO abstract: Stewart A, et al. "The Clinical Significance of a PSA Nadir > 0.2 to Patients With a Rising Post-operative or Post-radiation PSA Treated with Androgen Deprivation"

Please also refer to the FDA endpoints web page for additional background documents and slides from the June 2004 Prostate cancer workshop presentations
http://www.fda.gov/cder/drug/cancer_endpoints/default.htm.