Summary Minutes of the
Oncologic Drugs Advisory Committee
May 30, 2008
Location: Hyatt Regency McCormick Place, Regency Ballroom, 2233 South Martin L. King Drive, Chicago, Illinois

All external requests for the meeting transcripts should be submitted to the CDER, Freedom of Information office.

These summary minutes for the May 30, 2008 Meeting of the Oncologic Drugs Advisory Committee of the Food and Drug Administration were approved on __6/23/2008_____

I certify that I attended the May 30, 2008 meeting of the Oncologic Drugs Advisory Committee of the Food and Drug Administration and that these minutes accurately reflect what transpired.

_____/s/_____	**_____/s/_____**
Nicole Vesely, Pharm.D.	**Maha Hussain, M.D.**
Designated Federal Official, ODAC	**Committee Chair**

Meeting of the Oncologic Drugs Advisory Committee
May 30, 2008

The Oncologic Drugs Advisory Committee of the Food and Drug Administration, Center for Drug Evaluation and Research met on May 30, 2008 at the Hyatt Regency McCormick Place, Regency Ballroom, 2233 South Martin L. King Drive, Chicago, Illinois (immediately prior to the opening session of the 2008 ASCO annual meeting.) Prior to the meeting, members and invited consultants were provided copies of the background material from the FDA and the sponsor. The meeting was called to order by Maha Hussain, M.D. (Committee Chair); the conflict of interest statement was read into the record by Nicole Vesely, Pharm.D. (Designated Federal Official). There were approximately 175 persons in attendance. There was one (1) speaker for the Open Public Hearing session.

Issue: The committee will discuss new drug application (NDA) 022-291, proposed trade name PROMACTA (eltrombopag olamine), GlaxoSmithKline, proposed indication for the short-term treatment of previously-treated patients with chronic idiopathic thrombocytopenic purpura (ITP) to increase platelet counts and reduce or prevent bleeding.

Attendance:

Oncologic Drug Advisory Committee Members Present (Voting):
Maha Hussain, M.D. (Committee Chair), Michael Link, M.D., Virginia Mason, RN (Consumer Representative), Joanne Mortimer, M.D., Ronald Bukowski, M.D., David Harrington, Ph.D., Michael Perry, M.D., Gary Lyman, M.D., S. Gail Eckhardt, M.D.

Special Government Employee Consultants (Temporary Voting Members):
Timothy Lesar, Pharm.D., Ralph D'Agostino, Ph.D., Irma Szymanski, M.D., S. Gerald Sandler, M.D., Barbara Alving, M.D., Julie Vose, M.D., Theodore Gull, Ph.D. (Patient Representative)

Non-voting Participant:
Gregory Curt, M.D. (Acting Industry Representative)

Oncologic Drugs Advisory Committee Members Not Present:
Ronald Richardson, M.D.
Jean Grem, M.D., FACP
Margaret Tempero, M.D.
Wyndham Wilson, M.D.

FDA Participants (Non-Voting):
Richard Pazdur, M.D., R. Dwaine Rieves, M.D., Andrew Dmytrijuk, M.D., Suzanne Berkman, Pharm.D.

Designated Federal Official:
Nicole Vesely, Pharm.D.

Open Public Hearing Speaker:
Joan Young, Founder and President, Platelet Disorder Support Association

The agenda was as follows:

Call to Order and Introductions	**Maha Hussain, M.D.** Committee Chair Oncologic Drugs Advisory Committee
Conflict of Interest Statement	**Nicole Vesely, Pharm.D.** Designated Federal Official
ODAC Member Appreciation	**Richard Pazdur, M.D.** Director, Office of Oncology Drug Products (OODP), Office of New Drugs (OND), CDER, FDA

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Sponsor Presentation	**GlaxoSmithKline**
Introduction	**Debasish Roychowdhury, M.D.** GlaxoSmithKline Vice President, Global Clinical Development
Idiopathic Thrombocyotpenic Purpura	**James Bussel, M.D.** Platelet Disorders Center Departments of Pediatrics and Medicine Weill Cornell Medical College
Clinical Overview	**Michael Arning, M.D., Ph.D.** GlaxoSmithKline Group Director, Global Clinical Development
Concluding Remarks	**Debasish Roychowdhury, M.D.** GlaxoSmithKline Vice President, Global Clinical Development

FDA Presentation	**NDA 022-291**
FDA Review of Clinical Data	**Andrew Dmytrijuk, M.D.** Medical Officer, Division of Medical Imaging and Hematology Products, OODP, OND, CDER, FDA

Questions to the Presenters

Open Public Hearing

Questions to the ODAC
and ODAC Discussion

Adjourn

Questions to the committee:

In two randomized, "short term" clinical studies of adult patients with chronic immune (idiopathic) thrombocytopenic purpura (ITP), a greater proportion of patients who received eltrombopag experienced a "platelet response" than patients who received a placebo (70% versus 11% in one study and 58% versus 16% in another study). To assess a treatment effect upon bleeding outcomes, the studies used a bleeding scoring system of unclear clinical meaningfulness. The studies signaled risks for serious hemorrhage following the discontinuation of eltrombopag as well as a risk for hepatotoxicity during the drug therapy. Clinical studies intended to thoroughly assess the safety and efficacy of long term eltrombopag use are ongoing and only limited, interim data are available.

1. (Vote) Eltrombopag is proposed for use in patients, such as those undergoing a surgical procedure, who have a specific need for short term therapy. The patients in the completed, controlled studies did not have this specific need and some experienced serious hemorrhage when eltrombopag was discontinued. Since ITP is generally a chronic condition, long term therapy is anticipated. Given these observations, should FDA delay marketing authorization until it has reviewed the final data from the on-going clinical studies (RAISE, EXTEND)?
If no, please answer the next question.
Discussion:

- *Committee members questioned the definition of short term in the proposed indication as members felt that eltrombopag could be used for multiple short terms.*

- *Committee members felt that if approved for short term use, there was a potential for eltrombopag to be used off label for recurrent short terms (multiple 42 day treatments).*

- *During the discussion of this question, it was decided that the committee would not vote on Question #1 and vote only on Question #2.*

Please see the transcript for detailed discussion.

2. (Vote) Do the current clinical data demonstrate a favorable risk-benefit profile for the use of eltrombopag in the "short term" treatment of patients with chronic ITP?

Vote : ***Yes=16*** ***No = 0*** ***Abstain = 0***

Discussion:

- *Committee members were concerned that eltrombopag would be used for multiple short terms and were concerned with the lack of adverse event data and dose regimen data for long term use.*

- *The committee agreed that to ensure safe use of the product a Risk Management Plan should be put in place that states that long term data is pending.*

- *The committee agreed that it was important for patients to have access to this drug and also agreed that they as physicians would be willing to register these patients as needed for the Risk Management Plan.*

- *Committee members noted that they felt that the drug was efficacious but would like more safety data in specific populations.*

Please see the transcript for detailed discussion.
The session adjourned @ approximately 11:30 a.m.