



One Amgen Center Drive  
Thousand Oaks, CA 91320-1799  
Telephone (805) 447-4587  
Fax (805) 499-3507  
[www.Amgen.com](http://www.Amgen.com)

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## **Amgen Statement on Briefing Materials Prepared for ODAC Meeting on March 13, 2008**

THOUSAND OAKS, Calif. (March 11, 2008) – Amgen Inc. (NASDAQ:AMGN) issued the following statement regarding the online posting of the Amgen and Food and Drug Administration (FDA) erythropoiesis stimulating agents (ESAs) briefing documents for the Oncologic Drugs Advisory Committee (ODAC) meeting on March 13, 2008. Both the Amgen and FDA briefing materials for the ODAC meeting are available at [www.fda.gov](http://www.fda.gov) and also will be posted on [www.amgen.com](http://www.amgen.com).

“Amgen strongly believes that ESAs provide an important clinical option for some patients, and looks forward to collaborating with the ODAC and FDA to maximize the benefits of these drugs when used according to the approved labeling while minimizing the risks.

“Amgen will provide detailed responses to address each of the concerns outlined by the FDA at the March 13<sup>th</sup> ODAC meeting. The ODAC is an advisory committee for the FDA, whose general function is to provide advice and recommendations on FDA’s regulatory issues.

“At the ODAC meeting, Amgen will address the benefits and risks of ESAs when used according to the approved product label, and how ESAs provide the only therapeutic alternative to red blood cell transfusions. We will discuss in some detail the totality of evidence and potential hypotheses as to what may be causing the safety signals in the off-label or higher hemoglobin targeted studies. In addition, Amgen will provide a detailed risk management program designed to reduce ESA risks as well as propose an additional new clinical trial that will address the critical unanswered questions.

“ESAs provide an unequivocal treatment benefit for cancer patients undergoing chemotherapy by reducing the need for blood transfusions which have both known and unknown risks. The current concern about the use of ESAs in oncology is related to the extrapolation of the risks seen in studies with higher than recommended hemoglobin targets and for uses other than those to treat anemia resulting from chemotherapy. What is known is that if the ESA option were removed, more than twice as many patients receiving chemotherapy would require red blood cell transfusions based on data from placebo-controlled clinical trials. The result would be that one out of every two cancer patients undergoing chemotherapy would be subjected to the known and unknown risks of red blood cell transfusions and the associated disruption to their care caused by having to receive a transfusion.

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“In situations like this, where patients and physicians are facing competing risks, Amgen believes it should be up to each fully informed patient in consultation with their physician to decide which treatment approach is in his or her best interest.”

SOURCE: Amgen

Amgen, Thousand Oaks

Ashleigh Koss, (213) 280-4030 (media)

Arvind Sood, (805) 447-1060 (investors)

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