



Investor News

Bayer Responds to study and commentary published in Journal of American Medical Association (JAMA)

Leverkusen / February 6, 2007 – Bayer has conducted a preliminary review of the observational study entitled “Mortality Associated with Aprotinin During 5 Years Following Coronary Artery Bypass Graft Surgery” by Mangano et al. as well as the editorial by T. Bruce Ferguson, Jr., MD from the East Carolina University, Greenville, scheduled for publication on February 7, 2007 in the *Journal of the American Medical Association* (JAMA) regarding long-term mortality rates in coronary artery bypass graft surgery patients including those treated with aprotinin.

The study published in JAMA is a follow-on to a previous observational study from the Ischemia Research and Education Foundation published in January 2006 on which Dr. Mangano was also the lead author. Bayer believes the methodological and analytical approaches used in the earlier study were not reliable and do not support the authors’ reported conclusions. This newest paper reports on a subset of the same patient population and uses methodology and analytical approaches similar to those used in the earlier publication.

One of the limitations of both of these studies is that doctors chose whether to administer aprotinin or another treatment based on the patient’s condition. Generally, sicker patients who were already at greater risk for mortality were treated with aprotinin. As noted in the editorial by Dr. Ferguson, “Aprotinin use in cardiac surgery has never been uniformly standardized, but generally has been reserved for patients in whom the surgical team anticipated a higher risk for intraoperative blood loss. This anticipation was driven by the surgical team’s perception of increased technical complexity, increased risk of adverse outcome, or both for the patient in question.” The statistical methodologies as applied by Mangano et al. in the JAMA paper did not adequately address this bias.

In addition, and applicable to both studies, major differences in clinical practice among the contributing countries have been reported in the literature. These differences have also been reported to influence outcomes. Both studies involved more than 60 sites from all over the world and these differences in clinical practice may have affected the reported findings.

Pointing out differences in the percent of patients in the different treatment groups who underwent complex surgical procedures, Dr. Ferguson comments, “Importantly, these biases, at the level of the surgical team, were not captured in the extensive patient level data collection process nor in the analysis.” Dr. Ferguson concludes, “The mechanism for this late mortality difference is not clear and causality [to aprotinin] cannot be inferred from this data set analysis.”

Patient safety is always Bayer’s highest priority. Based on this initial review, Bayer believes that the results of this study should not serve as a basis for affecting the use of aprotinin in clinical practice. Bayer will work with regulatory agencies and external experts in the field to further evaluate the findings.

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