Request to offer an oral presentation at the FDA Advisory Committee Meeting to Review the drug, BiDil. June 16, 2005.

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General Nature of Presentation.

1. The published results from A-HeFT indicate that BiDil is efficacious for the treatment of heart failure when added to existing therapies.

2. If approved, BiDil should be approved for use in the general population without regard to race or ethnicity.

3. The data from A-HeFT support no claims that BiDil works differently or better in an African-American population than any other racial or ethnic group.

4. Approving BiDil as a race-specific drug would ratify the claim that the race of the A-HeFT subjects was a relevant biological variable in assessing the efficacy of the drug. But there is no evidence to support this claim.

- In this regard it should be noted that several inaccurate claims regarding statistical difference between blacks and whites in mortality from heart failure have been put forward to frame the BiDil application.

- Claims that blacks suffer mortality from heart failure at a rate twice that of whites are wrong. Current data from the CDC indicates that the black:white ratio of overall age-adjusted mortality from heart failure is 1.08:1

- Claims that in age range from 45-64, blacks suffer mortality at a rate 2.5 times that of whites are accurate. But that age group captures only about 6% of overall mortality from heart failure. In the age group 65 and above, where about 92% of mortality occurs, the ratio approaches 1:1.

5. Most drugs on the market today were approved by the FDA based on trials conducted almost exclusively in white populations. But these are not designated as "white" drugs. Neither should BiDil be designated as a drug for "African-Americans." Such a designation would be fundamentally different from other labeling designations that suggest different dosages or varying degrees of efficacy based on correlations with race or ethnicity. When approving drugs tested in white populations, the proper assumption of the FDA was that the category "white people" did not differ in any meaningful way from the category "human being." The same assumption should apply to a drug tested in African-American populations.

Requested Time:

5-10 minutes