



For immediate Release: March 28, 2006

Contact: James Learned, (917) 620-0349, James_Learned@prodigy.net
Judith Dillard, (817) 570-9296, msjdillard@yahoo.com.

SCHERING-PLOUGH BANS AFRICAN AMERICANS FROM EARLY HEPATITIS C CLINICAL TRIAL

In an egregious and cynical tactic to make a drug in development look as good as possible, an entire racial group has been explicitly excluded from the clinical trial of an experimental drug. Schering-Plough Corporation has banned African Americans from participating in the dose-finding study of its experimental drug, SCH 503034, for the treatment of hepatitis C virus (HCV).

We demand that Schering-Plough end this unethical and baseless exclusion.

“Schering-Plough has offered no valid safety reason for the exclusion,” said Brian Klein of the Hepatitis C Action & Advocacy Coalition (HAAC), who participated in a call with company representatives on March 17. “Compelling safety concerns would justify such an exclusion, but the company provided only vague comments that this was an ‘efficient’ way to develop the drug. It is clear to us that Schering-Plough chose to exclude an entire racial group from the study to achieve the best efficacy results possible on the road to marketing the drug.”

Over four million Americans have been infected with HCV in the United States, and HCV infection is as much as three times more prevalent in African Americans than in whites. Complications of HCV infection—cirrhosis, liver cancer, end-stage liver failure, and death—appear to be more common in African Americans.

Studies show that, in general, African Americans have lower response rates to current HCV treatment compared to other racial groups. New treatment options are urgently needed for this population. In these studies, African Americans did not experience side effects or safety risks that were any more severe than those of other racial groups.

Phase 2 studies test different doses of an investigational drug to find one that is within acceptable safety limits for further study. Phase 2 studies also provide crucial safety information and sometimes suggest how effective the drug might be. Schering-Plough, insists on excluding African Americans from participating in the Phase 2a study of SCH 503034. The company has agreed to allow a few African Americans into a recently added, higher drug dose arm of the study but will not integrate African Americans into the other study arms.

The SCH 503034 study includes safety criteria using laboratory tests and side effect monitoring to ensure that no participants enter or continue in the study if their health

status is outside the acceptable ranges or if they are co-infected with HIV or hepatitis B or have advanced liver disease such as cirrhosis. HAAC members agree that these safety criteria are appropriate but assert that excluding anyone from participating in the trial due to race is inexcusable.

“The bottom line is that African Americans have been left out of this study to make the drug look good,” said Judith Dillard of the Community HIV/AIDS Mobilization Project (CHAMP). “This is not about protecting people’s health or even genetics—in fact, people of African descent are allowed into the trial as long as they are not African Americans! My community needs equal access to early research so we can find treatments that work for us, not just a few token people brought in later for the high dose arm to try to cover up this racist exclusion.”

More detailed background information about the study follows.

###