Prezista Approved for First-Time Treatment Takers

October 22, 2008

The U.S. Food and Drug Administration (FDA) has approved the protease inhibitor Prezista (darunavir) for HIV-positive people beginning antiretroviral (ARV) treatment for the first time, the drug's manufacturer, Tibotec Therapeutics, announced today. Prezista must be combined with Norvir (ritonavir), but can be taken once a day by HIV-positive people who have not used other ARVs in the past.

Prezista was initially granted accelerated approval by the FDA in June 2006 for ARV-experienced adults, such as those with HIV that is resistant to more than one protease inhibitor. In addition to approving Prezista for treatment-naïve adult patients, the FDA granted "full" approval to twice-daily therapy for treatment-experienced adult patients.

The newest approvals are based on the results from two yearlong Phase III clinical trials in ARV-naïve and ARV-experienced patients and two 96-week Phase II clinical trials involving treatment-experienced people with advanced HIV disease.

Recommended dosing for first-time ARV takers is two 400 mg tablets taken with 100 mg Norvir once daily. The new 400 mg tablet will be available by November 1. For treatment-experienced adult patients, Prezista dosing remains the same: one 600 mg tablet taken with one 100 mg Norvir capsule twice daily. Prezista must be used with Norvir—and other ARVs—and taken with food to be effective.

The latest guidelines from the International AIDS Society-USA Panel, which were published in the August 6, 2008, issue of The Journal of the American Medical Association, recommend Prezista as one of the initial treatment options as part of combination therapy for adults living with HIV.