Once-Daily Dose of HIV Drug Prezista Approved for Treatment Experienced

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The U.S. Food and Drug Administration (FDA) has announced its approval of once-daily dosing of Prezista (darunavir) for people living with HIV who have used other antiretrovirals (ARVs) in the past, provided their virus is fully sensitive to the protease inhibitor, which is manufactured by Tibotec Therapeutics. Those who have HIV with one or more mutations conferring resistance to Prezista must use the drug twice a day.

The FDA initially approved Prezista in 2006 to treat people with resistance to multiple classes of HIV drugs. The drug was approved again in 2008 for people starting ARV treatment for the first time. Until now, all treatment-experienced individuals were instructed to take 600 milligrams (mg) of Prezista, boosted by 100 mg of Norvir (ritonavir) twice daily, while those new to treatment were directed to take 800 mg of Prezista with a single 100 mg Norvir tablet once per day.

The new recommendations are based on the ODIN study (Once-daily Darunavir In Treatment-Experienced Patients), which compared once-daily to twice-daily dosing in treatment-experienced individuals. In that study, once-daily Prezista had equivalent efficacy to twice-daily dosing, provided that a person did not have detectable strains of the virus known to confer resistance to the drug.

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