Protease Progeny

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The newest PRODUCT on the protease inhibitor (PI) shelf arrived in September, when the FDA approved another much-needed treatment option for HIVers, Abbott Laboratories' Kaletra (formerly ABT-378). The drug is actually a combo of the new PI lopinavir and a small dose of Abbott's older PI, ritonavir (Norvir). The theory is that, as ritonavir does with other PIs, it can dramatically increase the body's blood levels of lopinavir. Trial results so far show strong viral suppression, even in PWAs with drug resistance. The med is available in both capsule and liquid form, and is approved for use in children as young as six months old. (HIVers using the "cotton-candy"–flavored liquid should note that the solution contains 42 percent alcohol.) Kaletra should be taken with food twice a day (three capsules or one teaspoon each dose). And like other PIs, it must be used in combination with nucleosides or NNRTIs. Some users may experience nausea, vomiting and diarrhea. As with most other PIs, Kaletra has been associated with above-normal blood sugar and cholesterol levels; there have also been some cases of pancreatitis (a dangerous inflammation of the pancreas) and elevated liver enzymes—so monitor your blood values regularly. Because of ritonavir's ability to cause many drug interactions (some potentially harmful), Kaletra takers should inform their doc about all other meds they are taking.

Abbott charges wholesalers $6,500 for an annual supply of Kaletra pills (most pharmacies charge about 10 percent more). That's $270 below the price of market leader nelfinavir (Viracept) and $400 less than Abbott's own ritonavir—and, the company says, lower than first planned. Last spring, after the Fair Pricing Working Group, a coalition of AIDS advocates, submitted a letter with 250 organizational sign-ons calling for a modest price, Abbott agreed to a rare pre-marketing dialogue with Working Group members, including several state directors of AIDS Drug Assistance Programs (ADAPs). The discussion convinced Abbott, according to Arthur Higgins, president of the firm's pharmaceutical division, that "for this product to gain rapid access to patients, we can't increase the financial burden on ADAPs." Project Inform's Marty Delaney, a Working Group member, comments: "While the price is still too high, it's a step in the right direction—the first time a new and better drug has been priced lower than the ones it's replacing." Abbott has a patient assistance program (800.222.6885) for those who can't afford Kaletra.

For more info on Kaletra, click on www.projinf.org/fs/lopinavir.html

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