Talking Tipranavir

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If promise alone could bring new HIV drugs to marker, tipranavir would have already been approved, bottled, and gracing the shelf of a pharmacy near you. This protease inhibitor (PI), originally developed by Pharmacia & Upjohn and recently purchased by Boehringer Ingelheim, is just entering a Phase II studies but is already being heralded as the next best thing for people with HIV at the end of their protease rope.

Tipranavir binds to HIV's protease gene differently from now the current PIs do and, according to recent lab studies, is active against some of the toughest drug-resistant strains of the virus. But the amount of tipranavir it takes to topple HIV in a test tube is difficult to achieve in humans; because the drug speeds up the biological pathway responsible for drug metabolism, high doses need to be taken up to three times a day. Knowing that fed-up med-takers will find it hard to swallow, Boehringer is fine-tuning a new formulation.

"Tipranavir will also need to be used in combination with low doses of ritonavir [Norvir]," explained Boehringer's head of virology and immunology, Stephen Polmar, MD, PhD. 'Once we've studied the new formulation and figured out its correct dose in combination with ritonavir, we can begin enrolling studies involving patients with multiple PI failures." At this time, studies involving folks with multiple PI resistance are not expected to begin until mid-2001; FDA approval won't likely be granted until 2003.

The delays in developments have come with a cost. "In addition to formulation problems the acquisition of the drug Boehringer from Pharmacia has set back the clinical trials timestable by at least a year," says Linda Grindberg, founder of the Foundation of AIDS and Immune Research (FAIR) in Los Angeles and member of the all-activist Coalition for Salvage Therapy. 'We hope these obstacles can be overcome quickly, but at this point, the drug's utility is all conjecture.

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