Playing for Time

August 1, 2001 By Tim Murphy

The promising new anti-HIV drug tenofovir DF (disoproxil fumarate) is ready for its FDA close-up. But has its maker kept HIVers who need it from getting up close?

California biotech Gilead Sciences was beaming last February when it released findings from its Phase III tenofovir trial. The upshot: In a study of some 550 HIVers with an average five-year history of HAART, viral load (originally between 400 and 10,000 copies) fell by an average of 75 percent by 24 weeks after the new drug was added to their regimen. Viral load also dropped below the "cutting edge" undetectable marker of 40 copies for 22 percent and the "old school" marker of 400 for 45 percent.

Such impressive results recommend tenofovir as a lead player in the most urgent treatment drama—combating the resistance that many pre-protease pill-poppers have to current cocktails. Plus, Gilead's new offering has demonstrated no major side effects—good news in light of the nasty kidney kinks that made the FDA nix Gilead's earlier adefovir.

Fast-forward to May 2001, when Gilead submitted tenofovir to the FDA for approval under its fast-track AIDS-drug program, which has a six-month-max review. All signs indicate smooth sailing for the drug, which is due to hit the market right before or just after the new year.

When it does, tenofovir (no brand name yet) will be the first in a new class of anti-HIV drugs called nucleotide analogs—not to be confused with the nucleosides, or NRTIs, such as AZT—that prevent HIV from entering the nucleus of healthy CD4s and producing new virus. It will have to be taken in a cocktail with an NRTI and at least one protease inhibitor or NNRTI.

Precisely because tenofovir is such a bright 11th-hour hope for HIVers facing treatment failure due to resistance, Gilead started an expanded-access program (in which pre-approval drugs are made available for free in emergency situations) last February—but one with Byzantine restrictions: patients had to have a viral load over 10,000 and a CD4 count under 100, unless their CD4s were up to 200, in which case they had to have had an AIDS-defining illness in the past 90 days, or to have failed on a two-PI or a PI/NNRTI combo. All this was very different from tenofovir expanded access in Europe, where a failing regimen was qualification enough.

Soon, Gilead's program came under fire from the Coalition for Salvage Therapy (CST), an ad hoc group of treatment activists founded in 1998. CST sent a letter accusing the biotech of deliberately limiting and slowing enrollment—to save money on drug giveaways. In response to Gilead's official

explanation that processing paperwork was time consuming, the CST missive clarified exactly what is at stake: the lives of “patients with few or no remaining options for treatment…[and those] whose disease has been allowed to progress to the point where ‘waiting for things to get sorted out’ with the program is simply not an option.”

Stung by bad publicity, Gilead dropped all requirements for the program except “for adults whose physicians feel they need a viable treatment regimen,” according to Gilead rep Amy Flood, who says that the program has been “steadily ramping up” to about 1,000 people. “We’ve worked closely with our CRO [contract research organization, which arranges such programs for pharmaceuticals] to make sure there are no steps that are a time hang-up,” she says. “We have an ongoing dialogue with CST and are open to feedback.”

The question of who got early tenofovir will be overshadowed when it wins FDA OK. But advocates call the flap a sad commentary on the current availability of investigative drugs for HIVers for whom the difference between life and death can be a vexing game of time.

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