POZ in Sydney: Notes from IAS 2007

August 8, 2007 By Tim Horn

Sydney's white beaches, blue harbors and renowned skyline sketched the backdrop for the fourth International AIDS Society Conference on HIV Pathogenesis, Treatment and Prevention (IAS 2007). A biannual event, IAS is one of the most important scientific gatherings of researchers, doctors and people living with HIV. This year's confab, which took place July 22 to 25, yielded a bumper crop of new data, shedding additional light on the advances and challenges we face in a world where 40 million people are living with the virus. While our full coverage is plentiful, here's a snapshot of some of the biggest news from this year's conference:

The Return of Early Treatment

Evidence is mounting to support the early initiation of HIV medications, at CD4 counts higher than current guidelines recommend. New research suggests that immune activation caused by HIV, even during the early stages of infection, can permanently damage the immune system and may be helping to produce the higher rates of heart disease, non-AIDS cancers, and liver and kidney problems among positive people. More tolerable medications are available today than back in the mid-1990s, when the "hit hard, hit early" eradication theory was in full swing. Whether early treatment with these newer meds will prolong survival and health is a question the nearly completed START (Strategic Timing of Antiretroviral Therapy) study will address.

A View From the Pipeline

Delegates crammed auditoriums to hear the latest on HIV drugs in development. Several experimental meds are showing advantages over current options, with something for treatment newbies and veterans alike:

Etravirine (TMC-125), Tibotec's non-nucleoside reverse transcriptase inhibitor, could win FDA approval by the end of this year. The twice-daily med is the first NNRTI contender to show promise for those with HIV resistant to NNRTIs Sustiva, Viramune and Rescriptor. In the Phase III DUET studies, etravirine combined with the protease inhibitor (PI) Prezista (darunavir) worked well for patients who'd been on many previous combos.

Sustiva (efavirenz), the most popular NNRTI for those starting their first HIV combo, may have met its match in another Tibotec non-nuke: Rilpivirine (TMC-278). It appears to work just as well for up to 48 weeks, with fewer central nervous system problems—including vivid dreams and muddled thinking—and lipid (fat) abnormalities.

Isentress (raltegravir), Merck's eagerly awaited integrase inhibitor, has already been shown to

perform well in treatment-experienced patients. Now, data show that Isentress worked safely and effectively in combination with Viread (tenofovir) and Epivir (lamivudine) in a treatment-newbie comparison with Sustiva/Viread/Epivir. Unfortunately, two case reports reviewed at the conference suggest that there is cross-resistance between Isentress and Gilead's elvitegravir, currently in Phase II studies—HIV that develops resistance to one will be able to resist the other as well.

Selzentry (maraviroc), Pfizer's CCR5-blocking entry inhibitor, may not be a reliable first-line option. While the med is likely to be a useful choice for some treatment-experienced patients—for whom it was recently approved—Sustiva edged it out in patients new to treatment. But might Selzentry team up with Sustiva or a potent PI in a nucleoside reverse transcriptase inhibitor (NRTI)–sparing regimen? Additional studies will tell.

In an early phase study, PRO 140, a CCR5 inhibitor, kept viral loads 90 percent below pretreatment levels for up to two to three weeks—after a single dose. While the drug can't be taken orally, its developer is working to replace its cumbersome intravenous formulation with a self-administered injection.

Starting or Switching With Current Options

To prove their worth, virtually all of the available NNRTIs and PIs have lined up for studies comparing them to Kaletra or Sustiva, the tried and true components of first-line regimens.

At last year's 16th International AIDS Conference, Norvir (ritonavir)-boosted Lexiva (fosamprenavir) performed well against Kaletra. At IAS 2007, Norvir-boosted Reyataz ran neck and neck against Norvir/Lexiva after 48 weeks of treatment: 75 percent of those in the Lexiva group, compared to 83 percent in the Reyataz group, had undetectable viral loads (below 50 copies), not a statistically significant difference, meaning that it could have been due to chance.

Early results from another clinical trial comparing Norvir-boosted Invirase (saquinavir) to Kaletra suggest that both options work well in patients starting therapy for the first time. While the rate of virologic failure (meaning viral loads rebounded in patients after being undetectable while on treatment) has thus far been higher in the Norvir/Invirase group, the six-month data show that Norvir-boosted Invirase is less likely than Kaletra to increase lipids.

Until recently, it was generally believed that the NRTIs were more alike than different, so it seemed safe to say that any two would do. But we now know that not all NRTIs are equal, with long-term follow-up data from one key study offering a case in point. After nearly three years (144 weeks), an ongoing Gilead-sponsored study has shown Truvada (tenofovir plus emtricitabine) to have safety and efficacy advantages over Combivir (zidovudine plus lamivudine) in patients starting HIV meds for the first time.

There was some good news for treatment veterans as well:

Results from a major study indicate that Norvir-boosted Prezista is more effective than Kaletra—once the gold standard option for patients with PI resistance—for treatment-experienced

patients.

Last but not least, a genetic screening test presented excellent results from a clinical trial, raising hopes that the assay may virtually eliminate the risk of the dreaded—and potentially life-threatening—hypersensitivity reaction to abacavir (found in Ziagen, Epzicom [Kivexa] and Trizivir). The test, which looks for the HLA-B*5701 gene, already widely used in Europe and Australia, is now available in the United States.

HIV Complications

Where antiretroviral (ARV) treatment is widely available, rates of opportunistic infections (OIs) and other classic AIDS diseases remain low. However, the risk of non-AIDS complications, including higher rates of skin cancer and kidney disease, remains a concern, especially among the growing number of people who are aging with HIV.

Of great interest, some studies showed that ARV treatment—despite its effects on lipid levels—may actually be lowering rather than raising the risk of cardiovascular disease. Data from the SMART study, comparing patients undergoing treatment interruptions to those remaining on their meds, suggest that the cardio risk is higher among those off therapy, even among patients with relatively high CD4 counts. Other intriguing study results showed that controlling viral load with treatment significantly improves blood vessel function in HIV-positive people.

While there were no groundbreaking discoveries in the area of lipodystrophy, expert Donald Kotler, MD, and Eric Daar, MD, talked with POZ about the HIV medications that likely cause it and some treatments that may reverse it. And delegates at IAS 2007 discussed the recent FDA decision to deny the approval of Serostim (recombinant human growth hormone) for HIV-associated adipose redistribution syndrome (HARS).

For the first time, a study report confirmed what some have suspected: that using crystal methamphetamine can reduce CD4 counts in HIV-positive people.

Prevention Inventions

Beyond the realm of treatment for those with HIV, biomedical strategies to help limit the spread of the virus were a major focus of IAS 2007. High on the list: pre-exposure prophylaxis (PrEP), vaginal and rectal microbicides, and male circumcision.

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