2010 Treatment News in Review (Part 1)

December 27, 2010 By Tim Horn

The first of a two-part glimpse at the most significant HIV/AIDS treatment news of 2010:

The Berlin Patient

We've actually known about this fella since 2008, when his case was unceremoniously reported in the form of a 3' X 5' poster tacked to a cork board at the 15th Conference on Retroviruses and Opportunistic Infections (CROI) in Boston in February 2008. It looked as if he'd been cured of the virus then, but it took a few more years of additional testing and a follow-up article published earlier this month by the medical journal *Blood* to confirm everyone's initial suspicions.

I don't envy Timothy Ray Brown, the American citizen identified as the Berlin Patient in a profile published by *Stern* magazine (and a man I had the pleasure of communicating with before his story was told). To get to where he is today, he had to endure three bouts of debilitating leukemia and two rounds of stem cell transplants requiring brutal (and potentially fatal) chemotherapeutic conditioning to wipe out his cancer-prone and HIV-susceptible immune system.

Make no mistake, this will never be the path to a cure for the overwhelming majority of people living with HIV. Even if Brown's results can be duplicated, the risks and toxicities he faced are simply too great for HIV-positive people not dealing with imminently fatal systemic cancer. And while biotechs are experimenting with gene modification of stem cells to sidestep the need for matching donors who just so happen to have an HIV-resistant immune system, it's not at all clear if a cure can be achieved without the need for pre-transplant conditioning.

But for the first time ever, we have proof that this virus can be beaten into complete submission and essentially eradicated from the human body. And if this isn't inspiration to help drive cure research forward--at least one group of activists is dedicating itself to this major cause--I don't know what is.

Prevention Performance

It was a huge year for HIV prevention news. In July, at the International AIDS Conference in Vienna, we learned the results of CAPRISA 004, which demonstrated a 39 percent reduction in the number of new HIV infections among women using a vaginal gel containing Gilead Science's nucleotide analogue tenofovir. And in November, the results of the iPrEX study made headlines, indicating a 44 percent reduction in the number of new infections among men who have sex with men (MSM) and transgender women who took daily Truvada (tenofovir/emtricitabine) tablets.

Encouraging news indeed, especially when considering the higher rates of efficacy among individuals in both studies who strictly adhered to their assigned preventive medication--54 percent fewer infections in CAPRISA and 73 percent fewer infections in iPrEx--along with the finding that no tenofovir (or emtricitabine) resistance was detected in any of the women or men who became infected while using these strategies.

So what's next? Hopefully, a lot more data from clinical trials. Can the moderate efficacy results reported thus far be improved upon? Which populations of women and MSM are most likely to benefit from

microbicides or oral pre-exposure prophylaxis (PrEP)? Will the study results be duplicated in other at-risk populations (e.g., oral PrEP for injection drug users and microbicides for rectal use in men)? Can adherence be improved? What's the real-world risk of drug resistance, or long-term side effects for that matter? Will these approaches be affordable?

Lots of questions, for sure, but it's already clear we're on the right track.

Drug Development Woes

Unfortunately, the hope (and hype) surrounding curative and HIV prevention research that dominated bandwidth during the second half of 2010 hardly nullifies the more sobering HIV treatment news that emerged during the first half of the year.

Avexa and Myriad Genetics suspended development of their experimental antiretrovirals this past spring. From press statements, it appears that both companies determined that their drugs--apricitabine (a nucleoside reverse transcriptase inhibitor) and bevirimat (a maturation inhibitor)--could not be brought profitably to market. While neither drug was perfect, some activists and researchers saw their failure as evidence of a paradox: That today's highly effective drugs are hurting the development of tomorrow's promising agents.

"The very incentives that got industry involved to develop HIV drugs are now working against us," Jay Lalezari, MD, the director of clinical research at Quest Clinical Research in San Francisco, told AIDSmeds for a June 22 web exclusive on the subject.

This news is most unsettling, especially for people living with HIV who can't claim success using today's current crop of HIV agents, given heir HIV has developed high-level drug resistance to virtually all available antiretrovirals. According to one estimate, at least 1,500 HIV-positive people in the United States are in this dire situation. And while this may be good news from a public health perspective, it is very bad news for the *growing number* of people whose lives depend on the development of innovative new therapies.

Fortunately, advocacy efforts are well under way to keep the pipeline dilated and flowing, as much as possible, for those in need.

Health Care: Reformed

After more than a year of contentious, sometimes vitriolic debate and political maneuvering, Congress succeeded in delivering approved health care reform bills to the desk of President Barack Obama. Though the drama is far from over--federal lawsuits and threats of legislative repeal of the law abound--President Obama and our elected representatives managed to put up a shield for millions of Americans, including many living with HIV, against the economic whims of the health insurance industry that have translated into life-and-death scenarios for many people.

With the signing of both the original and reconciliation bills last winter, President Obama affirmed health insurance as a right of every U.S. citizen. Indeed, the health care reform bill is the most significant expansion of federal health care oversight since Medicare was first enacted in 1965 and is the first piece of major social legislation to have been passed in decades.

The benefits of health care reform to people living with HIV are numerous. Insurance providers will no longer be able to discriminate against us--deny us coverage or charge us higher premiums--because we are living with HIV. Tax credits will be given to small- and medium-sized business to help provide HIV-positive employees with health insurance. A reduction (but not elimination) of the Medicare "donut hole" gap in prescription drug coverage. Community health clinics will be able to increase their services. And new health insurance options will be created for those of us with no or limited coverage.

Sadly, the bill lacked a strong public insurance option, which, according to numerous polls, was viewed favorably by the American public. The legislation also failed to incorporate the Early Treatment for HIV Act (ETHA), which would have extended Medicaid to all low-income people living with HIV, whether or not they have been classified as "disabled" in association with an AIDS diagnosis. And the final bill's reproductive rights restrictions, an eleventh hour gambit to rally Democratic support, were awful.

Yet despite these shortcomings, we are officially on a course to universal health care in the United States. I for one will sleep better knowing I can soon eliminate insurance discrimination from my list of fears and take solace in the fact that I am not one step away from financial ruin because I have HIV.

A Treatment for Lipodystrophy Approved (Finally)

We finally have a proven treatment for abnormal body fat accumulation, one of the hallmark signs of HIV-associated lipodystrophy. Egrifta was approved by the U.S. Food and Drug Administration on November 10, 2010.

The drug, which acts on pituitary cells in the brain to stimulate growth hormone production, works relatively well. According to Phase III studies, it reduces the amount of deep belly fat (visceral adipose tissue, or VAT) by 15 to 17 percent. While this won't magically translate into a return to trim physiques for many with lipodystrophy, it will certainly allow for a tightening of the belt by a notch or two. And, as was argued by community activists before an FDA review committee in May, the benefits or Egrifta treatment outweigh its risks--certainly much more so than with an earlier contender, Serostim, which presented a significant risk of glucose impairment and diabetes.

It has taken more than 12 years of drug research, development and advocacy--it was first suggested that growth hormone might reduce VAT in people with lipodystrophy at the 12th International AIDS Conference in Geneva in 1998--but, yes, we finally have a treatment for this disabling condition.

Prescriptions for Egrifta will start being filled in January 2011. Unfortunately, Egrifta is not expected to be cheap. Fortunately, EMD Serono--the Massachusetts-based company that will be selling the drug in the United States--is putting the finishing touches on what activists agree are generous co-payment and patient assistance programs for the insured and uninsured, respectively.

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