HIV Therapeutic Vaccine Shows Signs of Promise

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Vacc-4x, a therapeutic HIV vaccine being developed by Bionor Pharma, showed signs of promise in a recent clinical trial, according to results reported Wednesday, September 14, at the AIDS Vaccine 2011 conference in Bangkok. Though the majority of study volunteers in both the vaccine and placebo groups were able to stay off treatment by the end of the main 52-week study, Vacc-4x nearly doubled the chance of staying off antiretrovirals for more than a year in a subset of patients—a potentially important measure of therapeutic vaccine efficacy.

Therapeutic vaccines have long been eyed as a valuable contribution to the HIV treatment tool chest. Therapeutic vaccines—few of which have made it into advanced clinical trials—may have the potential to "functionally" cure HIV. By training the immune system to more effectively respond to the virus, it may be possible to push viral loads down to very low levels, thereby reducing the risk of health complications and slowing the ongoing spread of the virus while also reducing the need for antiretroviral (ARV) therapy.

The new data from the latest Vacc-4x trial, presented in Bangkok by Jan van Lunzen, MD, of the University Medical Center in Hamburg-Eppendorf, Germany, suggest that it may in fact be possible to teach the immune system to at least partially control HIV replication in some people living with the virus.

The study presented by van Lunzen's group enrolled 135 people living with HIV who were receiving ARV therapy and who had undetectable viral loads for at least six months and a pre-trial CD4 count no less than 400.

During the first 18 weeks of the study, 88 patients received six doses of Vacc-4x and 38 received placebo—in addition to their prescribed ARV regimens. Then ARV therapy alone was continued for another 10 weeks. At the beginning of week 28, provided that study volunteers had CD4 counts in excess of 350, all HIV meds were discontinued. And as long as a patient's CD4 count didn't fall below 350 or drop 50 percent or more, he or she remained off treatment through the final 52nd week of the study and into an extended follow-up period lasting another year.

A primary goal of the study was to compare the time ARV treatment needed to be resumed between the two study groups. Here, no significant difference was reported—across the board, when looking at all patients in the study, patients using placebo were no more likely to require

resumption of therapy, compared with those in the Vacc-4x group, between weeks 28 and 52. The majority of patients in both groups were able to remain off treatment for roughly six months.

A second goal of the study was to look at viral load levels among those who actually made it through week 52 without having to restart ARV treatment. Among the 56 patients in the Vacc-4x group who met this qualification, the average viral load at week 52 was roughly 20,000 copies. Among the 25 patients in the placebo group who didn't need to restart therapy, the average viral load at week 52 was approximately 40,000 copies. This difference between the two groups was statistically significant, meaning it was too great to have occurred by chance.

Van Lunzen's group also found that viral load "set points"—the plateau in HIV levels seen in the absence of treatment—were lower among those who received Vacc-4x and remained off treatment, at least at week 52. During this last half of the main 52-week study, the viral load set point averaged 13,525 among those who received Vacc-4x and remained off treatment, compared with an average viral load set point of 32,000 in the placebo group.

However, among those who remained off ARV treatment for at least a year—extending into the follow-up period—average viral load set points were similar in both groups: 14,000 among those who received Vacc-4x and 13,000 among those who received placebo.

Twenty-six of the original 88 patients, or 30 percent, of the patients randomized to receive Vacc-4x remained off ARV treatment for at least a year, compared with seven of the original 38 (18 percent) patients randomized to receive placebo.

Among those who had pre-ARV viral load information available and remained off treatment in the placebo group, the average viral load at week 52 was 0.8 log below pre-ARV therapy levels; among those who remained off treatment in the Vacc-4x group, the average viral load at week 52 was slightly more than a half-log below pre-ARV treatment levels. Only in in the Vacc-4x group who remained off treatment through week 52 was the viral load difference, compared with pre-ARV treatment levels, statistically significant.

These data are encouraging and suggest that at least some patients are nearly twice as likely to remain off ARV treatment for a prolonged period of time after receiving a series of Vacc-4x vaccinations. At least one researcher, quoted in an article by Bloomberg News, agrees but doesn't find the results "compelling," given that a detectable viral load—even if its lower than pre-treatment levels—is still concerning.

When asked about the Vacc-4x study results, Michael Saag, MD, of the University of Alabama at Birmingham, told Bloomberg: "Several years ago I would have been tremendously excited. Now I find it interesting, but not as compelling. The reason is that we have growing evidence that, even with no detectable virus among folks not on antiretroviral therapy, there is evidence of increased inflammation."

Bionor is continuing its development of Vacc-4x and recently announced a clinical trial in which the

vaccine will be paired with Revlimid, an anti-cancer drug produced by the Celgene Corporation, to help boost production of vital immune system cells.

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