HIV Vax in Advanced Trial Posts Promising 2-Year Results

Ninety-six–week data from the Phase I/IIa trial showed the mosaic vaccine was safe and offered a broad and durable immune response.

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The experimental HIV vaccine currently under investigation in an advanced trial has shown promising 96-week results from an earlier human study. The so-called mosaic vaccine offered a broad array of immune responses to the virus at this point, and such responses persisted up to a year after the last vaccination shot.

Findings from the Phase I/IIa randomized double-blind placebo-controlled APPROACH study were presented at the International AIDS Conference in Amsterdam (AIDS 2018). The study, which will monitor participants for five years, is evaluating the safety and tolerability as well as the immune-system-prompting effects of various HIV vaccine regimens.

Earlier results from APPROACH were presented a year ago at the 9th International AIDS Society Conference on HIV Science in Paris (IAS 2017). Fifty-two–week findings were just published in The Lancet.

The mosaic vaccine on which the study is based is intended to spur the immune system into protecting against an array of HIV clades, or subtypes. Primate-based research indicated that the most effective vaccine regimen tested in that study reduced the risk of SHIV, a simian version of HIV, by 94 percent per exposure and 67 percent after six exposures to the virus. This regimen also led to the best immune response in humans.

In the human trial, 400 participants received four vaccinations during the study's initial 48-week period, consisting of two doses of a prime vaccine followed by a pair of booster shots. The participants were randomized into eight groups of 50; each group received a different vaccine regimen, including one group that received a placebo. After the third vaccination, most participants showed signs of having developed immune responses to HIV, including those based in immune cells and those based in antibodies. The second booster shot only increased these responses.

Forty-six percent of the participants were female and 54 percent were male. The racial breakdown of the group was: 56 percent Black, 26 percent white and 16 percent Asian. Thirty-eight percent of

the participants were in the United States, 33 percent were in East Africa (15 percent in Rwanda and 18 percent in Uganda), 15 percent were in Asia (Thailand) and 14 percent were in South Africa.

Ninety-six–week follow-up data showed that the participants experienced no vaccine-related serious adverse health events. Nor did any of them experience vaccine-related Grade 3 or 4 adverse health events.

The vaccine regimen that the researchers identified as the most promising prompted a 100 percent immune response rate to the HIV protein gp140 and to HIV clade C for one year after the last vaccination shot. They also found that the immune response this regimen prompted in humans compared favorably to the response seen in primates given the same regimen. Furthermore, in humans, this regimen boasted responses to a wide range of HIV clades. Such responses were also durable through one year after the last vaccination shot. Lastly, the cellular-based immune response persisted in a high proportion of the participants for one year post-vaccination.

At the end of 2018, researchers launched the Phase IIb Imbokodo trial of the preferred vaccine regimen among women in Southern Africa, with a planned enrollment of 2,600 people.

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