HepB-CpG Vaccine Superior to Conventional Hepatitis B Vaccine for Nonresponding People With HIV

99% of people who received three doses of the HepB-CpG vaccine achieved protection against hepatitis B, compared to 81% receiving the conventional vaccine.

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ACTG CROI Presentation Demonstrates Superiority of HepB-CpG Vaccine Over Conventional Hepatitis B Vaccine Among People Living With HIV Who Have Not Previously Responded to Vaccination

Los Angeles -- ACTG, a global clinical trials network focused on HIV and other infectious diseases, today [March 8] made the oral presentation “HepB-CpG Vaccine is Superior to HepB-alum in People with HIV and Prior Vaccine Non-Response (A5379)” at the Conference on Retroviruses and Opportunistic Infections (CROI 2024) in Denver, Colorado. These data demonstrated that the HepB-CpG vaccine achieved up to 99% protection among people living with HIV who had previously not responded to conventional hepatitis B vaccines, a noteworthy increase compared to the protection achieved by conventional vaccines.

People living with HIV, especially those with lower CD4 counts, often do not develop protective antibodies after receiving conventional hepatitis B vaccines. The HepB-CpG (HEPLISAV-B) vaccine includes a TLR-9 agonist adjuvant (CpG 1018 adjuvant) and is known to achieve high protection against hepatitis B among people living with HIV, but until now there have been limited data about its protection among people living with HIV who have not responded to conventional hepatitis B vaccines.

“Hepatitis B remains a significant issue for people living with HIV, as having both viruses increases the likelihood of liver complications,” said ACTG Chair Judith Currier, MD, MSc, University of California Los Angeles. “Today’s presentation demonstrated extremely high rates of protection among those receiving the HepB-CpG vaccine and are likely to change clinical practice.”

A5379 is an ongoing, open-label study that compares protection of the HepB-CpG vaccine to the conventional hepatitis B vaccine among people living with HIV who had not responded to prior hepatitis B vaccination and are on antiretroviral therapy (ART). Of the 561 eligible participants

enrolled at 41 sites in 10 countries, 64% were male, 42% were Black, 35% were White, 17% were Asian, 22% were Hispanic, and the median age was 46 years old.

They were equally randomized to one of three groups, receiving either:

- Two doses of HepB-CpG intramuscularly at week 0 and week 4;
- Three doses of HepB-CpG intramuscularly at week 0, week 4, and week 24;
- Three doses of HepB-alum (conventional hepatitis B vaccine) intramuscularly at week 0, week 4, and week 24.

Today's analysis showed that 93% of participants receiving two doses of the HepB-CpG vaccine and 99% receiving three doses of the HepB-CpG vaccine achieved protection against hepatitis B, compared to 81% receiving three doses of the conventional hepatitis B vaccine. The most frequently reported adverse events were vaccination site pain, fatigue, headache, malaise, and myalgia. No unexpected safety issues were observed.

"In all of our HIV clinics, we see large numbers of people living with HIV who have been vaccinated against hepatitis B but show no evidence of a vaccine response," said Lead Author and Protocol Co-Chair Kristen Marks, MD, Weill Cornell Medicine. "Today's remarkable findings are game changing for those individuals and offer them a potential path toward protection against hepatitis B."

A5379 is led by Kenneth Sherman, MD, PhD, University of Cincinnati and Massachusetts General Hospital (Protocol Chair) and Dr. Marks. ACTG is led by Dr. Currier and Joseph J. Eron, MD, University of North Carolina (ACTG Vice-Chair). It is sponsored by the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (which also funds ACTG) under award numbers UM1 AI068636, UM1 AI107716, and UM1 AI068634. HEPLISAV-B was provided by Dynavax Technologies Corporation.

About ACTG

ACTG is the world's largest and longest running clinical trials network focused on HIV and other infectious diseases and the people living with them. It is funded by NIAID and collaborating NIH Institutes. Founded in 1987, ACTG conducts research to improve the management of HIV and its comorbidities; develop a cure for HIV; and innovate treatments for tuberculosis, hepatitis B, and emerging infectious diseases. It comprises thousands of dedicated researchers, staff, and community members who are pursuing research into novel treatments and cures for infectious diseases at 65 locations across four continents, with the ultimate goal of advancing science that meaningfully impacts the lives of the people we serve.

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