



Treatment: New Meds on Hold

Two studies were paused after some people receiving both drugs had decreases in their CD4 T-cell or absolute lymphocyte count.

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The Food and Drug Administration (FDA) has paused clinical trials of two investigational antiretrovirals due to safety concerns. The clinical hold affects studies of Gilead Sciences' GS-1720, a novel long-acting integrase inhibitor, and GS-4182, a prodrug of the capsid inhibitor lenacapavir. The WONDERS-1 trial is evaluating a weekly oral combination of GS-1720 plus GS-4182 as a switch option for people currently on HIV treatment, while WONDERS-2 is testing the combo for people starting treatment for the first time. The studies were paused after some people receiving both drugs had decreases in their CD4 T-cell or absolute lymphocyte count. This side effect has not been seen among people using lenacapavir for HIV treatment or PrEP. In 2021, the FDA put a clinical hold on Merck's islatravir after some trial participants experienced white blood cell declines, but this no longer occurred when studies resumed using lower doses. Gilead like-wise will analyze the adverse events in the WONDERS trials with the hope of moving forward with GS-1720 and GS-4182.

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