Early Trial of Gilead's HIV Capsid Inhibitor Supports 3-Month Dosing

The antiretroviral GS-6207 is injected under the skin and would need to be combined with other meds to fully suppress HIV.

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Gilead Sciences' investigational capsid inhibitor GS-6207 showed promise in an early study as a new long-acting form of HIV treatment that could be dosed only every three months. The drug proved safe and well tolerated in a small study including HIV-negative participants.

While GS-6207 was administered via subcutaneous (under the skin) injection in the study, Gilead is attempting to develop an oral formulation of the antiretroviral (ARV).

Capsid inhibitors, a new class of ARV, interfere with the breakdown of the capsid, which shelters HIV's genetic material, after the virus enters an immune cell. Medications in this class—GS-6207 is the first—also prevent the assembly of the capsid during the production of new viruses after HIV has incorporated its RNA into a cell's genome.

Jennifer E. Sager, PhD, a clinical pharmacologist at Gilead presented interim findings from a Phase I randomized, blinded, placebo-controlled study that tested the safety, tolerability and metabolization of different doses of GS-6207. The study, which is ongoing and remains blinded, included 40 HIV-negative participants who were randomized into four groups and further randomized four to one to receive different doses of GS-6207 in a single subcutaneous injection or a placebo injection.

The groups were staggered such that those who received the lower doses—participants received 30 milligrams, 100 mg, 300 mg or 450 mg of GS-6207—received the drug first. Thus far, the participants in the 30 mg have been followed for 20 weeks while those in the 450 mg arm are bringing up the rear with just four weeks of follow-up.

The study has seen no deaths, serious adverse health events or grade 3 or 4 adverse health events. Most adverse events were mild and resolved in time.

After analyzing the levels of GS-6207 in the blood over time, Sager and her colleagues resolved that a dose of 100 mg or greater was sufficient for dosing the medication every three months.

Gilead has already begun a Phase Ib study of GS-6207 in HIV-positive participants.

Meanwhile, in a separate study, also presented at this year's Conference on Retroviruses and Opportunistic Infections (CROI 2019), Gilead researchers studied GS-6207 in a laboratory experiment and found that it was greater than 100 times more potent than commonly prescribed antiretrovirals. Additionally, when combined with the ARVs tenofovir alafenamide (TAF), Sustiva (efavirenz), Tivicay (dolutegravir) or Prezista (darunavir), GS-6207 worked synergistically to suppress HIV. The capsid inhibitor was also fully potent against a broad range of strains of HIV that are resistant to other classes of ARVs.

To read a press release about the studies, click here.

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