Islatravir Shows Double Potential

Merck’s experimental HIV drug proves effective and well tolerated

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Merck’s investigational antiretroviral (ARV) islatravir has shown promise both for treatment and prevention of HIV in a pair of studies. The drug, formerly known as MK-8591, is a nucleoside reverse transcriptase translocation inhibitor, belonging to a new ARV class.

Touting the drug’s benefits, Jean-Michel Molina, MD, of Hôpital Saint-Louis in Paris, who led the study of its use as treatment, says, “Islatravir combines a high potency at low doses even against resistant viruses, with a high genetic barrier to resistance, a long intracellular half-life and so far a good tolerability profile.”

The treatment study included 121 first-timers to ARVs who were randomized to start a regimen of one of four doses of islatravir—between 0.25 milligrams and 2.25 mg—plus Pifeltro (doravirine) and lamivudine, or to receive Delstrigo (doravirine/tenofovir disoproxil fumarate/lamivudine). If those who received islatravir had an undetectable viral load at 24 weeks, they dropped the lamivudine.

The regimen of islatravir plus Pifeltro proved safe and suppressed HIV at a high rate, regardless of the islatravir dose. The two-drug regimen was comparable in efficacy to Delstrigo.

The researchers concluded that Phase III trials of islatravir plus Pifeltro are warranted.

A separate 12-week, placebo-controlled trial that included 16 HIV-negative volunteers suggested that a matchstick-sized islatravir-infused implant likely has the potential to work as pre-exposure prophylaxis (PrEP) for an entire year before it requires replacement. Levels of the drug reached and remained above the threshold previously found to protect against a simian form of HIV in monkey studies.

A Phase II trial of an oral once-monthly dose of islatravir for HIV prevention is launching this fall.

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