HIV Regimen of Islatravir and Pifeltro Doesn’t Appear to Affect Kidney Function

A mid-stage trial of the experimental drug islatravir plus Pifeltro did not see notable shifts in measures of kidney function.

October 7, 2020 By Benjamin Ryan

People who started their first HIV treatment regimen with the experimental antiretroviral islatravir plus Pifeltro (doravirine) in a recent mid-stage trial did not see substantial shifts in indicators of their kidney function.

Islatravir is the first nucleoside reverse transcriptase translocation inhibitor under investigation.

Frank A. Post, MBBS, PhD, of King’s College Hospital NHS Foundation Trust in London, presented findings from the 96-week, double-blind Phase II trial at the virtual HIV Drug Therapy Glasgow meeting.

The study enrolled 121 people with HIV who had never been treated for the virus. They were randomized to receive daily islatravir at a dose of either 0.25 milligrams, 0.75 mg or 2.25 mg plus Pifeltro and lamivudine or to receive the fixed-dosed combination tablet Delstrigo (doravirine/tenofovir disoproxil fumarate/lamivudine).

Those who received islatravir and achieved a viral load below 50 between weeks 20 and 48 of the study were taken off lamivudine at their next study visit. After that, they continued on their initial islatravir dosage plus Pifeltro until at least week 60 and then switched to 0.75 mg of islatravir plus Pifeltro by week 84.

Efficacy results at week 96 were also presented at the Glasgow meeting.

At weeks 48 and 96 of the study, median changes in serum creatinine and estimate glomerular filtration rate (eGFR)—measures of kidney function—were minimal in all the treatment groups.

Two people, each of them on 0.25 mg of islatravir, had isolated instances of a 0.5 mg per deciliter increase in their serum creatinine. None had a 1.0 mg per dL or greater increase in serum creatinine or a doubling of this measure. Twelve percent of the participants receiving islatravir and

15% of those receiving Delstrigo experienced a greater than 30% reduction in their eGFR; most of these shifts were transient.

Four percent of those in the islatravir group experienced an eGFR below 60 milliliters per minute per 1.73 meters squared—an indication of compromised kidney function. None of the participants discontinued treatment due to kidney-related issues.

The study authors will continue to examine kidney safety measures in the Phase III program investigating islatravir plus Pifeltro.

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