FDA Approves New HIV Combo Pill Idvynso

Once-daily doravirine/islatravir single-tablet regimen is a switch option for people with viral suppression.

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On April 21, the Food and Drug Administration (FDA) approved Idvynso, Merck's once-daily single-tablet regimen containing doravirine and islatravir, as a replacement for people currently on treatment with an undetectable viral load. Late-stage clinical trials showed that Idvynso maintains viral suppression when people switch from a standard daily oral antiretroviral regimen.

Doravirine (sold alone as Pifeltro) is a next-generation non-nucleoside reverse transcriptase inhibitor with a high barrier to resistance. Islatravir is a first-in-class nucleoside reverse transcriptase translocation inhibitor. As the first complete regimen without an integrase inhibitor or tenofovir, Idvynso offers a new type of treatment option.

"Advances in HIV treatment mean more people living with HIV are living longer—a remarkable achievement," Carl Baloney Jr., president and CEO of AIDS United, said in a Merck news release. "People aging with HIV face additional health challenges, including managing multiple chronic conditions and medications at the same time. It is essential that management of HIV considers these factors in addition to virologic suppression when choosing an HIV treatment regimen."

As reported at the Conference on Retroviruses and Opportunistic Infections (CROI) in February, results from two Phase III trials showed that people with viral suppression who switched to Idvynso from either Gilead Sciences' Biktarvy (bictegravir/tenofovir alafenamide/emtricitabine) or various other two- or three-drug oral regimens were as likely to maintain an undetectable viral load as those who stayed on their current combination. In the first study, 89% of people randomly assigned to Idvynso maintained viral suppression at 96 weeks, compared with 90% of those who stayed on Biktarvy. Treatment outcomes were similar for men and women and across race and age subgroups, including people ages 65 and older.

Treatment was safe and generally well tolerated, and side effects were uncommon. Kidney function biomarkers remained stable in the Idvynso group but declined in the comparison groups. (Kidney toxicity is a possible side effect of tenofovir disoproxil fumarate but less so with the newer tenofovir alafenamide in Biktarvy.) Further data presented at last year's European AIDS Conference showed that Idvynso was associated with minimal changes in weight or body

composition and had no clinically meaningful effects on lipid or blood sugar levels or insulin resistance.

Importantly, study participants did not experience decreases in their white blood cell counts. Development of islatravir hit a snag in 2021 when some people in earlier trials saw a decline in their CD4 T-cell or total lymphocyte counts, but scientists determined that the doses used in those studies were too high. This side effect has not been seen using the lower 0.25 milligram dose in Idvynso.

The FDA approved Idvynso for adults on stable antiretroviral treatment with an undetectable viral load (below 50 copies) who have no history of virological treatment failure and no known viral mutations associated with resistance to doravirine. The recommended dose is one tablet taken once daily with or without food.

Idvynso is a complete regimen and should not be used with other antiretroviral medications. It is also contraindicated with drugs that are strong inducers of cytochrome P450 3A (CYP3A), an enzyme that metabolizes many medications, as this could reduce its effectiveness. Neither doravirine nor islatravir are active against hepatitis B virus (HBV), unlike tenofovir. Treatment guidelines recommend that people with HIV/HBV coinfection should receive medications that are active against both viruses.

The wholesale cost of Idvynso is $4,455 a month, according to Managed Healthcare Executive, comparable to the cost of Biktarvy. Merck offers support for people who are prescribed Idvynso, including information about individual insurance coverage, out-of-pocket costs, co-pay assistance and how they can access treatment through the Merck Access Program (call 877-709-4455 or visit https://www.merckaccessprogram.com).

Idvynso is also being developed as a first-line treatment option. Another study presented at CROI showed that Idvynso worked as well as Biktarvy for people starting HIV treatment for the first time. At 48 weeks, 92% of people randomly assigned to Idvynso and 91% of those on Biktarvy had an undetectable viral load.

What's more, islatravir has a long half-life in the body, making it a potential candidate for longer-acting treatment. Merck is testing a once-weekly oral regimen of islatravir and its investigational non-nucleoside reverse transcriptase inhibitor ulonivirine in a Phase II trial (NCT06891066). Merck and Gilead are collaborating on the development of a once-weekly pill containing islatravir and Gilead's capsid inhibitor lenacapavir (Sunlenca); two Phase III trials are underway (ISLEND-1/NCT06630286 and ISLEND-2/NCT06630299).

Click here for full prescribing information for Idvynso.
Click here for more news about HIV treatment.
