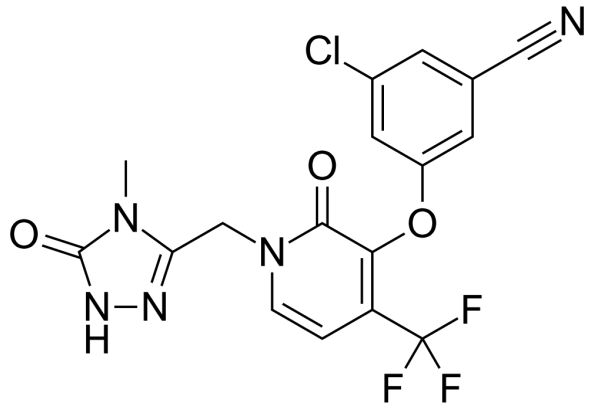
Brand Name: Pifeltro
Generic: doravirine
Type: small molecule
Year Accepted/Phase: 2018

Mechanism:

Doravirine is a non-nucleoside reverse transcriptase inhibitor (NNRTI). It works by binding to the reverse transcriptase enzyme, which is critical for the replication of HIV-1. By inhibiting reverse transcriptase, doravirine prevents the virus from converting its RNA into DNA, thereby blocking the replication of HIV-1 in infected cells.

Chemical Structure:



Indication:

Pifeltro (doravirine) is indicated for the treatment of HIV-1 infection in adult patients.

Clinical trials:

DRIVE-FORWARD (Phase III)
Pubmed: https://pubmed.ncbi.nlm.nih.gov/31740348/
Purpose: Evaluate the efficacy and safety of doravirine compared to darunavir/ritonavir in treatment-naive adults with HIV-1 infection.
Dates: Conducted from 2014 to 2016.
Results: After 48 weeks, 84% of patients in the doravirine group achieved viral suppression (HIV-1 RNA <50 copies/mL) compared to 80% in the darunavir/ritonavir group. Doravirine was generally well-tolerated with fewer adverse effects related to lipid levels compared to darunavir/ritonavir.
Impact: This trial demonstrated that doravirine was non-inferior to darunavir/ritonavir in achieving viral suppression, supporting its use in treatment-naive adults.

DRIVE-AHEAD (Phase III)
Pubmed: https://pubmed.ncbi.nlm.nih.gov/33336698/
Purpose: Compare the efficacy and safety of doravirine/lamivudine/tenofovir disoproxil fumarate (DOR/3TC/TDF) versus efavirenz/emtricitabine/tenofovir disoproxil fumarate (EFV/FTC/TDF) in treatment-naive adults with HIV-1 infection.
Dates: Conducted from 2014 to 2016.
Results: At week 48, 84% of patients in the DOR/3TC/TDF group achieved viral suppression compared to 81% in the EFV/FTC/TDF group. The DOR/3TC/TDF group experienced fewer neuropsychiatric adverse events compared to the EFV/FTC/TDF group.
Impact: The results showed that doravirine-based therapy was non-inferior to efavirenz-based therapy with a better side effect profile, particularly regarding neuropsychiatric symptoms.

DRIVE-SHIFT (Phase III)
Pubmed: https://pubmed.ncbi.nlm.nih.gov/30985556/
Purpose: Evaluate the efficacy and safety of switching to doravirine/lamivudine/tenofovir disoproxil fumarate from a stable antiretroviral regimen in virologically suppressed adults.
Dates: Conducted from 2015 to 2017.
Results: At week 48, 93.7% of patients who switched to DOR/3TC/TDF maintained viral suppression compared to 94.6% in those who continued their baseline regimen. The switch to DOR/3TC/TDF was generally well-tolerated, with fewer lipid abnormalities observed.

Impact: This trial supported the use of doravirine as part of a switch regimen in virologically suppressed adults, demonstrating maintenance of viral suppression and improved lipid profile.