



# HIV Clinical Program Overview

Merck has been with the HIV community since the early days of the epidemic, with more than 35 years of research and discovery leading to scientific breakthroughs that have helped change HIV treatment.

We are pushing the bounds of science to research areas of unmet medical need in HIV prevention and treatment, and our investigational HIV pipeline includes:

- **Islatravir (MK-8591):** an investigational nucleoside reverse transcriptase translocation inhibitor (NRTTI) under evaluation with other HIV medicines for the treatment of HIV-1
  - **MK-8591A:** an oral once-daily combination of doravirine and islatravir (DOR/ISL) in Phase 3 development
  - **MK-8591D:** an oral once-weekly combination of islatravir and Gilead’s lenacapavir in Phase 2 development
- **MK-8527:** a novel oral once-monthly NRTTI candidate that is in Phase 2 development for HIV-1 pre-exposure prophylaxis (PrEP)

| Treatment Development Program |                                      | PrEP** Development Program |                    |
|-------------------------------|--------------------------------------|----------------------------|--------------------|
| Daily Oral Treatment Options  | doravirine / islatravir<br>Phase 3   | Monthly Oral PrEP Options  | MK-8527<br>Phase 2 |
| Weekly Oral Treatment Options | islatravir / lenacapavir*<br>Phase 2 |                            |                    |

\*Collaboration with Gilead  
\*\*Pre-exposure Prophylaxis

| Development Program   | Study Number & Link                                      |
|---|--|
| <b>Doravirine / Islatravir</b>  |  |
| A Switch to Doravirine/Islatravir (DOR/ISL) in Participants With Human Immunodeficiency Virus Type 1 (HIV-1) Who Are Virologically Suppressed on Antiretroviral Therapy (ART) (MK-8591A-051)                                  | <a href="#">NCT05631093</a>                              |
| A Switch to Doravirine/Islatravir (DOR/ISL) in Participants With Human Immunodeficiency Virus Type 1 (HIV-1) Who Are Virologically Suppressed on Bictegravir/Emtricitabine/Tenofovir Alafenamide (BIC/FTC/TAF) (MK-8591A-052) | <a href="#">NCT05630755</a>                              |
| DOR/ISL in HIV-1 Antiretroviral Treatment-naïve Participants (MK-8591A-053)   | <a href="#">NCT05705349</a>                              |
| A Study of Doravirine/Islatravir (DOR/ISL, MK-8591A) for the Treatment of Human Immunodeficiency Virus 1 (HIV-1) Infection in Participants Who Previously Received DOR/ISL (MK-8591A-054)                                     | <a href="#">NCT05766501</a>                              |
| Open-label, Follow-up of Doravirine/Islatravir for Participants With Human Immunodeficiency Virus -1 (HIV-1) Infection (MK-8591A-033)   | <a href="#">NCT04776252</a>                              |
| <b>Islatravir / Lenacapavir (in collaboration with Gilead)</b>  |  |
| Study Evaluating the Safety and Efficacy of Islatravir in Combination With Lenacapavir in Virologically Suppressed People With HIV  | <a href="#">NCT05052996</a><br>(Gilead is study sponsor) |
| <b>MK-8527</b>  |  |
| MK-8527 Single-Dose Trial in HIV-1 Infected Participants (MK-8527-004)  | <a href="#">NCT05494736</a>                              |
| Safety and Pharmacokinetic Study of Oral MK-8527 QM in Participants at Low-Risk for HIV-1 Infection (MK-8527-007)   | <a href="#">NCT06045507</a>                              |