

Amy E. Colson¹, Gordon E. Crofoot², Peter J. Ruane³, Moti N. Ramgopal⁴, Alexandra W. Dretler⁵, Ronald G. Nahass⁶, Gary I. Sinclair⁷,
Mezgebe Berhe⁸, Fadi Shihadeh⁹, Shan-Yu Liu⁹, Stephanie Klopfer¹⁰, Sharline Madera⁹, Hadas Dvory-Sobol⁹, Martin S. Rhee⁹, Elizabeth G. Rhee¹⁰,
Conor Moran^{11*}, Jared Baeten⁹, Joseph Eron¹²

¹Community Resource Initiative, Boston, Massachusetts, USA; ²The Crofoot Research Center, Houston, Texas, USA; ³Ruane Clinical Research, Los Angeles, California, USA; ⁴Midway Immunology & Research Center, Fort Pierce, Florida, USA; ⁵Infectious Disease Specialists of Atlanta, Decatur, Georgia, USA; ⁶IDCare, Hillsborough, New Jersey, USA; ⁷Prism Health North Texas, Dallas, Texas, USA; ⁸North Texas Infectious Diseases Consultants, Dallas, Texas, USA; ⁹Gilead Sciences, Foster City, California, USA; ¹⁰Merck & Co., Inc., Rahway, New Jersey, USA; ¹¹Gilead Sciences Ireland UC, Dublin, Ireland; ¹²University of North Carolina, Chapel Hill, North Carolina, USA. *Listed as author for presentation purposes only with permission of all authors

Weekly oral ISL+LEN maintained high rates of virologic suppression (94.2%) at Week 48 in people with HIV who were virologically suppressed

— No participant on ISL+LEN had HIV-1 RNA ≥ 50 c/mL at Week 48 or at study discontinuation

Weekly oral ISL+LEN was well tolerated, as evidenced by the absence of any treatment-related Grade ≥ 3 AEs or serious AEs

There were no between-group differences in CD4+ T-cell or lymphocyte count changes from baseline through Week 48

There were no between-group differences in body weight or BMI changes from baseline through Week 48

Participants demonstrated high rates (99.2%) of adherence to oral weekly ISL+LEN

The Phase 2 results support advancing the weekly oral ISL+LEN regimen to Phase 3 trials: ISLEND-1 and ISLEND-2 (NCT06630286; NCT06630299)

ISL + LEN has the potential to become the first oral weekly complete regimen for the treatment of HIV-1 infection

- Once-weekly (QW) oral antiretrovirals (ARVs) have the potential to address pill fatigue and adherence challenges related to daily oral treatment for HIV-1 infection¹
- Islatravir (ISL) is a nucleoside reverse transcriptase translocation inhibitor²
 - Prior ISL studies have shown dose/exposure-related decreases in CD4+ T-cell and lymphocyte counts³
 - Pharmacokinetic modelling indicates such declines are not expected with the 2 mg dose chosen for this study⁴
- Lenacapavir (LEN) is a first-in-class capsid inhibitor⁵
- Both ISL and LEN have multiple mechanisms of action, potent ARV activity at low doses, and long half-lives ($t_{1/2}$) that allow for QW dosing^{6-9,8,4}
- Primary endpoint data (Week 24) from the current, ongoing Phase 2 study (NCT05052996) were previously reported — Most participants (94.2%) maintained viral suppression in the QW oral ISL+LEN group⁹
 - ⁴LEN $t_{1/2}$ = 10–12 days; ⁸ISL-triphosphate $t_{1/2}$ = 7–9 days.

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Correspondence: Dr Amy Colson, acolson@roath.org.

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*Adherence (%) calculated as: (total pills taken / total pills prescribed) x 100. Denominator for the adherence rate category summaries was based on number of participants who returned at least 1 bottle and had calculable adherence. For ISL, 2 capsules taken (1 mg each) was considered as a pill.
B/F/TAf, bictegravir/emtricitabine/tenofovir alafenamide; ISL, islatravir; LEN, lenacapavir.