Results From the ISLEND-1 Study After 48 Weeks: Comparing ISL/LEN Once a Week With B/F/TAF Once a Day in People With HIV

Jürgen K Rockstroh (University Hospital Bonn, Bonn, Germany)
Moti N Ramgopal (Midway Immunology and Research Center, Fort Pierce, FL, USA)
Adrian Curran Fabregas (Vall d'Hebron University Hospital, Barcelona, Spain)
Malcolm Hedgcock (Spectrum Health, Vancouver, BC, Canada)
Kimberly A Workowski (Emory University, Atlanta, GA, USA)
Sylvie Ronot-Bregigeon (Hôpital Sainte-Marguerite, Aix-Marseille Université, Marseille, France)
Isabel Cassetti (Helios Salud, Buenos Aires, Argentina)
Cynthia Brinson (Central Texas Clinical Research, Austin, TX, USA)
Samir K Gupta (Indiana University School of Medicine, Indianapolis, IN, USA)
Chien-Ching Hung (National Taiwan University Hospital Yunlin Branch, Yunlin, Taiwan)
Mark O'Reilly (East Sydney Doctors, Darlinghurst, NSW, Australia; Taylor Square Private Clinic, Surry Hills, NSW, Australia)
Jihad Slim (New York Medical College, Valhalla, New York, NY, USA)
Hiroyuki Gatanaga (Japan Institute for Health Security National Center for Global Health and Medicine, Tokyo, Japan)
Peter Shalit (Peter Shalit MD and Associates, Seattle, WA, USA)
Shan-Yu Liu, Fadi Shihadeh, Renée-Claude Mercier, Hadas Dvory-Sobol, Devi SenGupta, Martin S Rhee (Gilead Sciences, Inc., Foster City, CA, USA)
Stephanie O Klopfer, Nidhi Patel, Melissa Shaughnessy, Cyril Llamoso (Merck & Co, Rahway, NJ, USA)
Chloe Orkin (Queen Mary University of London, London, UK)

Background

ISL/LEN is a new drug combination being studied for the treatment of HIV. It combines the medicines islatravir (ISL) and lenacapavir (LEN) in a single tablet taken once a week.

B/F/TAF is an HIV treatment that is already available. It combines the medicines bictegravir (B), emtricitabine (F), and tenofovir alafenamide (TAF) in a single tablet once a day.

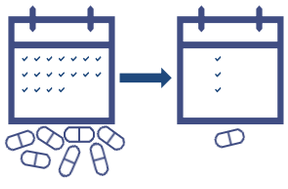
A once-weekly HIV treatment may be helpful for people who find it difficult to take medicine every day or prefer not to receive injections. In the ongoing ISLEND-1 study, researchers are comparing how well ISL/LEN works and how safe it is compared with B/F/TAF in people who were taking B/F/TAF before joining the study.

This summary presents the main findings from ISLEND-1 after 48 weeks, which was the study's halfway point.

Why did researchers do this analysis?

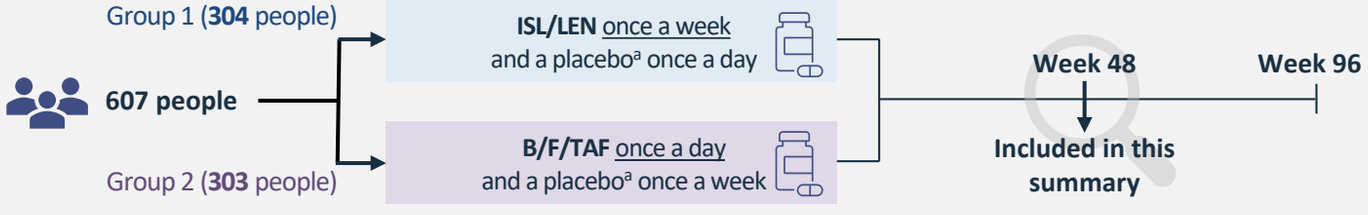
Researchers want to know how well ISL/LEN taken once a week works and how safe it is when compared with B/F/TAF taken once a day.

Switch from daily to weekly treatment



Who took part in the study and how was the treatment studied?

ISLEND-1 included **607 adults with HIV** from 106 sites around the world. These people already had very low levels of HIV in their blood while taking B/F/TAF once a day.



[a]Participants in each group were also given a placebo (a tablet without medicine), which looked like the real medicine from the other group. Researchers designed the study this way so that the doctors did not know which treatment they gave, and the participants did not know which treatment they received.

Study participants

- **15% aged at least 65 years**
- **46% White**
- **31% Black**
- **11% Asian**
- **79% male and 21% female at birth**
  - 98% cisgender
  - 2% transgender, gender nonbinary, or gender nonconforming

This summary looks at how well the treatments worked and how safe they were after 48 weeks. Researchers looked at the following questions:

How many participants had **undetectable HIV levels**?
- If HIV levels were detectable and high enough, a test was done to check if that person's HIV had developed resistance to treatment

How many **CD4 cells** and **lymphocytes** did participants have compared with at the start of the study?

How many participants had **side effects** (that may or may not have been related to the treatment)?

HIV levels
If an HIV treatment works, the amount of virus in a person's blood drops to levels that are too low to be measured precisely by routine tests. This is also known as undetectable.

Resistance
HIV can develop changes (mutations) that cause resistance to some medicines, so that the medicine can no longer control the virus. Measurable HIV levels may be a sign of resistance in some people.

CD4 cells and lymphocytes
HIV attacks the body's immune system. It destroys white blood cells called lymphocytes, including CD4 cells that help the body fight infections. Higher numbers of CD4 cells and lymphocytes in the blood mean the immune system is working better.

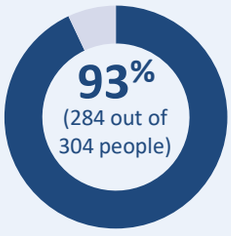
GILEAD

Results From the ISLEND-1 Study After 48 Weeks: Comparing ISL/LEN Once a Week With B/F/TAF Once a Day in People With HIV

What were the results of the study?

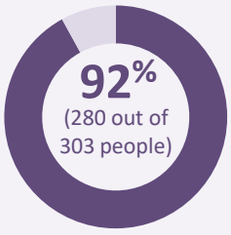
How many participants had undetectable HIV levels after 48 weeks?

ISL/LEN once a week:



0 participant had detectable HIV levels and 20 had no data

B/F/TAF once a day:



1 participant had detectable HIV levels and 22 had no data

Over 90% of participants who took ISL/LEN or B/F/TAF had undetectable HIV at Week 48. This means the virus was suppressed. The treatments worked similarly well.

The 1 participant taking B/F/TAF who had detectable HIV did not have a high enough level of HIV in their blood to be able to test for resistance.

How did the treatments affect the numbers of CD4 cells and lymphocytes?

The levels of CD4 cells and lymphocytes remained stable in both treatment groups over 48 weeks. No one had to stop the study because these cell levels became too low.

How many participants in the study experienced side effects?

The total number of participants who had side effects was the same (79%) in both treatment groups. Side effects thought to be related to treatment were similar for both treatments.

41 out of 304 participants (13%) had side effects thought to be related to ISL/LEN

The most common side effects thought to be related to ISL/LEN were:

- Feeling sick (nausea; in 9 participants)
- Headache (in 9 participants)

40 out of 303 participants (13%) had side effects thought to be related to B/F/TAF

For comparison, side effects thought to be related to B/F/TAF were:

- Feeling sick (nausea; in 10 participants)
- Headache (in 8 participants)

A similar number of participants stopped their study treatment because of side effects[a]

6 out of 304 participants (2%) stopped taking ISL/LEN because of side effects

5 out of 303 participants (2%) stopped taking B/F/TAF because of side effects

- 1 participant had a serious side effect, a skin rash, that was thought to be related to their treatment
- 1 participant had a hepatitis B infection. They had not received a hepatitis B vaccine before starting the trial
- There were no deaths over 48 weeks

[a]These side effects were low levels of platelets in the blood (thrombocytopenia; 1 person), muscle and joint pain (myalgia and arthralgia; 1 person), a severe mental health condition (psychotic disorder; 1 person), kidney problems and inflammation of the pancreas (acute kidney injury and pancreatitis; 1 person), confusion (1 person), memory impairment (1 person), hair loss (alopecia; 1 person), rash with discolored areas and small raised bumps (maculopapular rash; 1 person), arthralgia (1 person), brain fog and reduced attention (1 person), and new hepatitis B infection (1 person). The treatment group is not named for these side effects as the study is still blinded (the doctor does not know which treatment they gave, and the participants do not know which treatment they received).

Please scan the QR code to either:

- View or download a copy of this summary online
- View or download the original scientific presentation on which this summary is based

Conclusions

After 48 weeks of the ISLEND-1 study, researchers found that:

- ISL/LEN taken once a week was as effective as B/F/TAF taken once a day at keeping HIV levels very low. This means that the virus remained suppressed
- CD4 cell and lymphocyte levels stayed stable, with no important changes in either treatment group
- Most participants tolerated ISL/LEN well. Very few participants stopped treatment because of side effects

These results show that ISL/LEN taken once a week may be an effective treatment for HIV.

Reference: Rockstroh JK, et al. AIDS 2026, Presentation OAB1406LB

Acknowledgments: The authors are grateful to the individuals who participated in the study, their partners and families, the participating ISLEND-1 study investigators and their study teams. This study was funded by Gilead Sciences, Inc. Medical writing support was provided by Aspire Scientific Ltd (Manchester, UK) and was funded by Gilead Sciences, Inc. The authors thank the two plain-language expert reviewers for their considered review.

GILEAD