

# Evaluating how well BIC+LEN works for people with HIV switching from complex treatment regimens

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This is a plain language summary of a scientific presentation that was originally presented by Dr Segal-Maurer (oral presentation). This plain language summary only presents selected data and is not intended to replace the full oral presentation. Please refer to the oral presentation (available by QR code at the end of this document) for full details.

## Background

BIC+LEN is an HIV treatment where the medicines bicitegravir (BIC) and lenacapavir (LEN) are taken together. BIC+LEN is being developed so that in the future it can be taken as a single tablet.

People are more likely to take their medicine as prescribed if they only need to take one tablet, once a day. However, some people require more complex regimens (ones that involve multiple tablets, or dosing more than once a day, or a mixture of tablets and injectables). This may be because other treatments don't work (due to the virus having resistance) or because they have side effects. BIC+LEN may be an alternative to complex treatment regimens or to other single-tablet HIV treatments.

**This summary from the ARTISTRY-1 study looks at how well BIC+LEN works and how safe it is in people switching from a complex treatment regimen.**

## Why did researchers do this analysis?

- ARTISTRY-1 is a Phase 2 (mid-stage) study aiming to see how well BIC and LEN work in combination, and to see whether a bigger study is needed to look at a single-tablet version
- Researchers in the study have already looked at the results after people had taken BIC+LEN for 24 weeks
- In this longer-term analysis from ARTISTRY-1, researchers wanted to see **if BIC+LEN was still working well and was still safe over 48 weeks of treatment**

## Who took part in the study?

This study included **128** people who already had undetectable levels of HIV in the blood for at least 6 months on a **complex treatment regimen**.



**81%** of people had a history of treatment resistance, meaning the virus had mutations that stopped treatment working



On average people had taken HIV treatment for **27 years**



**27%** of people took **5 or more pills** a day



**41%** of people were taking medicines **twice a day**

## How was the treatment studied?

People on a **complex treatment regimen** were randomly assigned to **1 of 3 treatment groups**:

128 people



51 people took BIC 75 mg + LEN 25 mg

52 people took BIC 75 mg + LEN 50 mg

25 people continued with a complex treatment regimen



**CD4 cells:** A type of white blood cell targeted by HIV. Higher numbers of CD4 cells in the blood point to better immune system functioning.

Researchers looked at the following over 48 weeks:



How many people continued to have **undetectable HIV levels** in the blood



How many **CD4 cells** people had compared to the start of the study



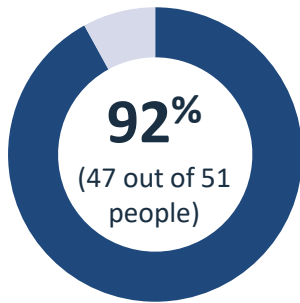
How many people experienced **side effects**

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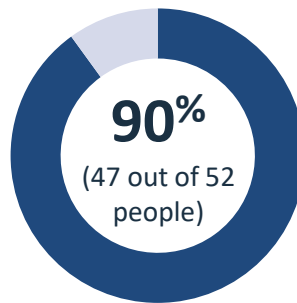
## What were the results of the analysis?

### How many people in the study continued to have undetectable HIV levels after 48 weeks?

People taking BIC+LEN 25 mg:



People taking BIC+LEN 50 mg:



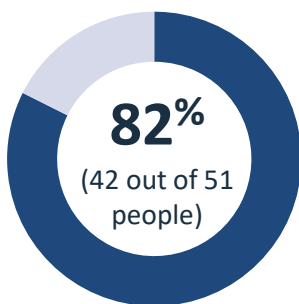
People who continued taking complex treatment regimens:



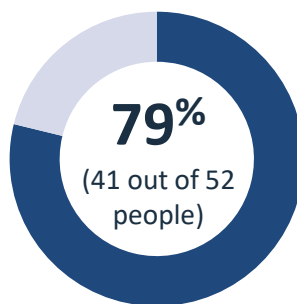
The number of CD4 cells people had in their blood and how that had changed over 48 weeks were similar between the 3 treatment groups.

### How many people in the study experienced side effects?

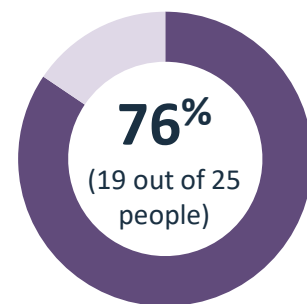
People taking BIC+LEN 25 mg:



People taking BIC+LEN 50 mg:



People who continued taking complex treatment regimens:



The most common side effects for people taking BIC+LEN were **COVID-19, infection of the nose, sinuses, or upper throat, and diarrhea**. Most side effects were not classed as serious. Of the small number of serious side effects, none were thought to be related to study treatment.



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SCAN ME

Reference: Mounzer, K, et al. AIDS 2024

Trial number: NCT05502341

## Conclusions

48 weeks after switching from a complex regimen to BIC+LEN treatment, researchers found that:

- BIC+LEN was very effective at keeping the levels of HIV in the blood undetectable in all treatment groups
- Most people did not have side effects related to BIC+LEN treatment, and side effects were similar with all studied LEN doses

This supports further studying of BIC+LEN for people who need to simplify their treatment regimen or those who can't take other single-tablet regimens.