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Conclusions

- At Week 48 in ARTISTRY-1, bictegravir/lenacapavir (BIC/LEN) single-tablet regimen (STR) maintained high rates of virologic suppression despite a high frequency of resistance-associated mutations (RAMs) at baseline
 - Overall, 96% treatment success was observed, regardless of baseline RAMs, including baseline integrase strand-transfer inhibitor (INSTI) RAMs
- No treatment-emergent resistance occurred in either treatment group at Week 48
- These data underscore the potential for the use of once-daily BIC/LEN to optimize therapy in people receiving a complex antiretroviral therapy regimen (CR)

Plain Language Summary

- People with human immunodeficiency virus (HIV) need at least two medicines (called antiretroviral drugs) to control the virus. However, some medicines may not work well for everyone. This can happen because of side effects or because the virus becomes resistant (the medicines no longer kill the virus). As a result, some people need to take several pills each day, which can be difficult
- Bictegravir (BIC) and lenacapavir (LEN) are approved HIV medicines that are usually taken with other drugs. Combining them into one pill taken once a day may reduce the number of pills and make treatment easier
- This study looked at people with HIV who were already taking about three pills per day and who had no HIV in their blood at the start of the study. After 48 weeks, people who switched to BIC and LEN had similar results to those who continued their previous treatments. This shows that the combination works well
- Many people had changes (mutations) in their HIV at the start of the study. Even so, BIC and LEN together controlled the virus and stopped it from making copies of itself

Introduction

- Once-daily STRs are standard of care for HIV treatment¹
- However, many people with HIV (PWH) take complex regimens (CRs) for reasons including drug resistance, intolerance, toxicity, drug-drug interactions, or contraindications to existing STRs¹⁻⁴
- The STR of BIC, an INSTI, combined with LEN, a first-in-class capsid inhibitor, demonstrated noninferior efficacy in virologically suppressed PWH switching from CRs in the Phase 3 ARTISTRY-1 trial (NCT05502341)⁵
 - The most common reason for receiving CRs was a history of resistance (81% of participants), followed by intolerance to components of STRs (23%)
 - Participants were receiving a median of three pills per day at baseline (range: 2-11)
 - At Week 48, 96% of participants receiving BIC/LEN and 94% of those receiving a CR had virological suppression (HIV-1 RNA < 50 copies [c]/mL)

Objective

- To characterize the baseline resistance profile of participants in the Phase 3 ARTISTRY-1 trial, and to analyze the potential emergence of resistance to study drugs after 48 weeks of treatment

Methods

Study Design of the Phase 3 Portion of ARTISTRY-1 (NCT05502341)

- ARTISTRY-1 is a Phase 2/3, randomized, open-label, multicenter trial

