PHASE 2 STUDY OF SWITCH TO DAILY BIC + LEN IN INDIVIDUALS ON A MULTI-TABLET HIV TREATMENT REGIMEN

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Background:
While single-tablet regimens (STRs) are currently the standard for HIV treatment, some people with HIV (PWH) take multi-tablet regimens (MTR) due to resistance, intolerance or drug interactions. The combination of bictegravir (BIC), and lenacapavir (LEN) could simplify treatment in virologically suppressed (VS) PWH for whom STRs are not indicated. We report the Phase 2, 24-Week (24W) primary outcomes for BIC+LEN versus stable baseline regimen (SBR) in VS PWH on a complex regimen.

Methods:
ARTISTRY-1 is an ongoing, randomized, open-label, multicenter Phase 2/3 study. In Phase 2, 128 participants on SBR (≥6 months prior to screening) were randomized 2:2:1 to receive daily oral BIC75mg+LEN25mg, oral BIC75mg+LEN50mg or continue SBR.. The primary endpoint was the proportion of participants with HIV RNA ≥50 copies/mL at 24W. Secondary endpoints included the proportion of participants with HIV RNA <50 copies/mL, change from baseline in CD4 cell count and treatment-emergent adverse events (TEAEs) up to 24W.

Results:
51 and 52 participants received BIC75mg+LEN25mg or BIC75mg+LEN50mg, respectively, and 25 continued SBR. . HIV-1 RNA was ≥50 copies/mL in 0/51 of participants in the BIC75mg+LEN25mg group, 1/52 (2%) in the BIC75mg+LEN50mg group (later suppressed to <50 copies/mL without regimen change) and 0/25 in the SBR group. CD4 counts were comparable in all groups. The most common TEAEs in the two BIC+LEN treatment groups up to 24W were diarrhea (7%), COVID-19 (6%), and constipation (5%). Drug-related TEAEs occurred in 18%, 6%, and 0% of participants, respectively.

Conclusions:
BIC+LEN was highly effective in maintaining viral suppression in participants switching from an MTR, with similar safety profiles observed in the two BIC+LEN treatment groups. These data support the use of BIC and LEN in combination to simplify treatment in VS PWH who are receiving complex regimens. A BIC/LEN STR will be tested in the Phase 3 part of the study.

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