Demographic and Clinical Characteristics of Phase 3 Participants in ARTISTRY-1, an Open-Label Study Comparing a Bictegravir/Lenacapavir Single Tablet Regimen With Complex Antiretroviral Therapy Regimens

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Conclusions

- At baseline, ARTISTRY-1 Phase 3 study participants, who were virologically suppressed (VS) on a complex regimen (CR), were predominantly > 50 years of age with:
- A high rate of comorbidities
- Extensive HIV treatment experience
- Mutations associated with resistance to multiple antiretroviral
- Participants had a high pill burden, and more than three-quarters were on a protease inhibitor (PI)-containing regimen
- This population could benefit from treatment optimization by switching to a bictegravir/lenacapavir (BIC/LEN) single tablet regimen (STR)

Plain Language Summary

Some people with HIV need to take several tablets each day for their HIV because existing single tablet treatments either don't work for them or cause side effects

- Taking several tablets a day for the same disease is called a "complex regimen"
- The ARTISTRY-1 study is testing if two HIV medicines, bictegravir (BIC) and lenacapavir (LEN) taken together are effective and safe for people with HIV who switch from a complex HIV regimen
- In the first part of the study, researchers found that taking BIC and LEN as separate tablets for 48 weeks effectively controlled HIV and didn't cause many side effects
- In the second part of the study, researchers are checking if a single tablet containing both BIC and LEN, taken once a day, will work as well as taking a complex regimen
- · At the start of the second part of the study, researchers found that people who took complex regimens typically:
- Were older than 50 years of age
- Had other medical conditions such as high cholesterol, high blood pressure, or diabetes
- Had taken HIV treatment for many years
- Had genetic changes in the virus that stop other HIV medicines from working properly
- Took several tablets a day, with many taking tablets twice a day
- People with HIV who are like people in this study may benefit from switching to a single daily tablet containing both BIC and LEN

Introduction

- · Once-daily STRs are standard of care for HIV treatment12 and are associated with improved adherence compared with multitablet regimens3-
- · However, many people with HIV (PWH) take complex antiretroviral treatment (ART) regimens because of drug resistance, intolerance, toxicity, drug-drug interactions, or contraindications to current STRs1,5-7
- · A BIC/LEN STR could help optimize treatment for PWH who are VS on a CR and unable to use currently available STRs
 - BIC is a guideline-recommended integrase strand transfer inhibitor (INSTI) with a high barrier to resistance1,2,8,9
- LEN is a first-in-class HIV-1 capsid inhibitor, with no expected resistance in PWH with no prior exposure to LEN1,10,11 ARTISTRY-1 (NCT05502341) is an ongoing, randomized, open-label, multicenter
- active-controlled Phase 2/3 study evaluating the safety and efficacy of switching to a BIC/LEN STR in PWH who are VS on a CR
- In the Phase 2 portion of the study, BIC + LEN was well tolerated and maintained virologic suppression through Week 48 in participants switching from a CR, including those with baseline resistance12,13
- In the ongoing Phase 3 portion of the study, a BIC 75 mg/LEN 50 mg STR is being assessed

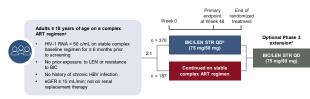
Objective

· To describe the baseline demographics and clinical characteristics of participants in the Phase 3 portion of ARTISTRY-1, in order to better understand this population with an unmet medical need

Methods

· ARTISTRY-1 (NCT05502341) is an ongoing, randomized, open-label, multicenter, active-controlled Phase 2/3 study

Study Design of the Phase 3 Portion of ARTISTRY-1



- A complex regimen was defined as:
- · A regimen containing a boosted PI or NNRTI plus ≥ 1 other third agent from a class other than NRTI, or
- A regimen of ≥ 2 pills/day, or a regimen requiring
- dosing more than QD, or · A regimen containing parenteral agent(s) (excluding
- a complete long-acting injectable regimen) as well as oral agents

Endonints at Week 48:

- Primary endpoint: Proportion of participants with HIV-1 RNA ≥ 50 c/mL (by US FDA-defined Snapshot algorithm)
- · Secondary endpoints:
- Proportion of participants with HIV-1 RNA < 50 c/mL Change from baseline in CD4 cell count
- Proportion of participants with TEAEs through

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Results

Baseline Demographics and Disease Characteristics

	Total Participants N = 557
Age, years, median (range)	60 (22-84)
Male sex assigned at birth, n (%)	457 (82)
Gender identity, n (%) Cisgender / transgender / non-binary* / other / not disclosed	540 (97) / 4 (1) / 1 (< 1) / 3 (1) / 9 (2)
Sexual orientation, n (%) Heterosexual / gay / lesbian / bisexual / not disclosed	160 (29) / 334 (60) / 0 / 23 (4) / 6 (1) ^b
Race, n (%) ^c White / Black / Asian / Other	384 (69) / 97 (17) / 25 (4) / 15 (3)
Hispanic or Latine ethnicity, n (%)c	122 (22)
CD4 count, cells/µL, median (Q1, Q3)	612 (456, 809) ^d
CD4 count > 200 cells/µL, n (%)	534 (96) ^d
Past medical history of AIDS, n (%)	67 (12)
Duration of HIV treatment, years, median (range) ^e	28 (3-45)
Number of prior ART regimens, median (range)	7 (2-29)
Reasons for taking a complex regimen, n (%) ^t History of resistance / intolerance to components of STRs / contraindication to STRs	450 (81) / 128 (23) / 33 (6)
eGFR _{co} , mL/min, median (Q1, Q3)	83 (66, 103)
BMI, kg/m², median (Q1, Q3)	26 (23, 29)
Comorbidities, n (%) ^{t.e} Dyslipidemia / hypertension / new onset diabetes mellitus or hyperglycemia / CKD	375 (67) / 279 (50) / 324 (58) / 106 (19)

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Recruitment by Country



Historical Resistance-Associated Mutations

	Participants With RAMs to a Given Drug Class, n (%)*	Mean Number of RAMs ^b
NRTI	374 (85)	4
M184V/I	278 (63) ^d	N/A
TAMs ^e	294 (67)	3
≥ 3 TAMs	209 (48)	4
NNRTI ^f	292 (67)	2
PI®	226 (53)	3
INSTI ^h	3 (1) ⁱ	1

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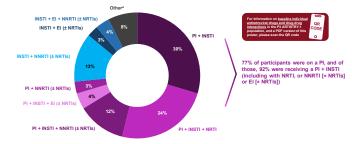
Complexity of ART Regimens at Baseline^a

	Total Participants N = 557
Number of pills/day at baseline, median (range)	3 (2-11)
Number of ARVs at baseline, median (range)	3 (2-6)
Twice-daily dosing of ARVs at baseline, n (%)	218 (39)

Proportion of Participants by Number of Pills/Day at Baseline



Diversity of Complex ART Regimens at Baseline



*Can contain PI. El. entri inhibitor, INSTI, integrase strand transfer inhibitor; PI, non-nucleoside reverse transcriptase inhibitor; NRTI, nucleoside/mucleotide reverse inhibitor; NRTI,

Acknowledgments: This study was snonsored by Glead Sciences. Inc. We thank all study naticipants and all naticipating study investigators and staff. Editing and production assistance were provided by Lindsay Fawcett, BSc (Aspire Scientific Ltd UK), and was funded by Gilead Sciences, Inc.

Disclosures: MH reports payment or homorais for lectures, support for attending meetings or travel, and participation on advisory boards for Glead Sciences, Inc., Mercix, and VIVI Healthcare. COH reports research grants, consulting fees, and homorains for lectures, speakers buseaus, or educational events from Glead Sciences, Inc. PD reports research grants, and gayment or homorains for lectures, speakers buseaus, or educational events from Vite-Balthcare, and consulting fees from Glead Sciences, Inc., Mercix, and VIVI Healthcare. And consulting fees from Glead Sciences, Inc., Mercix, and VIVI Healthcare. And consulting fees from Glead Sciences, Inc., Mercix, and VIVI Healthcare.

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