Baseline Demographics in the Phase 2b Registrational EXTEND 4M Trial: Evaluating a Novel Every-4-Month Cabotegravir Formulation in a Population Who Could Benefit From PrEP

WEPEB096

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Key Takeaways

- EXTEND 4M is an ongoing phase 2b PK bridging study designed to evaluate a novel long-acting formulation of cabotegravir (CAB 1600) given 3 times yearly to prevent HIV-1
- The study was conducted in US regions with a high incidence of HIV-1 and enrolled a population representative of people who could benefit from PrEP in clinical practice
- The development of CAB 1600 given 3 times yearly for HIV prevention is supported by EXTEND 4M and the established clinical program of CAB 600, aiming to balance lifestyle convenience with connectedness to one's sexual health care

EXTEND 4M

Plain Language Summary

- Cabotegravir is a drug/medicine approved as an injection given 6 times per year for prevention of HIV-1 (also called pre-exposure prophylaxis or PrEP)
- EXTEND 4M is a study testing if a new injectable formulation of cabotegravir given 3 times a year for HIV-1 prevention works as well as the currently approved option
- EXTEND 4M included a group of people who resembled everyday individuals who take PrEP

Introduction

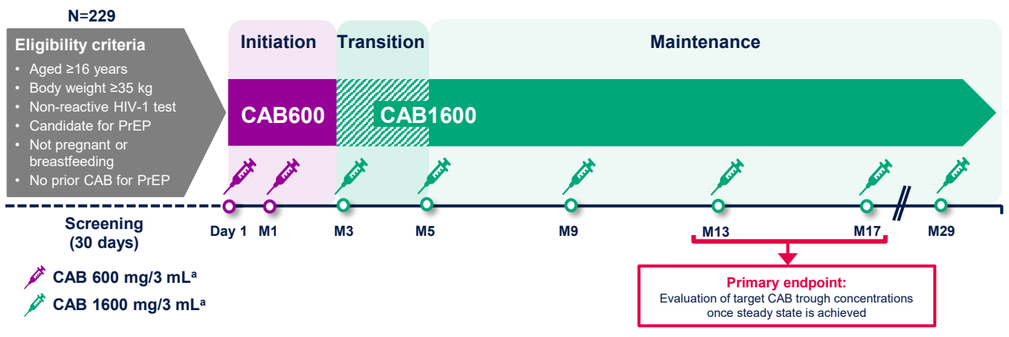
- Cabotegravir (CAB 600 mg/3 mL; CAB 600) has demonstrated superior efficacy to oral pre-exposure prophylaxis (PrEP), has a well-established tolerability profile, and is the most extensively studied injectable for HIV-1 prevention in the real-world among populations disproportionately affected by the HIV-1 epidemic[1-4]
- A new cabotegravir formulation is under investigation (CAB 1600 mg/3 mL; CAB 1600) to enable dosing 3 times per year, offering people eligible for PrEP the convenience of fewer injections while also aligning to the recommended frequency for HIV-1 testing and sexual health screening[5]
- EXTEND 4M is the registrational phase 2b pharmacokinetic (PK) bridging study designed to confirm that CAB 1600 achieves similar trough concentrations to CAB 600 when dosed 3 times per year
  - Achievement of target cabotegravir concentrations paired with the established efficacy and safety data from HPTN 083 and HPTN 084[6,7] provide the foundation for the CAB 1600 clinical development program
- Here, we present the baseline demographics and social determinants of health (SDoH) for participants enrolled in EXTEND 4M, a diverse population of people who may benefit from PrEP

Methods

Study Design

- EXTEND 4M is a phase 2b, open-label, single-arm, repeat-dose trial to evaluate the PK, safety, and tolerability of CAB 1600 for PrEP in adolescents and adults (Figure 1)
  - Secondary endpoints included CAB pharmacokinetics, characterization of HIV-1 infection, and treatment satisfaction, with safety assessed via adverse events, including injection site reactions, and lab abnormalities

Figure 1. EXTEND 4M Study Design

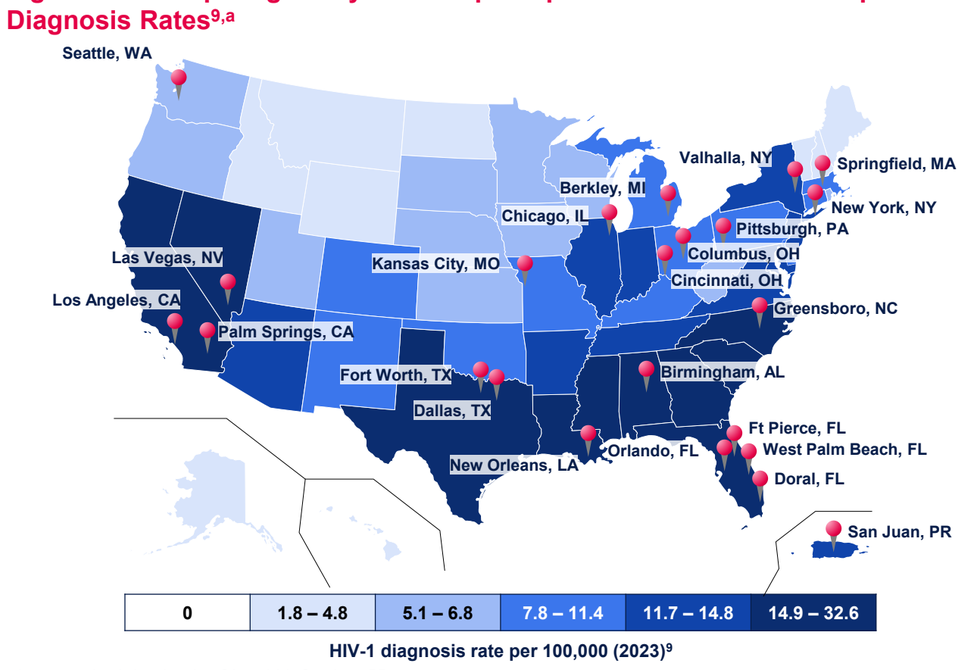


M, month. [a]Intramuscular injection to the *gluteus medius*.

Study locations

- The study is being conducted at 27 US sites in regions with significant HIV-1 transmission among subpopulations disproportionately affected by HIV-1 (Figure 2)[8]

Figure 2. Participating Study Sites Superimposed on a 2023 CDC Map of HIV-1 Diagnosis Rates[9,a]

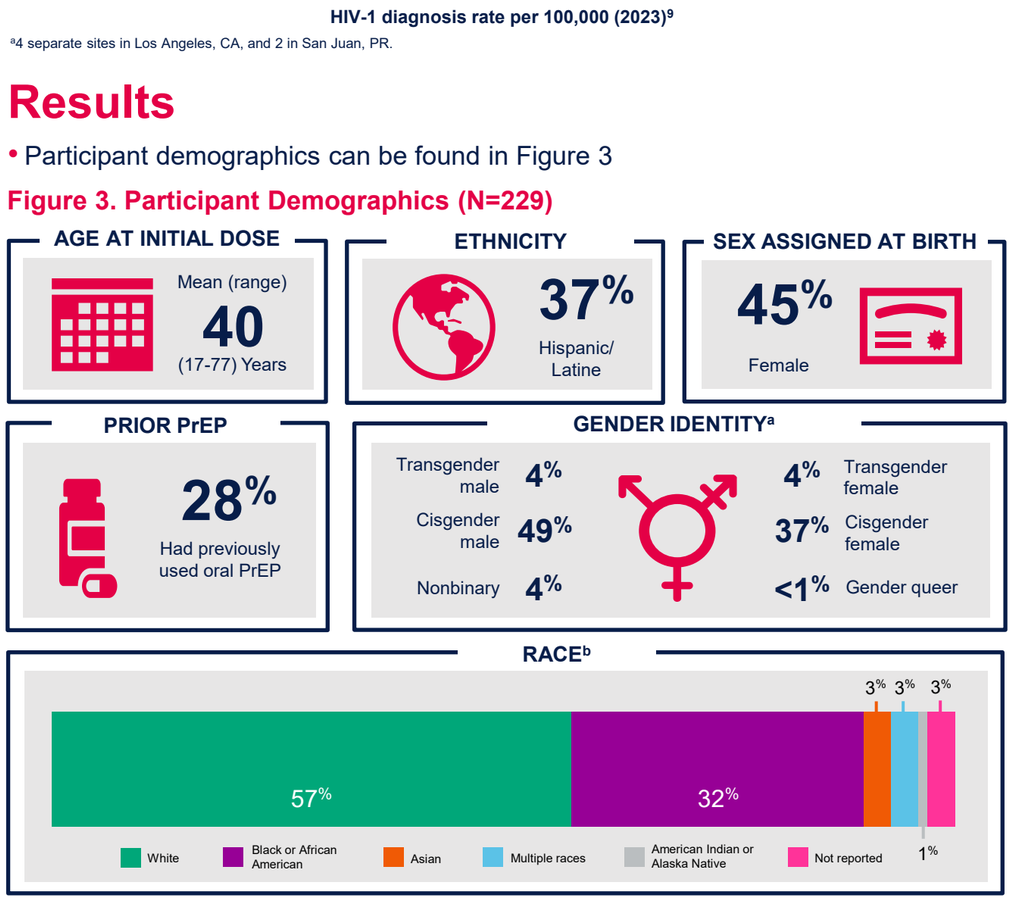


[a]4 separate sites in Los Angeles, CA, and 2 in San Juan, PR.

Results

- Participant demographics can be found in Figure 3

Figure 3. Participant Demographics (N=229)



[a]1% (n=2) declined to answer. [b]Percentages may equal less than 100% due to rounding.

Baseline Sexually Transmitted Infections and Laboratory Serologies

- 2% (4/229) of participants had positive swabs for gonorrhea and <1% (1/229) for chlamydia; among 103 participants assigned female sex at birth, 5 (5%) tested positive for trichomoniasis
- Syphilis and hepatitis serologies are shown in Table 1

Table 1. Syphilis and Hepatitis Serologies

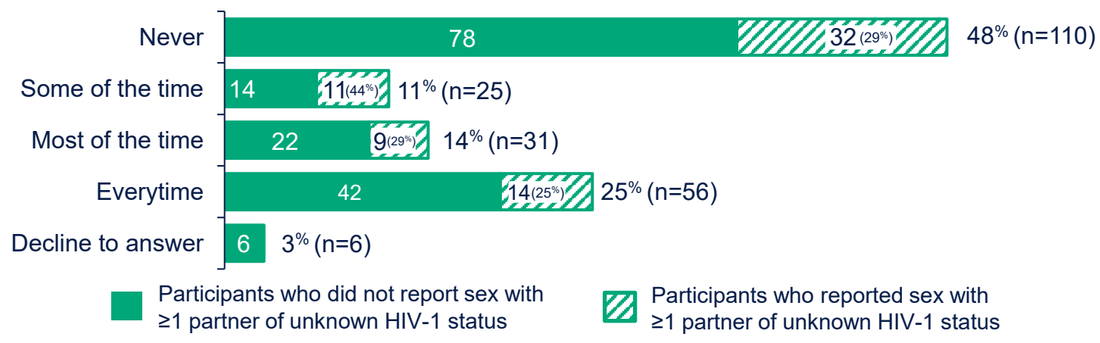
Parameter, n (%)	Overall (N=229)
Syphilis (*Treponema pallidum* antibody)	29 (13)
Hepatitis B core antibody	11 (5)
Hepatitis B surface antibody	139 (61)
Hepatitis C antibody[a]	2 (1)

[a]No participants were positive for Hepatitis C RNA.

Self-Reported Sexual Health Behavior Between Screening and Day 1

- Over half of participants (59%, 135/228) reported using condoms never or some of the time during sex (Figure 4)
  - Of those never using condoms, 29% (32/110) reported engaging in sexual acts with ≥1 sex partners of unknown HIV-1 status

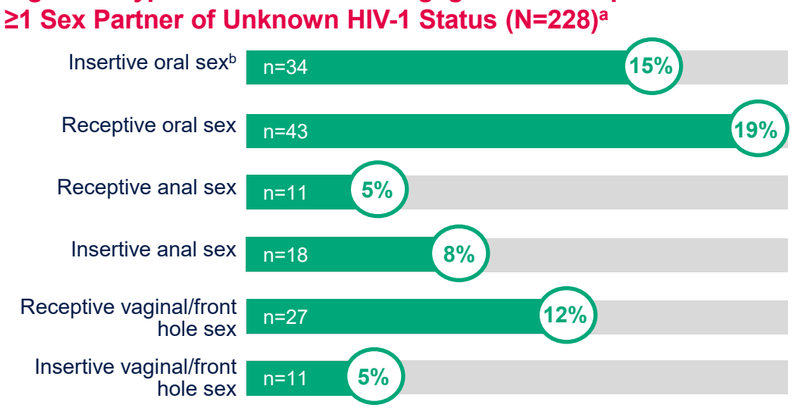
Figure 4. Self-Reported Frequency of Condom Use During Sexual Acts (N=228)[a,b]



[a]Participants engaged in any of the following sexual acts with ≥1 sex partner of unknown HIV-1 status: insertive oral sex, receptive oral sex, receptive anal sex, insertive anal sex, receptive vaginal/front hole sex and insertive vagina/front hole sex. [b]One missing response.

- One-third of participants from the overall population (29%, 66/228) reported engaging in any type of sexual act with ≥1 sex partner of unknown HIV-1 status, with similar proportions between males (27%, 34/126) and females (31%, 32/102)
  - See Figure 5 for breakdown by types of sexual acts
- Participants reported a mean (SD; min-max) of 1.3 (1.56; 0-10) sexual partners since their last visit (screening visit)
  - 5% (12/228) of participants reported having a sexual partner living with HIV-1
- Less than 1% (2/228) reported having transactional sex (ie, exchange of anything for sex)

Figure 5. Types of Sexual Acts Engaged in Participants With ≥1 Sex Partner of Unknown HIV-1 Status (N=228)[a]

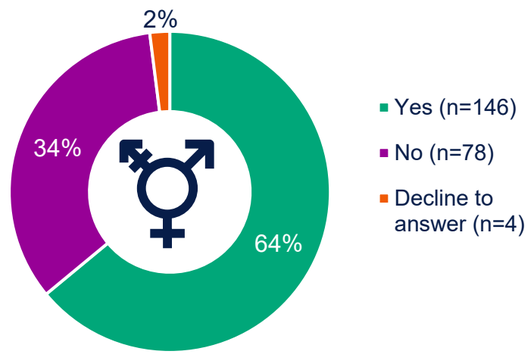


[a]One missing response. [b]Category included as a response to this item the questionnaire; however, oral sex carries negligible risk of HIV-1 transmission.

Results on Social Determinants of Health

- **Demography:** The majority self-identified as being part of the LGBTQ+ community (Figure 6)

Figure 6. People Who Identified Within the LGBTQ+ Community (N=228)



- **Language:** Overall, English was the primary language in most participants (187/228 [82%]) followed by Castilian Spanish (40/228 [18%])
- **Housing:** Over three quarters (76%, 174/228) of the sample maintained independent housing, while the remaining participants utilized shared living arrangements, including living in someone else's residence and/or congregate housing (13%, 30/228) or within a parental home (8%, 18/228), or other arrangements (3%, 6/228)
  - 96% (218/228) of participants had not experienced a housing problem in the 12 months before responding to the questionnaire
- **Schooling:** Over three quarters (78%, 177/228) of participants had completed some post-secondary education, including graduating college (27%, 62/228) or post-graduate studies (18%, 40/228). 22% (50/228) reported high school or below as their highest level of education
- **Work:** Most participants were active in the workforce (79%, 180/228): employed full-time (52%, 118/228), part-time or temporarily (15%, 34/228), or self-employed (12%, 28/228). Among the rest, 9% (20/228) were not employed, 5% (12/228) were unable to work due to disability, 4% (8/228) were students, and 3% (7/228) were retired
- **Access:** Approximately a quarter of the participants (24%, 54/228) reported issues with access to necessities (housing, food, utilities, childcare, clothing, medicine, phone)
- **Healthcare coverage**: Private insurance was the most common form of coverage (47%, 107/228), while public programs, Medicaid and Medicare, together covered 30% (68/228). One in ten participants were uninsured (10%, 22/228)
- **Healthcare environment:** Most participants did not feel talked down to or uncomfortable in a healthcare setting (81%, 185/228)
  - Most people (72%, 165/228) did not believe their age, race, religion, ethnic background, or culture made a difference in the kind of counseling or treatment received in a healthcare facility, while 25% (56/228) believed it did, and 3% (7/228) declined to answer

Conclusions

- EXTEND 4M was conducted in a population representative of those receiving PrEP in the real-world
- One-third of study sites in EXTEND 4M were in the southern region of the US where nearly half of all new HIV-1 infections are diagnosed[10]
- The enrolled participants were reflective of those disproportionately affected by the HIV-1 epidemic including 45% females, 32% Black or African American, and 37% Latine/Hispanic
  - Over 60% of participants self-identified as part of the LGBTQ+ community
- Over half of the population reported condom use 'never' or 'some of the time,' 29% of participants had ≥1 sex partner with an unknown HIV-1 status, and 28% were prior PrEP users
- The PK and safety data from EXTEND 4M that will support the regulatory submission for CAB 1600 three times yearly will be presented at a future congress

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