P-978

Early Expectations of Cabotegravir Every 4 Month Injections for HIV Pre-exposure Prophylaxis Among Individuals Using Cabotegravir Every 2 Month Injectable

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Key Takeaways

- **'TWO TO FOUR' is an ongoing Phase I study designed to evaluate switching from cabotegravir (CAB) 600 dosed 6 times a year to CAB 1600 dosed 3 times a year for HIV-1 prevention. We report on participants expectations of CAB 1600 prior to switch**
- **Participants expected CAB 1600 to be a highly acceptable and feasible option for HIV-1 prevention, and most did not have concerns about switching to CAB 1600 or about how receiving injections 3 times a year would fit into their lives**
- **Most participants felt positively about receiving CAB 1600, and many anticipated that the benefits of 3 times a year injections would include being able to address medication questions and would be the right number of visits to address other health issues**

Plain Language Summary

- CAB 600, given 6 times a year, is an approved medicine for the prevention of HIV-1
- The 'TWO TO FOUR' study looks at switching people from CAB 600 to a new formulation, CAB 1600, given as an injection 3 times a year to prevent HIV-1
- Before receiving CAB 1600, participants did not anticipate having concerns about switching or about injections 3 times a year fitting into their life. Many participants expected that 3 times a year injections would have benefits
- Healthcare professionals (HCPs) expected that the logistics of 3 times a year injections would be simpler than 6 times a year injections

Introduction

- CAB (600 mg/3 mL, CAB 600) is the first approved injectable formulation for HIV-1 prevention with superior efficacy to daily oral pre-exposure prophylaxis (PrEP) and a well-established tolerability profile[1–4]
- A new CAB formulation (CAB 1600 mg/3 mL; CAB 1600) is under investigation to enable dosing 3 times a 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[5,6]
- Data from the Phase IIb pharmacokinetic bridging study, EXTEND 4M, paired with the established efficacy and safety data from HPTN 083 and HPTN 084, form the foundation of the CAB 1600 clinical development program[5,7,8]
- 'TWO TO FOUR' is a Phase I study further supporting the development of CAB 1600 given 3 times a year for HIV-1 prevention[5,9]
- We report participants' and HCPs' anticipated perspectives of CAB 1600 acceptability, feasibility, and lifestyle fit at Month 7 of CAB 600 dosing (prior to switching to CAB 1600 at Month 9)

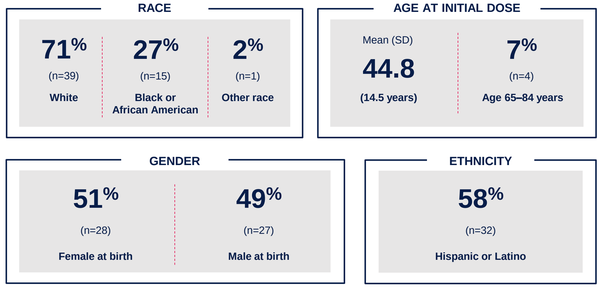
Methods

- 'TWO TO FOUR' (NCT06786520) is a Phase I, single-arm, repeat-dose study designed to evaluate the pharmacokinetics, safety, and tolerability of switching from CAB 600 dosed 6 times a year to CAB 1600 dosed 3 times a year in healthy adults in the United States[9]
  - This study is conducted at three sites in Alabama, Florida, and Illinois[9]
- Participants included were ≥18 years old; weighed ≥35 kg; did not have HIV, Hepatitis B virus or Hepatitis C virus; and had not used CAB PrEP within 1 year prior to enrollment
- HCPs included were site employees responsible for the administrative or clinical aspects of offering and administering CAB
- Participants received CAB 600 on Day 1 and at Months 1, 3, 5, and 7 before transitioning to CAB 1600 at Months 9 and 11. Participants then received CAB 1600 at Months 15 and 19; Month 23 is the end of the study. Both injections were given as 3 mL intramuscular injections into the gluteus medius
- Implementation science questionnaires (ISQs) were administered electronically to participants and HCPs at Month 7, before participants were switched from CAB 600 to CAB 1600
- ISQs explored participants' expectations regarding injections 3 times a year, including anticipated acceptability, feasibility, lifestyle fit, perceived benefits, concerns, and information received from HCPs (other than at consent, HCPs were not required to share information on CAB per the study protocol)
  - ISQs included the Acceptability of Implementation Measure (AIM), Feasibility of Implementation Measure (FIM), and custom questions. All questions had either a categorical or ordinal scale and scale values ranged from 1 to 5 with higher scores indicating greater acceptability or feasibility[10]
- ISQs also explored HCPs' expectations regarding implementation, acceptability, and feasibility

Results

- Participant demographics can be found in **Figure 1**

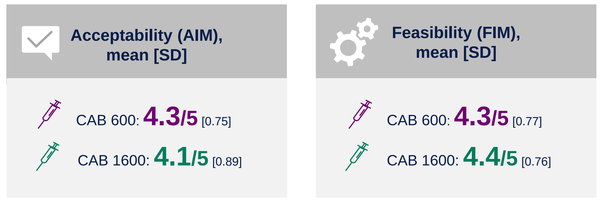
Figure 1. Baseline Demographics of Participants (N=55)*



*At Month 7, one participant (n/N=1/55) was excluded due to no available data, therefore, data was collected from 54 participants in this analysis, prior to switch
SD, standard deviation

- Participants reported similarly high levels of anticipated acceptability and feasibility of CAB 1600 as experienced with CAB 600 **(Figure 2)**

Figure 2. Participant Anticipated Acceptability and Feasibility of Receiving CAB 1600 3 Times a Year*



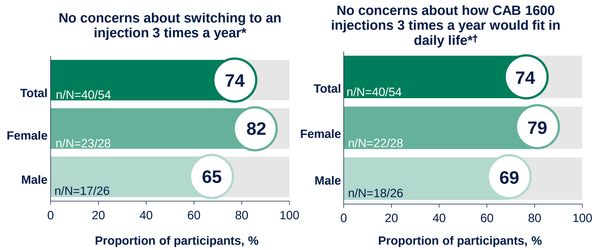
*A higher score indicates greater acceptability of the intervention

Figure 3. Participant Perspectives on Injections 3 Times a Year Prior to Receiving CAB 1600 Injections (N=54)*†



*Questions were asked separately and participants were able to respond to each question; †Percentages may not total to 100 due to rounding

Figure 4. Participant Concerns About Injections 3 Times a Year Prior to Receiving CAB 1600 Injections



*Proportions represent 'no' responses of options 'yes' or 'no'; †Prompt for survey section: 'Both CAB 600 injected 6 times a year and the new formulation of CAB 1600 injected 3 times a year are PrEP medications. PrEP is a medication used to prevent HIV. Thinking of your daily life and if you were to consider using PrEP outside of this clinical trial, please answer the following questions about CAB 1600 3 times a year'

- 78% (n/N=31/40) of participants who received information about CAB from HCPs had no concerns about switching to CAB 1600
  - Participants reported receiving information about the difference between CAB 600 and CAB 1600; what to expect when switching; and the visit frequency and side effects of CAB 1600
- 64% (n/N=9/14) of participants who did not receive information from HCPs had no concerns about switching to CAB 1600

Participant Perceived Daily Life Benefits of Receiving an Injection 3 Times a Year (N=54)

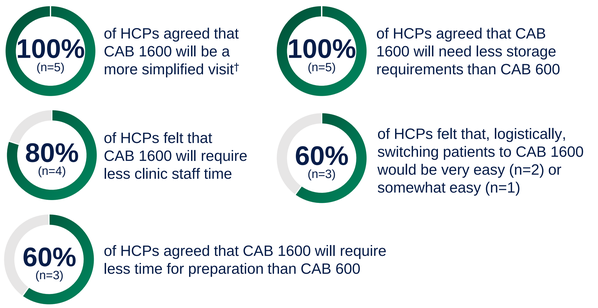
- The top three benefits for daily life of receiving an injection 3 times a year reported by participants are **(Table 1)**:
  - The ability to address questions about the medication and side effects (50%)
  - The assurance that the medication is working longer to prevent HIV (50%)
  - The right number of doctor visits to allow for addressing other health issues (37%)

Table 1. Participant Perspectives on the Benefits of Injections 3 Times a Year Prior to Receiving CAB 1600 Injections

What benefits would receiving an injection 3 times a year have for your daily life?* n (%)	Total (N=54)	Female (N=28)	Male (N=26)
Able to address questions about the medication and side effects	27 (50.0)	15 (53.6)	12 (46.2)
Assurance that the medication is working longer to prevent HIV with injections 3 times a year	27 (50.0)	16 (57.1)	11 (42.3)
The right number of visits with my doctor (3 times a year) that will allow for addressing other health issues	20 (37.0)	12 (42.9)	8 (30.8)
The right number of visits with my doctor (3 times a year) will help me feel in control of my health	19 (35.2)	11 (39.3)	8 (30.8)
Build a relationship with my doctor	17 (31.5)	9 (32.1)	8 (30.8)
People not knowing that I am on an injection for HIV prevention	16 (29.6)	10 (35.7)	6 (23.1)
Other benefits not listed	12 (22.2)	6 (21.4)	6 (23.1)
None of the above	8 (14.8)	2 (7.1)	6 (23.1)

*Prompt for survey section: 'Both CAB 600 injected 6 times a year and the new formulation of CAB 1600 injected 3 times a year are PrEP medications. PrEP is a medication used to prevent HIV. Thinking of your daily life and if you were to consider using PrEP outside of this clinical trial, please answer the following questions about CAB 1600 3 times a year'

Figure 5. Anticipated Perspectives from HCPs* on Switching Participants from Injections 6 Times a Year to Injections 3 Times a Year (N=5)



*HCPs (N=5) included a physician (n=1), nurse practitioner (n=1), and other staff (n=3); †In terms of scheduling and workflow

Conclusions

- Participants expected CAB 1600 to be highly acceptable and feasible, with the majority reporting no concerns about switching or how injections 3 times a year would fit into daily life
- Participants anticipated that visits 3 times a year would support addressing medication questions and other health issues, consistent with the aim of CAB 1600 to balance lifestyle convenience with ongoing connection to care
- HCPs anticipated that injections 3 times a year would simplify clinic visits, and reduce storage, preparation time, and staff resource requirements
- Overall, ahead of switching, participants and HCPs identified several potential benefits related to use of CAB 1600 administered 3 times a year. Future analyses from 'TWO TO FOUR' will describe how these expectations align with post-switch experiences

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