

# Alaska ID ECHO: HCV-HIV-PrEP-STIs



ALASKA NATIVE  
TRIBAL HEALTH  
CONSORTIUM



NPAIHB

*Indian Leadership for Indian Health*

April 12, 2022

# WELCOME

- AK ID ECHO sessions take place the second Tuesday of each month from noon – 1 p.m.
- Recording: we record the didactic portion of every session and make it available on the ANTHC .org AK ID ECHO page, <https://anthc.org/project-echo/hcv-hiv-prep-stis-echo/>
- Questions will be saved until the end of the didactic presentation. Feel free to put your question in the chat during the presentation and we will answer during the Q&A.
- Please connect your camera during the Q&A and group discussions.

Thank you for participating!



# Welcome to Alaska Infectious Disease ECHO – HCV, HIV, PrEP, STIs

## Approved Provider Statements:



In support of improving patient care, Alaska Native Medical Center (ANMC) is jointly accredited by the Accreditation Council for Continuing Medical Education (ACCME), the Accreditation Council for Pharmacy Education (ACPE), and the American Nurses Credentialing Center (ANCC), to provide continuing education for the healthcare team.

## Contact Hours:

ANMC designates this activity for a maximum of 12 contact hours, including 3 total pharmacotherapeutics contact hours, commensurate with participation.

## Financial Disclosures:

Youssef Barbour, MD & Lisa Townshend-Bulson, APRN / faculty for this educational event, are primary investigators in an ANTHC sponsored hepatitis C study funded in part by Gilead Sciences. All of the relevant financial relationships listed have been mitigated.

## Requirements for Successful Completion:

To receive CE credit please make sure you have actively engaged in the entire activity, your attendance is recorded by the facilitator, and complete the course evaluation form found here: <https://forms.gle/18t4EgvN2WdnM4P77>



For more information contact  
[jfielder@anthc.org](mailto:jfielder@anthc.org) or (907) 729-1387



# AK ID ECHO: CONSULTANT TEAM



- Youssef Barbour, MD Hepatologist
- Leah Besh, PA-C HIV/Hepatology Provider
- Terri Bramel, PA-C HIV/STI Provider
- Rod Gordon, R.Ph. AAHIVP Pharmacist
- Jacob Gray, MD Infectious Disease Provider
- Annette Hewitt, ANP Hepatology Provider
- Brian McMahon, MD Hepatologist
- Lisa Rea, RN HIV/STI Case Manager
- Lisa Townshend, ANP Hepatology Provider

April  
2022

# HIV Injectable Medications

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AK ID ECHO series

Presented by Katie Presser, Pharm.D., BCPS, BCIDP  
Infectious Diseases Clinical Pharmacy Specialist, Alaska Native Tribal Health Consortium

# Poll:

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There are more than 1 FDA approved injectable medication for treatment of HIV and for prevention of HIV.

- True
- False



FDA NEWS RELEASE

# FDA Approves First Extended-Release, Injectable Drug Regimen for Adults Living with HIV

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For Immediate Release: January 21, 2021

## Cabotegravir/Rilpivirine

Monthly injectable approved

<https://www.fda.gov/news-events/press-announcements/fda-approves-first-extended-release-injectable-drug-regimen-adults-living-hiv>



# Cabotegravir/Rilpivirine

First approved IM long acting injectable medication to treat HIV

- Cabotegravir- integrase inhibitor
- Rilpivirine- non-nucleoside reverse transcriptase inhibitor (NNRTI)

January 2021-  
oral lead in,  
monthly injections



February 2022-  
oral lead in, every  
2 month injections

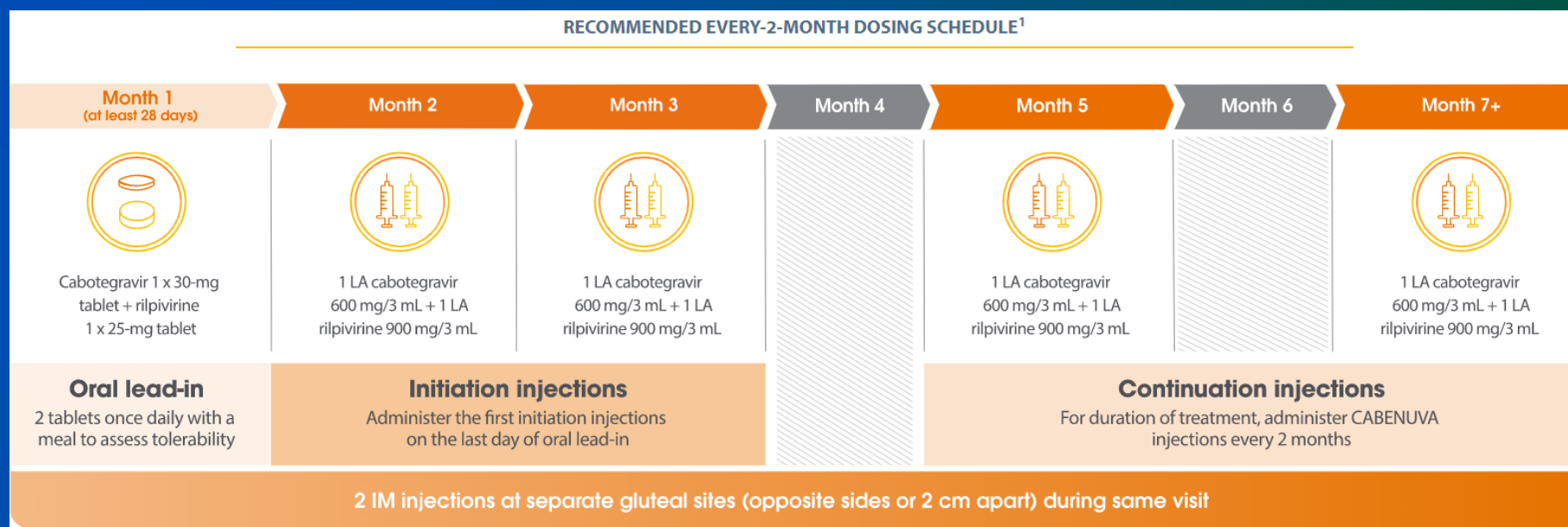


March 2022-  
removed oral lead  
in, optional prior to  
starting injections





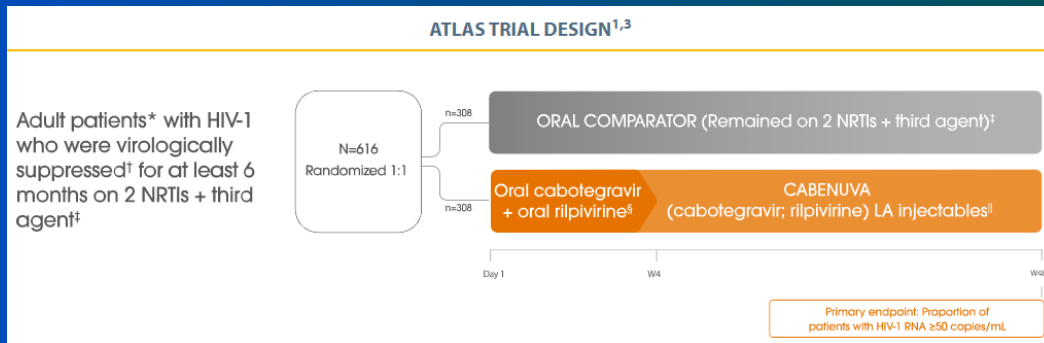
# Dosing



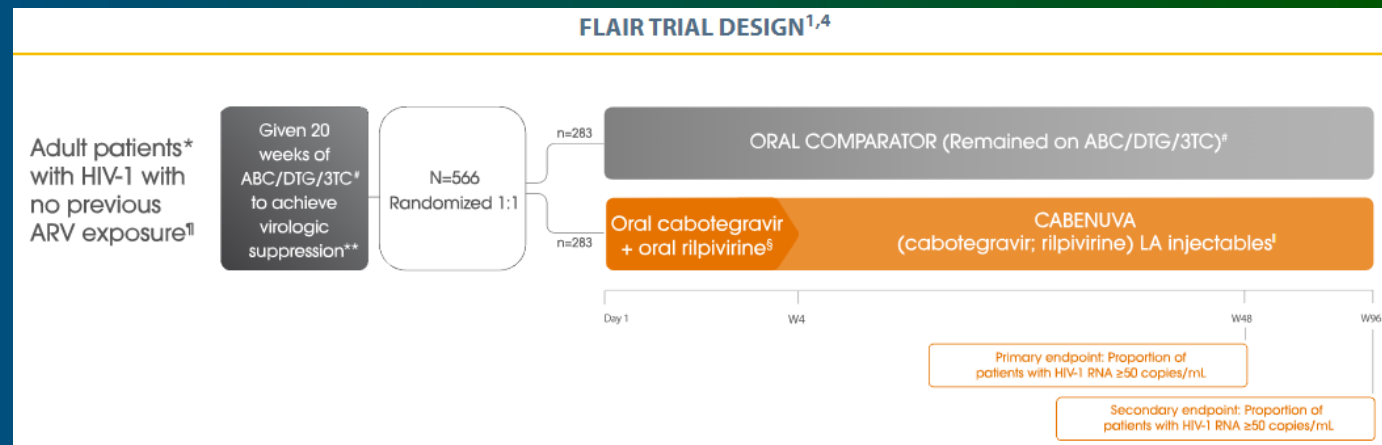
Oral lead-in comes from ViiV- cannot order through warehouses for cabotegravir piece (TheraCom Pharmacy)  
<https://cabenuvahcp.com/dosing/every-2-month/>

# Clinical Trials

## ATLAS



## FLAIR



Virological suppression- HIV-1 RNA  
<50 copies/mL

<https://cabenuvahcp.com/efficacy/atlas-flair/>

# Baseline Characteristics

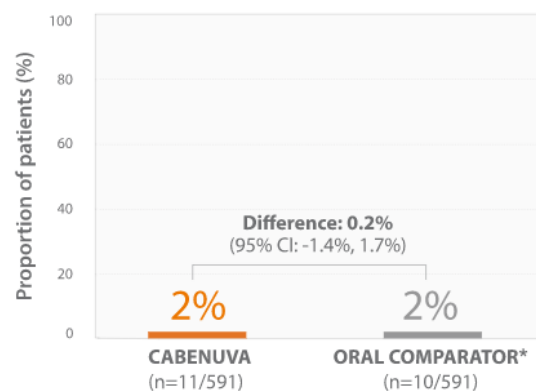
	ATLAS (N=616)		FLAIR (N=600)	
	CABENUVA (n=308)	2 NRTIs + third agent <sup>†</sup> (n=308)	CABENUVA (n=283)	ABC/DTG/3TC <sup>‡</sup> (n=283)
<b>Age</b>				
Median age, years (range)	40 (21-74)	43 (18-82)	34 (19-68)	34 (18-68)
<b>Sex at birth</b>				
Female	32%	34%	22% <sup>††</sup>	23%
<b>Race</b>				
White	69%	67%	76%	71%
African American or African heritage	20%	25%	17%	20%
Other	10%	8%	7%	9% <sup>†‡</sup>
<b>Clinical parameters</b>				
<b>Baseline HIV-1 RNA</b> Patients with ≥100,000 copies/mL	N/A	N/A	20% <sup>§§</sup>	20% <sup>§§</sup>
<b>Median baseline CD4<sup>+</sup> T-cell count<sup>  </sup></b> cells/mm <sup>3</sup> (IQR)	654 (497-816)	653 (488-844)	624 (473-839)	625 (472-799)
<b>Baseline CD4<sup>+</sup> T-cell count</b> <350 cells/mm <sup>3</sup>	7%	9%	7%	10%
<b>Median duration of prior ARV therapy,</b> years (range)	4 (1-19)	4 (1-21)	20 Weeks <sup>**</sup>	20 Weeks <sup>**</sup>
<b>Baseline third agent in ARV therapy</b> NNRTI INSTI PI	50% 33% 17%	50% 32% 18%	0 100 <sup>**</sup> 0	0 100 <sup>**</sup> 0
<b>Hepatitis C co-infection<sup>¶¶</sup></b>	7%	10%	7%	3%

Patient characteristics differ due to varying trial designs.

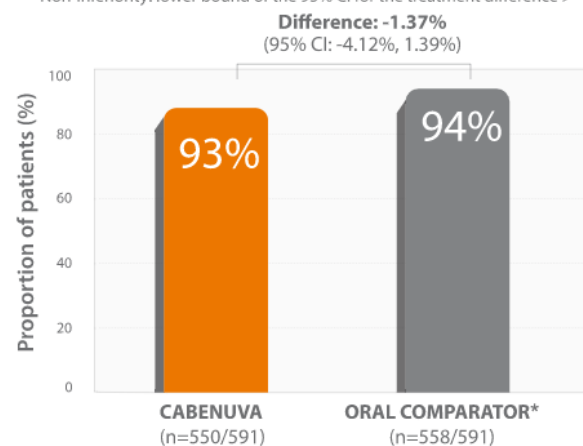
# Results

## POOLED ANALYSIS: ITT-E FDA SNAPSHOT VIROLOGIC OUTCOMES AT WEEK 48<sup>2</sup>

**Primary endpoint: HIV-1 RNA  $\geq 50$  copies/mL at Week 48**  
Non-inferiority: upper bound of the 95% CI for the treatment difference  $< 4\%$



**Secondary endpoint: HIV-1 RNA  $< 50$  copies/mL at Week 48**  
Non-inferiority: lower bound of the 95% CI for the treatment difference  $> -10\%$



\* In ATLAS, the oral comparator consisted of 2 NRTIs + a third agent (INSTI, NNRTI, or PI). In FLAIR, the oral comparator consisted of ABC/DTG/3TC (or DTG + 2 NRTIs if HLA-B\*5701-positive).<sup>3,4</sup>

CI=confidence interval; FDA=Food and Drug Administration; ITT-E=intent-to-treat efficacy.

• No virologic data at Week 48: 5% (30/591) CABENUVA; 4% (23/591) oral comparator<sup>2</sup>

# Eligible Patients

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- Virologically suppressed (HIV-1 RNA <50 copies/mL) on a stable antiretroviral regimen with no history of treatment failure and no suspected resistance to either agent
- Adverse reactions:
  - Injection site reactions- pyrexia, fatigue, headache, musculoskeletal pain, nausea, sleep disorders, dizziness, rash
  - Pain/discomfort at injection site (reported at >80% in trials)
    - Patients did not stop using b/c of this

# Acquisition

## Buy and bill

- Organization pays the money to obtain from the specialty distributor
- Reimbursement by clinic/organization after

## Specialty pharmacy

- Designated per state by ViiV
- Payment is coordinated by the specialty pharmacy as a prescription fill
- Practice coordinates delivery/receipt







# Pre-Exposure Prophylaxis

FDA NEWS RELEASE

# FDA Approves First Injectable Treatment for HIV Pre-Exposure Prevention

*Drug Given Every Two Months Rather Than Daily Pill is Important Tool in Effort to End the HIV Epidemic*

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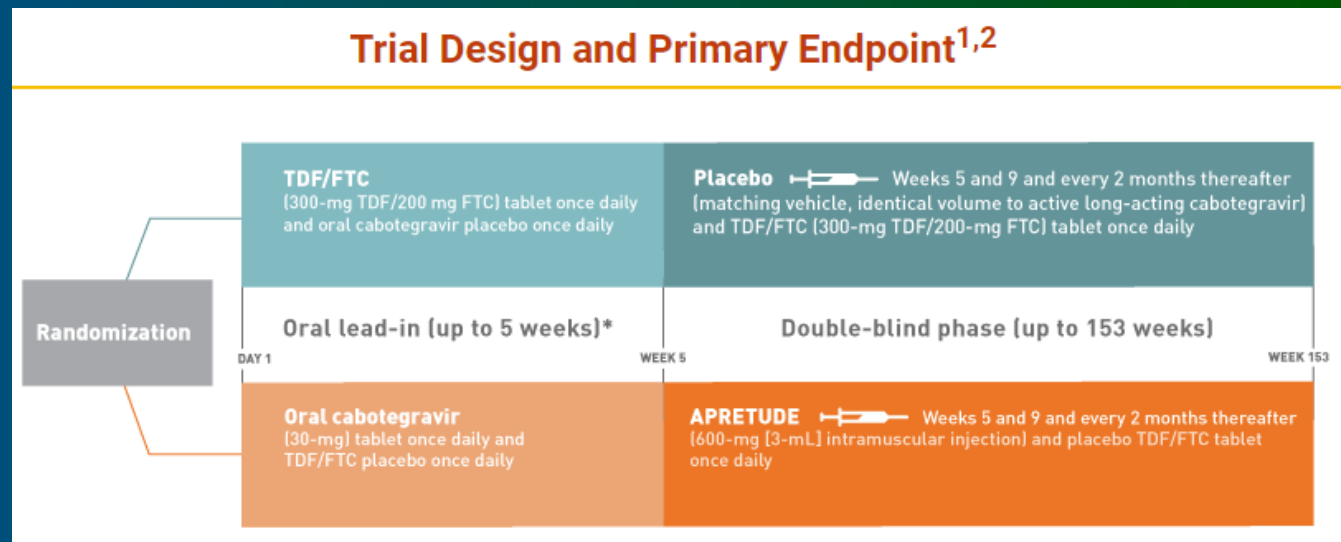
**For Immediate Release:** December 20, 2021

<https://www.fda.gov/news-events/press-announcements/fda-approves-first-injectable-treatment-hiv-pre-exposure-prevention>

# Apretude

## HPTN 083

- Randomized, double-blind, placebo-controlled noninferiority trial
- 43 sites world-wide
- Apretude vs daily oral TDF/FTC
- Adult cisgender men and transgender women who have sex with men
- Oral lead-in optional



HPTN= HIV Prevention Trials Network  
<https://apretudehcp.com/efficacy/hptn-083/>

# Baseline Characteristics

	Overall (%) N=4566	Apretude (%) N=2282	TDF/FTC (%) N=2284
<b>Gender &amp; Sexuality</b>			
Men who have sex with men	87	88	87
Transgender women who have sex with men	13	12	13
Preferred not to answer	0.1	0.1	<0.1
<b>Age</b>			
Median age, years [IQR]	26 [22-32]	26 [22-32]	26 [22-32]
18-29	68	69	66
30-39	23	22	24
≥40	10	9	10

## Significantly Lower Incidence of HIV-1 Infection vs a Daily Oral PrEP

**69%**  
LOWER INCIDENCE  
vs TDF/FTC

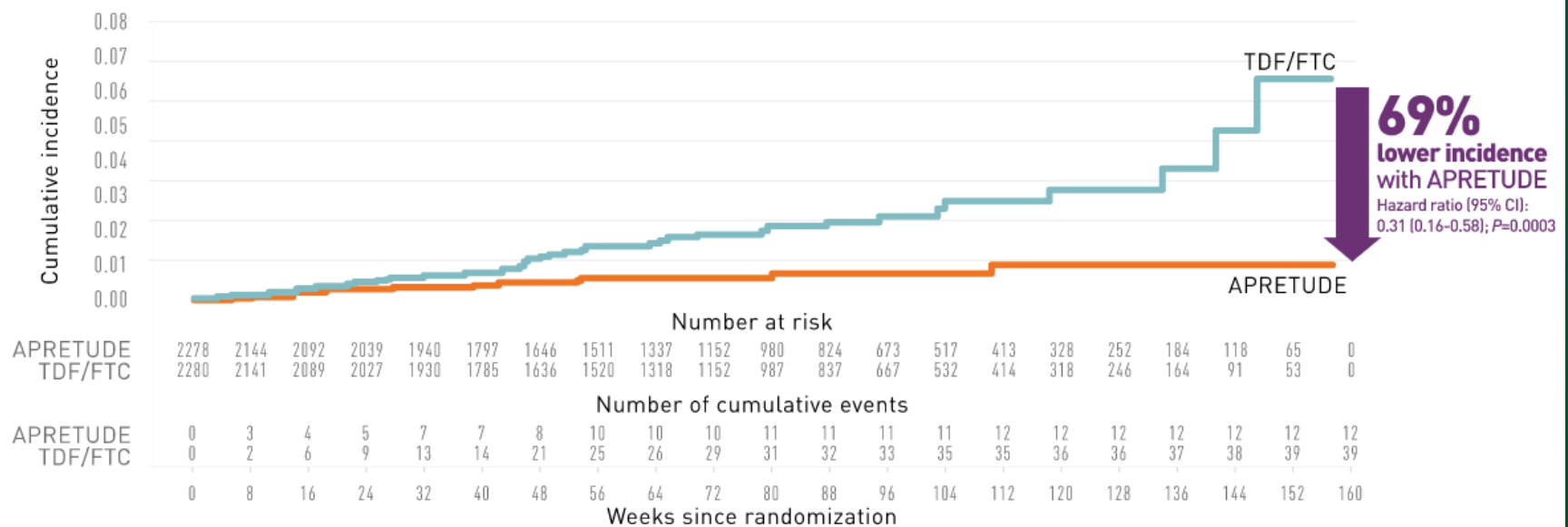
Incident HIV-1 infections  
APRETUDE: 12<sup>‡</sup>  
in 3211 person-years  
TDF/FTC: 39  
in 3193 person-years

HIV-1 infections occurred  
**>3x less often**  
WITH APRETUDE

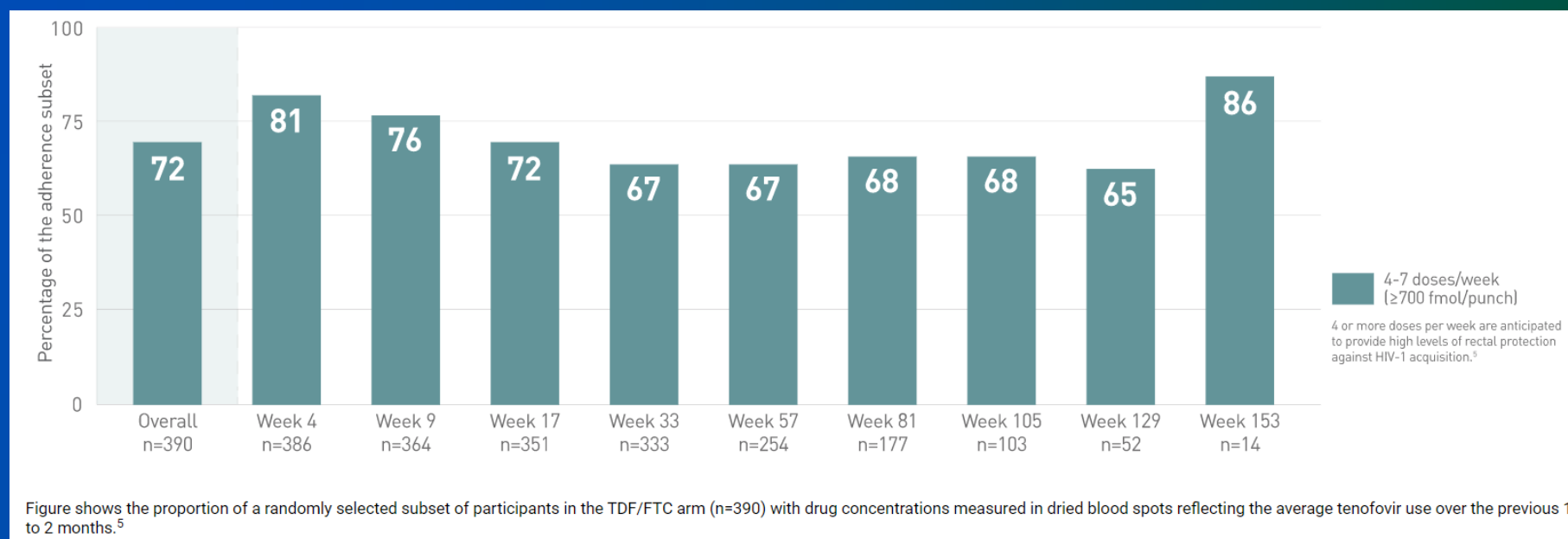
Hazard ratio (95% CI): 0.31 (0.16-0.58);  $P=0.0003$ . APRETUDE incidence rate 0.37/100 person-years vs 1.22/100 person-years for TDF/FTC.

<sup>‡</sup>An initial analysis showed 13 incident infections in the APRETUDE arm (hazard ratio [95% CI]: 0.34 [0.18-0.62]). Retrospective testing showed 1 of the 13 to be a prevalent infection, resulting in 12 incident infections.<sup>1</sup>

## Cumulative Incidence of HIV-1 Infections in HPTN 083



# Adherence with TDF/FTC



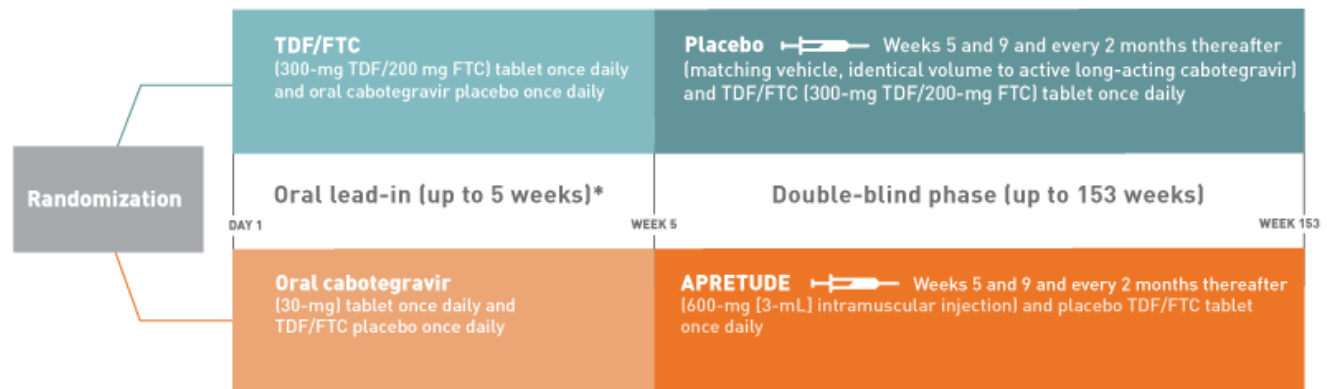


# Apretude

## HPTN 084

- Randomized, double-blind, placebo-controlled superiority trial
- 20 sites around sub-Saharan Africa
- Cisgender women

### Trial Design and Primary Endpoint<sup>1,2</sup>



# Baseline Characteristics & Efficacy

Characteristic	Cohort		
	Overall (%) N=3224	APRETUDE (%) n=1614	TDF/FTC (%) n=1610
<b>Gender identity</b>			
Cisgender women	>99%	>99%	>99%
<b>Age</b>			
Median age, years (IQR)	25 [22-30]	25 [22-30]	25 [22-30]
≤25	57	57	57
>25	43	43	43

## Significantly Lower Incidence of HIV-1 Infection vs a Daily Oral PrEP

**90%**

LOWER INCIDENCE  
vs TDF/FTC

Incident HIV-1 infections

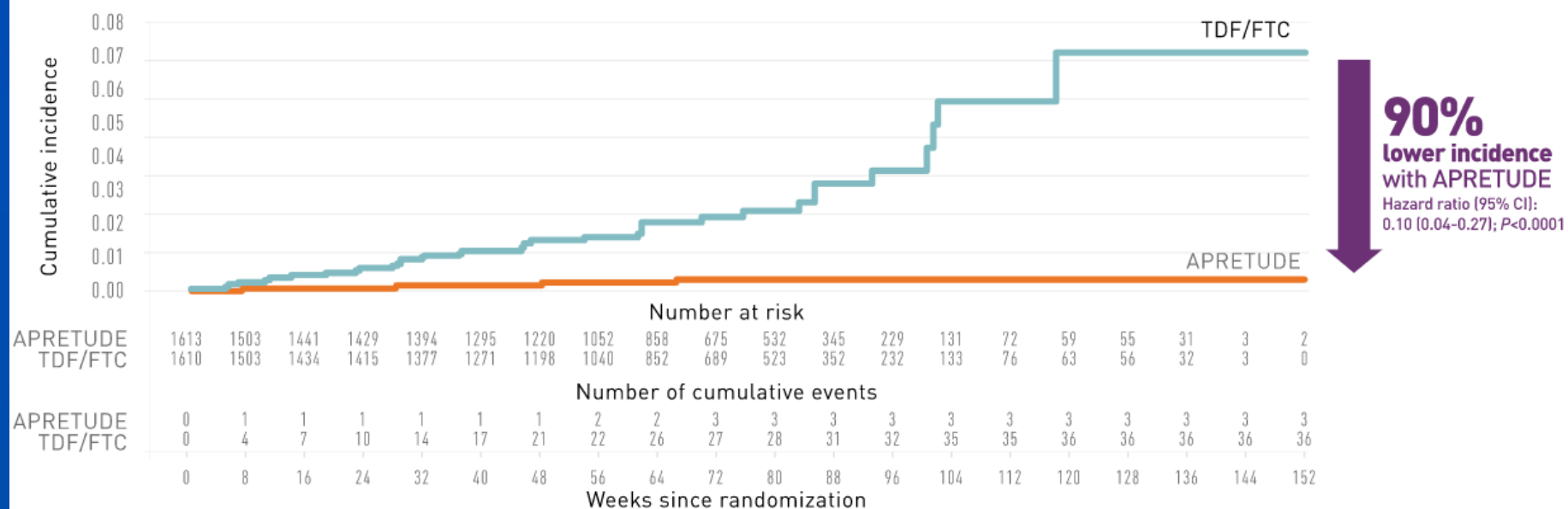
APRETUDE: 3<sup>†</sup>  
in 1960 person-years

TDF/FTC: 36  
in 1946 person-years



HIV-1 infections occurred  
**12x less often**  
WITH APRETUDE

### Cumulative Incidence of HIV-1 Infections in HPTN 084



# Subgroup analysis

Incidence of HIV-1 Infection by Age

Age	APRETUDE (incidence per 100 person-years)	TDF/FTC (incidence per 100 person-years)	Hazard ratio (95% CI)
<25 years	0.23	2.34	0.12 (0.03-0.46)
≥25 years	0.09	1.46	0.09 (0.02-0.49)

Incidence of HIV-1 Infection by BMI

BMI	APRETUDE (incidence per 100 person-years)	TDF/FTC (incidence per 100 person-years)	Hazard ratio (95% CI)
<30	0.22	1.88	0.12 [0.04-0.38]
≥30	0.00	1.76	0.04 (0.00-0.93)



# Brief Overview of Other Options

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## Trogarzo (Ibalizumab)

- Recombinant humanized monoclonal antibody
- Post attachment inhibitor
- For MDR HIV infections
- Add-on therapy to oral maintenance
- Every 2 week infusion



[https://www.uptodate.com/contents/ibalizumab-drug-information?source=auto\\_suggest&selectedTitle=1~1--1~4--ibal&search=ibalizumab](https://www.uptodate.com/contents/ibalizumab-drug-information?source=auto_suggest&selectedTitle=1~1--1~4--ibal&search=ibalizumab)



# Pipeline Agents

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- Islatravir
  - Trials halted December 2021
    - Immune system cell decline
  - Hoped for weekly or monthly pill
  - Also hoped for yearly implant
- Lenacapavir
  - Capsid inhibitor
  - SQ injection (belly) every 6 months
  - XDR patients studied
  - Needs to be added to other medications, not stand-alone
- Broadly neutralizing antibodies (bNAbs)
  - Treatment, prevention and long-term viral remission in study
  - Infusions to be paired with injections
- Leronlimab
  - CCR5 antagonist
  - Weekly SQ injection
- UB-421
  - CD4 attachment inhibitor
  - Infusion every 2 weeks

# Poll:

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There are more than 1 FDA approved injectable medication for treatment of HIV and for prevention of HIV.

- True
- False



# References

- FDA News Event. FDA Approves First Extended Release Injectable Drug Regimen in Adults Living with HIV. Updated Jan 21, 2021. Accessed March 27, 2022 via: <https://www.fda.gov/news-events/press-announcements/fda-approves-first-extended-release-injectable-drug-regimen-adults-living-hiv>
- CABENUVA [package insert]. Research Triangle Park, NC: ViiV Healthcare; 2021.
- Atlas-Flair Trials. ViiV. Accessed March 27, 2022 via: <https://cabenuvahcp.com/efficacy/atlas-flair/>
- FDA News Event. FDA Approves First Injectable Treatment for HIV Pre-exposure Prevention. Updated Dec 20, 2021. Accessed March 27, 2022 via: <https://www.fda.gov/news-events/press-announcements/fda-approves-first-injectable-treatment-hiv-pre-exposure-prevention>
- APRETUDE [package insert]. Research Triangle Park, NC: ViiV Healthcare; 2021.
- Delany-Moretlwe S; HPTN 084 Study Team. Long acting injectable cabotegravir is safe and effective in preventing HIV infection in cisgender women: results from HPTN 084. Presented at: HIV R4P Virtual Conference; January 27, 2021. Abstract LB1479.
- Marzinke MA, Delany-Moretlwe S, Agyei Y; HPTN 084 Study Team. Long-acting injectable PrEP in women: laboratory analysis of HIV infections in HPTN 084. Poster presented at: 11th International AIDS Society Conference on HIV Science; July 18-21, 2021. Virtual
- Centers for Disease Control and Prevention. Preexposure Prophylaxis for the Prevention of HIV Infection in the United States: 2021 Update. December 2021. <https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf>
- Ibalizumab. In: UpToDate, UpToDate, Waltham, MA. Accessed March 27, 2022 via: [https://www.uptodate.com/contents/ibalizumab-drug-information?source=auto\\_suggest&selectedTitle=1~1--1~4--ibal&search=ibalizumab](https://www.uptodate.com/contents/ibalizumab-drug-information?source=auto_suggest&selectedTitle=1~1--1~4--ibal&search=ibalizumab)
- Aids Map. What Do We Know About Injectable HIV Medication?. Updated Feb 15, 2022. Accessed March 27, 2022 via: <https://www.aidsmap.com/about-hiv/what-do-we-know-about-injectable-hiv-medication>

# QUESTIONS?

What questions do you have?

Please share questions in the chat or use the raise hand icon and unmute yourself.

# AK ID ECHO DIDACTIC TOPICS FOR 2022

- May 10: Common drug interactions for commonly prescribed medications for HCV, HIV, STIs - part 1
- June 14: Common drug interactions part 2: now adding COVID Tx meds into the mix
- Upcoming topics
  - Public health reporting – requirements/laws
  - Hepatitis B screening and lab interpretation
  - STI EPI Update to include HIV, C, G, w/ treatment update pearls
  - HCV Reinfection vs Treatment Failure

What topics would you like to learn about?



# ADDITIONAL LEARNING OPPORTUNITIES

## **ANTHC Liver Disease ECHO**

- Third Thursday of every month from 12:00-1:00 PM AKST
- April 21: Future Drugs for NAFLD

[anthc.org/project-echo/alaska-liver-disease-echo](http://anthc.org/project-echo/alaska-liver-disease-echo)

## **ANTHC LiverConnect**

- Second Tuesday of every month 8:00-9:00 AM AKST
- May 10: Hepatitis E

[anthc.org/what-we-do/clinical-and-research-services/hep/liverconnect](http://anthc.org/what-we-do/clinical-and-research-services/hep/liverconnect)





# ADDITIONAL LEARNING OPPORTUNITIES

## Addiction Medicine ECHO

- Second and fourth Thursday of every month from 12:00-1:00 PM
- April 14: Motivational Interviewing

[anthc.org/project-echo/addiction-medicine-echo](http://anthc.org/project-echo/addiction-medicine-echo)

## Indian Country ECHO Programs

- Harm Reduction, Infectious Disease, and more!  
[www.indiancountryecho.org/teleecho-programs](http://www.indiancountryecho.org/teleecho-programs)
- Ending the Epidemics Training Program: 4-part series in May, the second Tuesday each week from 10:30 a.m. – 12:00 p.m.

Register: <https://www.surveymonkey.com/r/EndingtheEpidemicsinIndianCountry>

Questions: [jrienstra@npaihb.org](mailto:jrienstra@npaihb.org)



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# Health Care Staff Survey

Your Input Matters!

The Alaska Native Tribal Health Consortium's Research Services and Ryan White Early Intervention Services are conducting an online survey in an effort to inform recommendations for HIV prevention and the delivery of health care services for Alaska Native People Living with HIV (PLWH). These recommendations will be shared with key stakeholders in the Alaska Tribal Health System (ATHS).

Clinical or hospital staff who provide services to patients are encouraged to take the survey.

This survey only takes 10-15 minutes to complete.

You will be entered to win one of three  
\$100 gift cards as a thank you for participating!

**LINK: <https://is.gd/healthcaresurvey>**

This survey is anonymous and confidential.



## Eligibility

- Who? Clinical or hospital employees who provide services to patients in the ATHS
- One-time electronic anonymous survey that takes about 15-20 minute to complete
- Three \$100 gift cards raffle at each participating region
- Approved through: Alaska Area IRB, ANTHC, SCF, BBAHC and YKHC



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ANTHC Liver Disease and Hepatitis Program: 907-729-1560

ANTHC Early Intervention Services/HIV Program: 907-729-2907

## Northwest Portland Area Indian Health Board

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*Thank you!*

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