Immune Mediated Viral Control off-ART

March 8, 2025

Pre-CROI HIV Cure Community Workshop

Arlene Nugent, MSc. (PhD), Scientific Director, Medical Affairs

Ana Pires, MD, MSc., M.B.A - Senior Medical Director, Clinical Development

Disclaimers

- **Conflict of interest: Arlene Nugent and Ana Pires** are Abbvie employees and may hold company shares
- This non-promotional scientific presentation has been developed and presented by AbbVie and is intended for your own professional scientific interest and education.
- AbbVie was invited by the Pre-CROI HIV cure community workshop organisers to give this presentation on immune mediated control without ART.
- During this presentation, we will be mentioning **investigational therapies that have not been approved by health authorities for any indication**, including FDA (USA), EMA (EU), MHRA (UK) or Health Canada (Canada) for any indication.
- AbbVie, in no way, intends to recommend or imply that the products should be used for unapproved uses.
- **All data presented are within the public domain** *(published peer reviewed journals, congress data and clinical trial sites*)

Research continues in the HIV treatment landscape from daily oral and injectable ART to long-acting regimens, with future therapeutics in the pipeline targeting off-ART disease control and elimination of the virus

	TODAY	2025-2029	2030+	TBD
VIRAL RESERVOIR	Short-term HIV suppression, no effect on latent reservoir	Longer-term HIV suppression, no effect on latent reservoir	Viral reservoir decay; not fully eliminated	Eradication of all virus after finite therapy
TREATMENT DESCRIPTION	• Continuous daily oral or bi-monthly injectable	• Longer-acting injectables (~4-6 months) • Longer acting orals (weekly, monthly)	• Finite therapy, immune targeting, for viral suppression without ARTs and off drug	• Sustained viral response • Treatment free • Disease free
TREATMENT TYPES	ART	LONG-ACTING ART / LONGER-ACTING ART	ART-FREE IMMUNE-MEDIATED TREATMENTS	GENE AND CELL TXs SINGLE SHOT CURE

abbvie

Note: ART = anti-retroviral therapy; bNAbs = broadly neutralizing antibodies
Adapted from Deeks et al. Lancet HIV. 2021; 8:e42-e50

Factors to consider with immune control off ART for HIV on the pathway towards cure

Controlling the virus so that it does not progress or cause damage to the immune system without ongoing treatment

Understanding the immune mechanisms that control the virus without ART offers key insights for developing and improving vaccines to induce similar immune responses in the broader population

Harnessing or replicating natural immune control has the potential to:

- reduce the need for lifelong ART, alleviating the burden of daily medication, reducing side effects, and lowering the risk of drug resistance
- Enhance QoL for peoples living with HIV (PLWH)
- Decrease stigma
- Lead to cost savings to PLWH and the healthcare system

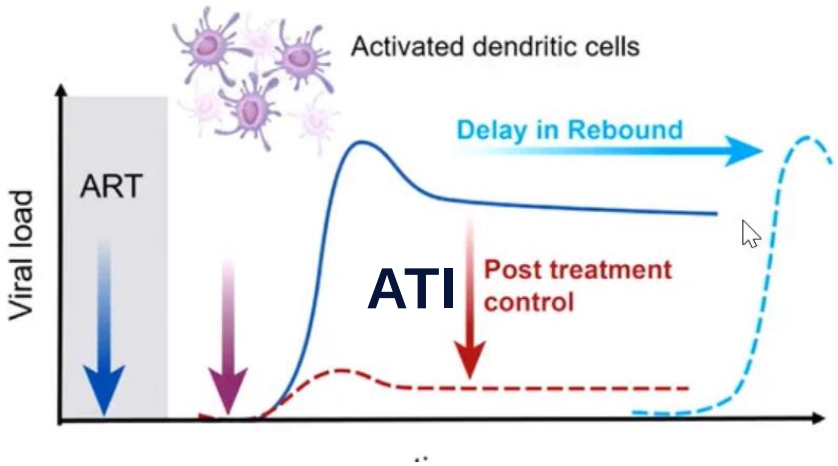
Considerations when developing an ideal regimen:

- Safe
- Achieve long-term viral suppression
- Eliminate risk of viral transmission
- Protect against re-infection
- Affordable and reach all people living with HIV

abbvie

Ming JL, Fidler S, Frater J. Curr Opin Infec Dis. 2022; 35:31-41

Immune mediated clinical trial designs often include an Analytical Treatment Interruption (ATI): Multiple studies are in proof of concept to control the virus post-ART

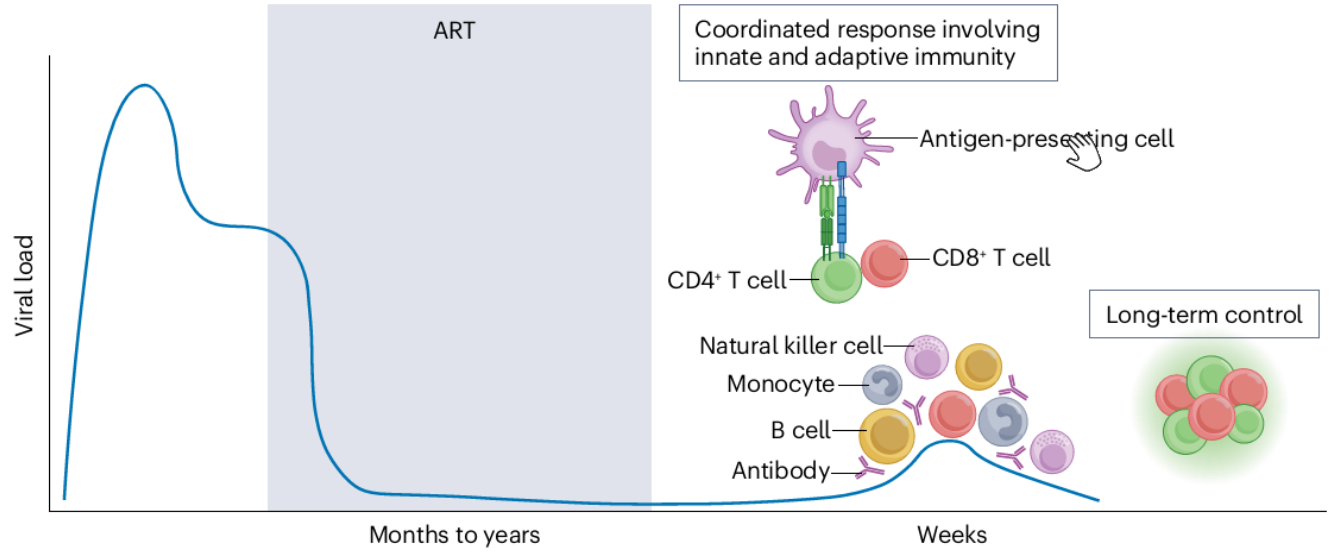


Lancet HIV 2019
Recommendations for analytical antiretroviral treatment interruptions in HIV research trials – report of a consensus meeting.
Julg et al

Long-term control will most likely be mediated by T-cells similar to those seen in post-treatment or natural (elite) controllers

Reproduced from Julg et al. Lancet HIV 2019; Mitchell et al. J Clin Inv 2020

There is no biomarker available that can predict time to rebound or post treatment control and therefore treatment interruption is needed as a clinical endpoint

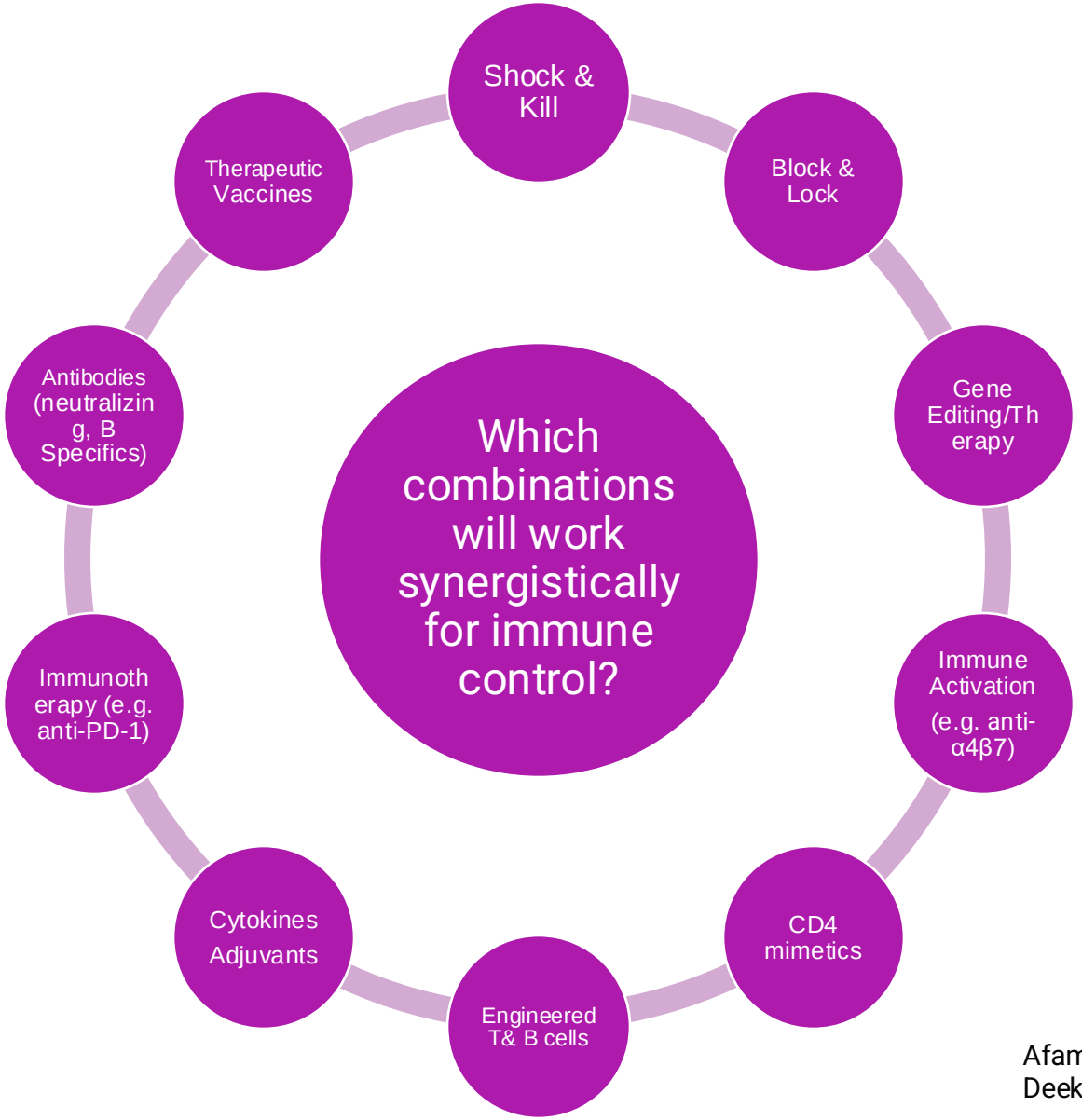


abbvie

Julg et al. 6(4):e259-e268
Landovitz RL, Scott H, Deeks SG. Nature Reviews Microbiology. 2023; 21:657–670

Several agents that are not classical antiretrovirals, but work by stimulating the immune system to leading to viral control are being investigated from pre-clinical to Phase 2 trials

Examples of targets towards HIV cure. Not an exhaustive list



PD-1, programmed cell death-1.

Afam Okoye. CROI 2024; Denver, CO, USA . Workshop-01
Deeks SG et al. Nature Medicine 2021; **27**: 2085–2098

PD-1 is Central to Immune Exhaustion

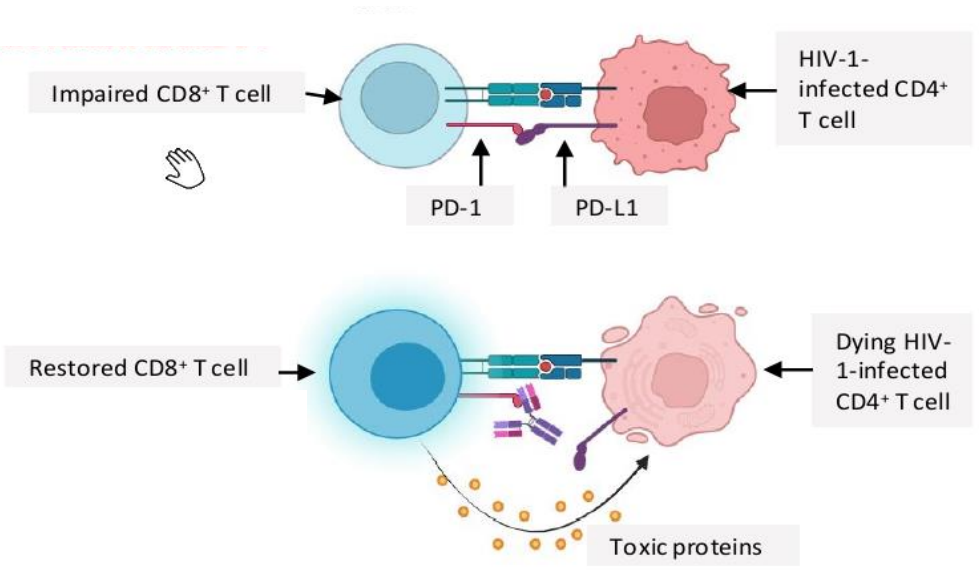
Upregulation of immune checkpoint proteins such as PD-1, may inhibit T-cell function by causing T-cell dysfunction/exhaustion[1-3]

PD-1 overexpression on CD4+ and CD8+ T cells has been shown to increase HIV disease progression[1]

PD-1 blockade may mediate functional restoration of exhausted CD8+ T cells resulting in enhanced cytotoxicity against HIV-infected cells[1-3]

PD-1, programmed cell death-1; TCR, T-cell receptor.

Proposed role of PD-1

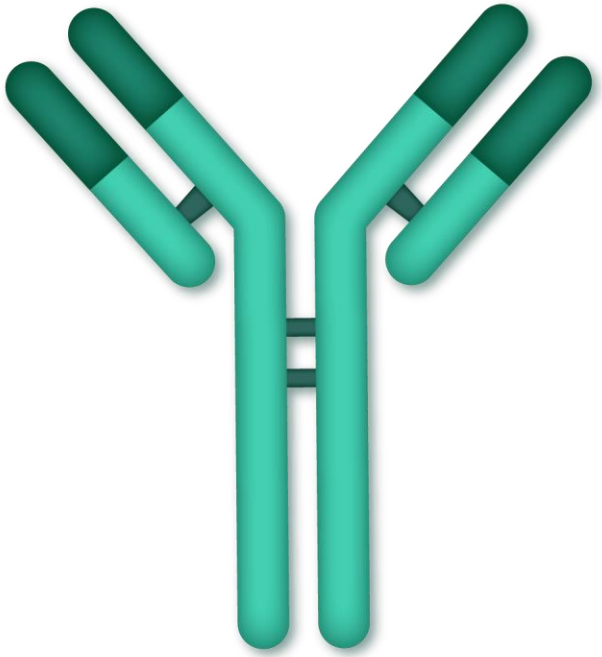


Small studies in rhesus macaques and in HIV individuals on stable ART with PD-1 blockade have reported viral control in the absence of ART[4-7]

1.Guebser C *et al*. *Ebio Medicine* 2022; https://doi.org/10.1016/j.ebiom.2022.103840; 2. Cai H, *et al. Viruses* 2020; **12:**1051; 3 He X, *et al. Miccrobiol Spec* 2023; Dec 12;11(6):e0335023
4. Perreau M, *et al. Trends Mol Med* 2017; **23:**945–961; 5. Routy JP et a. EACS 2023; oral: abstract 1077; 6. Riberio SP *et al.* *Nature Immunology* 2024; **25**; 1900–1912
7, Uldrick TS *et al.* Sci Transl Med, 2022; 14: eabl3836.

Anti-α4β7 mAb are Reported to Disrupt Viral Replication, Cell-to-Cell Transmission and Generate Viral-Specific Immunity

Anti-α4β7 mAb: Proposed Mechanisms of Action



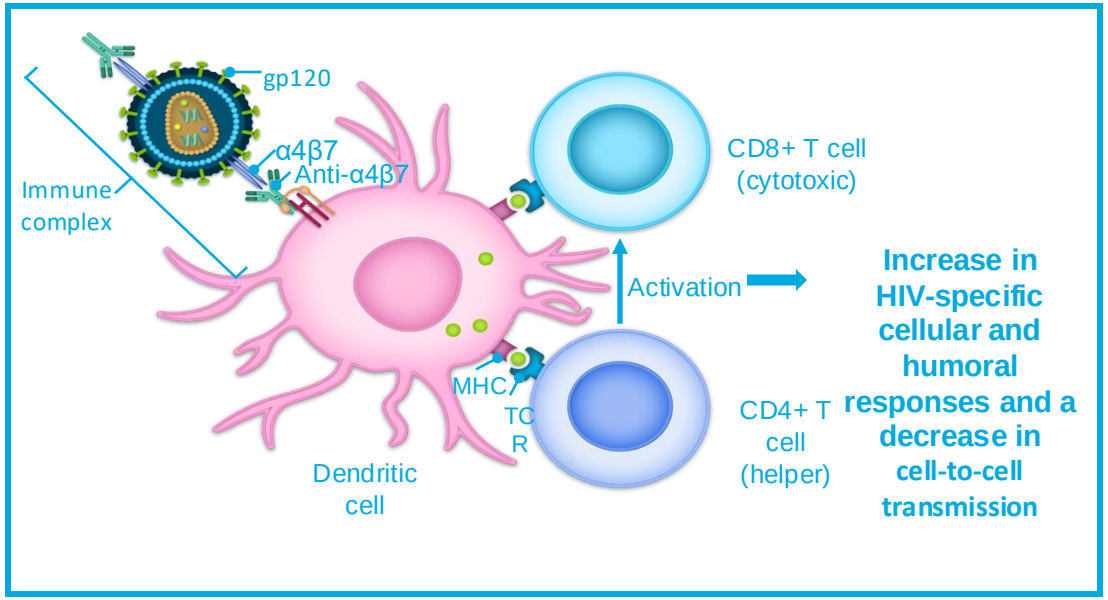
Fc domain independent:

- Disruption of the interaction between α4β7 and gp120 thereby preventing activation of LFA-1 and subsequent **cell-to-cell transmission**[1,3–5]
- Promotion of **lymphocyte trafficking** to GALT[1,2,4]

Fc domain dependent:

- Interaction of the intact Fc domain with FcγRs on effector cells or APCs which may enhance **antigen presentation** and/or **induce clearance** through Fc effector functions (**vaccinal effect**)[1,6–8]

Proposed Fc Domain-Dependent Function[1]

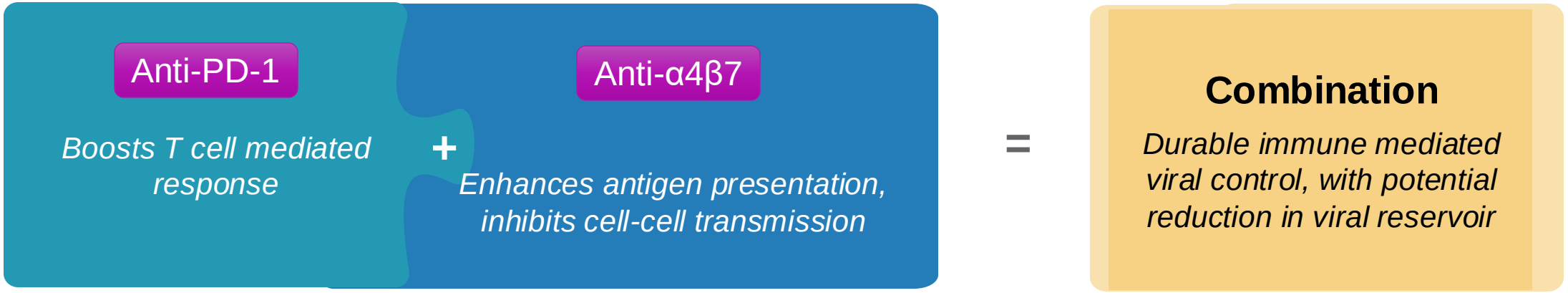


APC, antigen-presenting cell; Fc, fragment crystallizable; GALT, gut-associated lymphoid tissue; IgG, immunoglobulin G; LFA-1, lymphocyte function-associated antigen-1; mAb, monoclonal antibody; MHC, major histocompatibility complex; TCR, T-cell receptor.

1. Pre-investigational new drug document. AbbVie data on file; 2. Nawaz F, *et al*. *Mucosal Immunol* 2018; **11:**1342–1351;
3. Arthos J, *et al. Curr HIV/AIDS Rep* 2018; **15:**127–135; 4. Arthos J, *et al. Nat Immunol* 2008; **9:**301–309;
5. Guzzo C, *et al. Sci Immunol* 2017; **2:**eaam7341; 6. Wang P, *et al. Proc Natl Acad Sci U S A* 2020; **117:**18002–18009.
7. Byrareddy, et al (2016). 354(6309), 197–202. 8. Wells et al PLoS computational biology, 17(6), e1009031

abbvie

The combination of an anti-PD-1 with and anti-α4β7 could have synergistic effects for immune mediated control



- ✓ PD-1 and α4β7 blockade are complementary approaches that have the potential to synergize to induce a durable immune response

These are not antiretrovirals. They are hypothesized to work by stimulating the participant's immune system to respond to HIV, potentially leading to **ART-Free immune mediated** viral control.

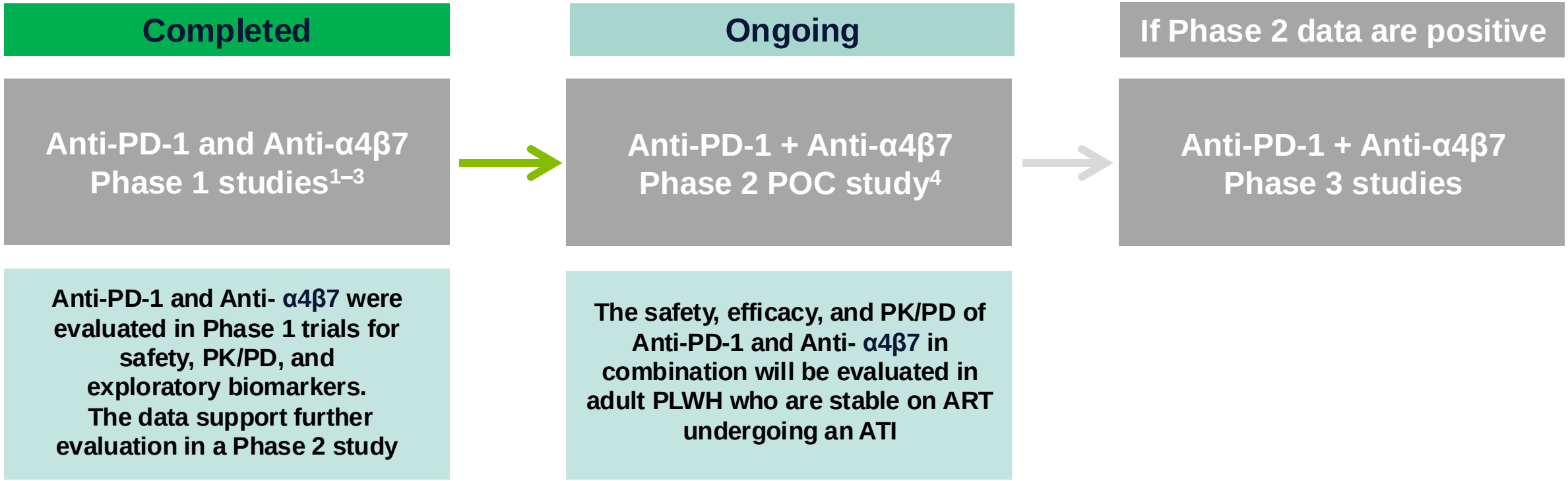
abbvie

Abbvie program overview: Focusing on Immune-mediated viral control

Ana Gabriela Pires dos Santos

Senior Medical Director – Clinical Development

Abbvie HIV viral control proposed clinical program



1. ClinicalTrials.gov identifier: NCT04223804. Available at: https://clinicaltrials.gov/ct2/show/NCT04223804 (accessed Jan 2025)
2. ClinicalTrials.gov identifier: NCT04799353. Available at: https://clinicaltrials.gov/ct2/show/NCT04799353 (accessed Jan 2025)
3. ClinicalTrials.gov identifier: NCT04554966. Available at: https://clinicaltrials.gov/ct2/show/NCT04554966 (accessed Jan 2025)
4. ClinicalTrials.gov identifier: NCT04799353. Available at: https://clinicaltrials.gov/ct2/show/NCT04799353 (accessed Jan 2025).

ATI, analytical treatment interruption; POC, proof of concept.

abbvie

Abbvie HIV viral control proposed clinical program

Completed

Anti-PD-1 and Anti-α4β7 Phase 1 studies[1–3]

Anti-PD-1 and Anti- α4β7 were evaluated in Phase 1 trials for safety, PK/PD, and exploratory biomarkers. The data support further evaluation in a Phase 2 study

Ongoing

Anti-PD-1 + Anti-α4β7 Phase 2 POC study[4]

The safety, efficacy, and PK/PD of Anti-PD-1 and Anti- α4β7 in combination will be evaluated in adult PLWH who are stable on ART undergoing an ATI

If Phase 2 data are positive

Anti-PD-1 + Anti-α4β7 Phase 3 studies

1. ClinicalTrials.gov identifier: NCT04223804. Available at: https://clinicaltrials.gov/ct2/show/NCT04223804 (accessed Jan 2025)
2. ClinicalTrials.gov identifier: NCT04799353. Available at: https://clinicaltrials.gov/ct2/show/NCT04799353 (accessed Jan 2025)
3. ClinicalTrials.gov identifier: NCT04554966. Available at: https://clinicaltrials.gov/ct2/show/NCT04554966 (accessed Jan 2025)
4. ClinicalTrials.gov identifier: NCT04799353. Available at: https://clinicaltrials.gov/ct2/show/NCT04799353 (accessed Jan 2025).

ATI, analytical treatment interruption; POC, proof of concept.

abbvie

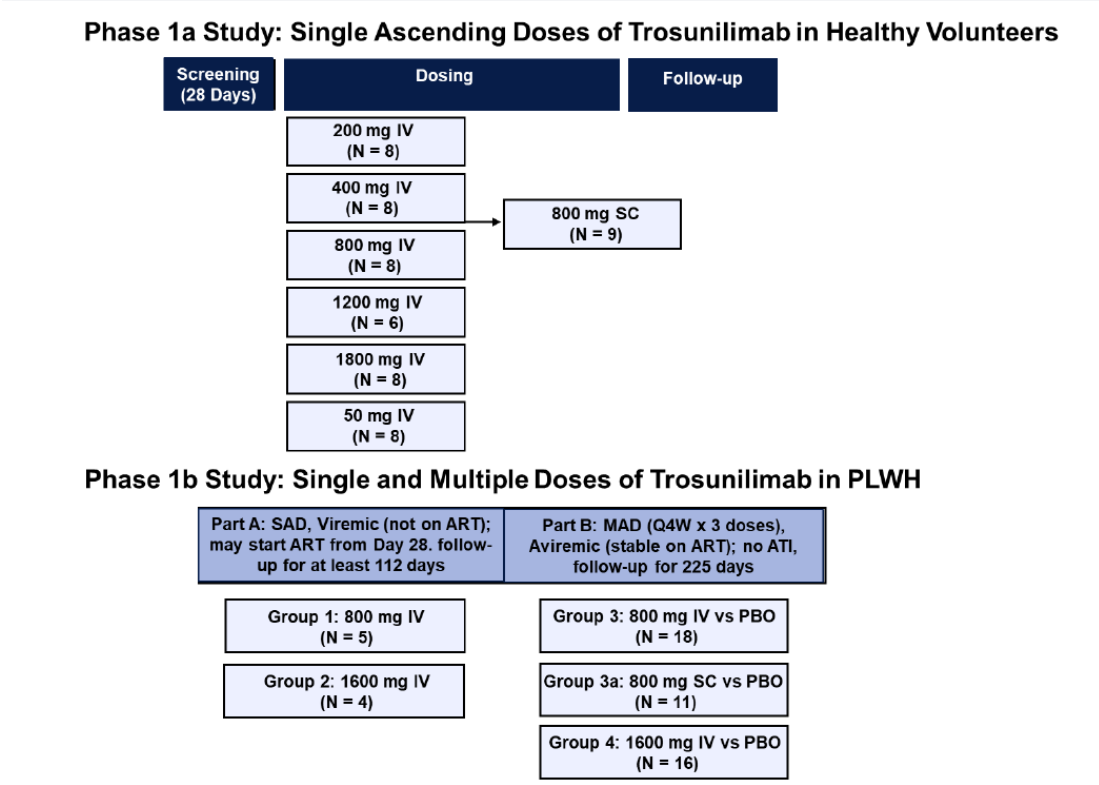
Anti-α4β7 phase 1b: Safety & pharmacokinetics in Healthy adults and PLWH

Main Objectives of the program[1]:

- To evaluate how safe ABBV-382 is and how it moves within the body in adult Healthy adults in single dose vs placebo (n=55)
- To evaluate how safe ABBV-382 is and how it moves within the body in adult PLWH in multiple doses (N=54)

Results will be presented at CROI 2025. Poster 0709 on March 11 at 2:30PM PST

Phase 1 Study Design



References:

1.ClinicalTrials.gov identifier: NCT04554966. Available at: https://clinicaltrials.gov/ct2/show/NCT04554966 (accessed Jan 2025)

2. Trosunilimab Safety, Pharmacokinetics and Pharmacodynamics in Healthy People and People With HIV-1. CROI poster 0709.

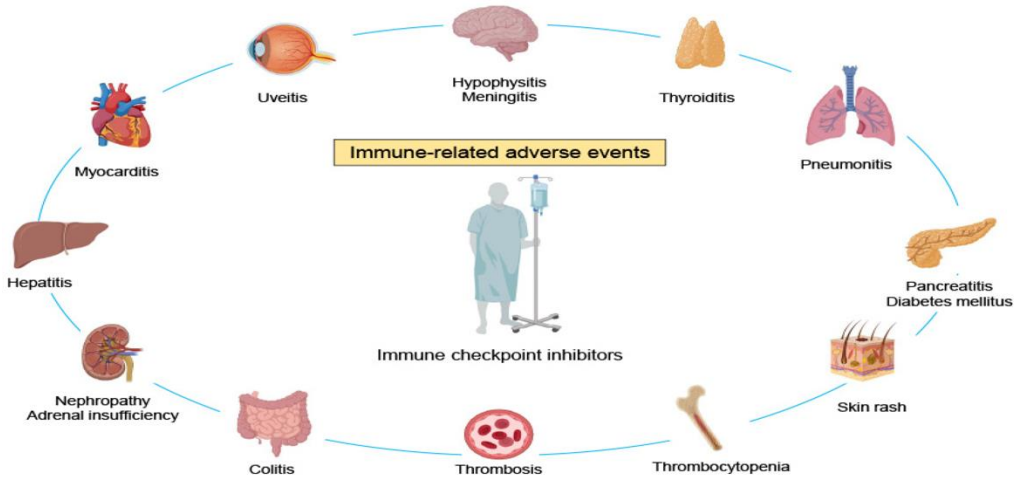
abbvie

Anti-PD1 phase 1b: Understand safety & pharmacokinetics to identify the lowest dose with favorable risk/benefit for PLWH

Main Objectives and endpoints of the program:

- To test how safe Budigalimab is and how it moves within the body in adult participants living with HIV, in single dose (M19-972) and multiple doses (M19-939)
- Pharmacodynamics including saturation of the receptor, viral load measurements and biomarkers (exploratory)

Anti-PD1s may harness auto-reactive T-cells, leading to the development of auto-immune reactions specifically known as immune-related adverse events (irAE)



AESI, adverse event of special interest; irAE, immune-related adverse event; MOA, mechanism of action; PD, pharmacodynamic; PD-1, programmed cell death-1; PK, pharmacokinetic; SAD, single ascending dose.

1. ClinicalTrials.gov identifier: NCT04223804. Available at: https://clinicaltrials.gov/ct2/show/NCT04223804 (accessed Jan 2025).
2. ClinicalTrials.gov identifier: NCT04799353. Available at: https://clinicaltrials.gov/ct2/show/NCT04799353 (accessed Jan 2025).

Safety, Pharmacokinetics, and Exploratory Efficacy of the PD-1 Inhibitor Budigalimab in ART-Suppressed People Living With HIV-1: Preliminary Analysis of 2 Phase 1b Studies Including an Analytical Treatment Interruption

Moti Ramgopal,[1] Jay Lalezari,[2] Ana Gabriela Pires dos Santos,[3] Preethi Krishnan,[3] Tanaya Vaidya,[3] Fei Zhou,[3] Nael M. Mostafa,[3] Till Geib,[3] Heide Betman,[3] Patrick Dorr,[3] Maria L. Alcaide,[4] Jean-Pierre Routy[5]

[1]Midway Immunology & Research Center, Fort Pierce, FL, USA; [2]Quest Clinical Research, San Francisco, CA, USA; [3]AbbVie, Inc., North Chicago, IL, USA; [4]University of Miami Miller School of Medicine, Miami, FL, USA; [5]McGill University Health Centre, Montreal, QC, Canada

abbvie

Information on investigational product (off label data)

COMMUNITY SLIDE

What do we know about the research with Budigalimab in HIV?

- Considering Budigalimab is a drug candidate that is similar to immunotherapy used in cancer., We need to know more about its safety and its effects in people living with HIV.

What was the key finding(s) and take-home message?

- In this first study in people living with HIV, very low doses of budigalimab administered for a fixed duration appeared to have a favorable safety profile.
- Treatment with very low dose budigalimab (Q2W x4 doses) appeared to delay viral rebound and/or prolong ART-free viral control in 6 of 9 participants who had stopped taking ART under close monitoring; 2 participants remained off ART until the end of the study due to continuing viral suppression.

Why is this important?

- Testing safety is a critical step in developing a drug candidate.

How is this related to cure?

- Budigalimab has the potential to impact the response of the immune system to HIV.

Why should we be excited (or not) about this?

- These studies suggest that we should keep studying budigalimab in HIV.

What are next steps?

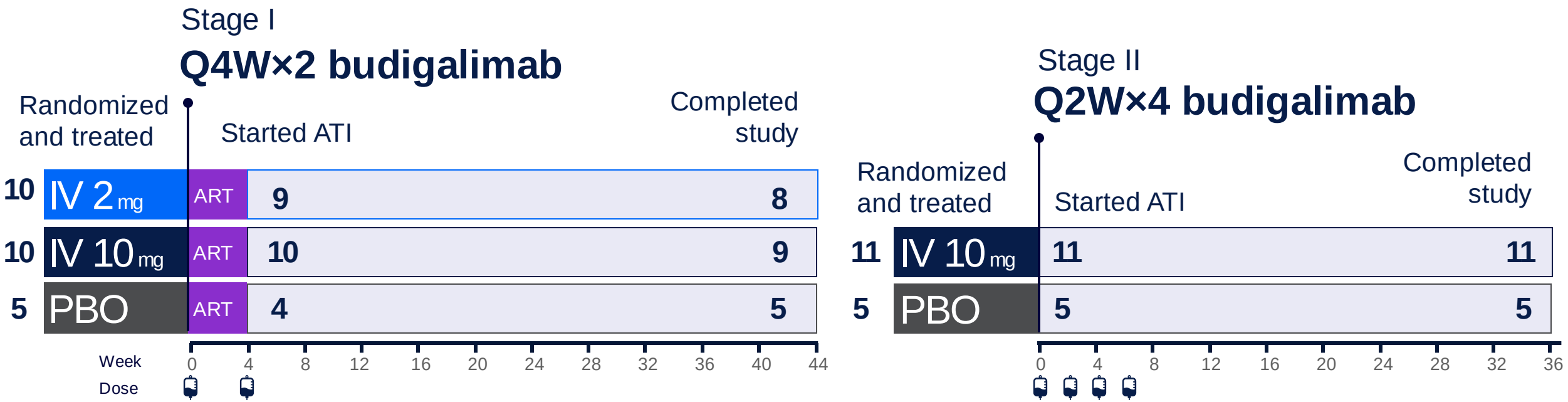
- More studies of budigalimab in combination with other immunotherapy drug candidates as a treatment for HIV.

abbvie

Routy JP et a. EACS 2023; oral: abstract 1077

M19-939 and M19-972: Phase 1b randomized double-blind studies of budigalimab in PLWH

- M19-939



Week 0 indicates baseline/start of treatment.
ART, antiretroviral treatment; ATI, analytical treatment interruption; IV, intravenous; PBO, placebo; PLWH, people living with HIV; Q2W, every 2 weeks; Q4W, every 4 weeks.

Routy JP et a. EACS 2023; oral: abstract 1077

Participant characteristics

M19-939					
	Stage I: Q4W×2			Stage II: Q2W×4	
Characteristic	**Placebo** N=5	**2 mg IV** N=10	**10 mg IV** N=10	**Placebo** N=5	**10 mg IV** N=11
Male	5 (100)	10 (100)	10 (100)	5 (100)	10 (91)
Race					
Black/African American	0	2 (20)	3 (30)	0	3 (27)
White	5 (100)	8 (80)	7 (70)	5 (100)	8 (73)
Ethnicity					
Hispanic/Latinx	3 (60)	5 (50)	3 (30)	2 (40)	3 (27)
Age, y	44 (14)	42 (13)	47 (14)	49 (11)	47 (14)
HIV-1 disease, y	11 (13)	9 (8)	13 (9)	19 (6)	11 (7)
CD4+ cell count, cells/µL	652 (143)	887 (263)	785 (175)	680 (160)	775 (203)
Viral suppression on ART, y	10 (12)	7 (5)	13 (9)	16 (5)	11 (6)

Data are expressed as number (%) or mean [SD].
ART, antiretroviral treatment; IV, intravenous; Q2W, every 2 weeks; Q4W, every 4 weeks.

Routy JP et a. EACS 2023; oral: abstract 1077

Combined safety data for budigalimab in 73 participants

AE Participants with at least 1 AE	Placebo Combined N=18	M19-939 Stage I[a] N=20	M19-939 Stage II[a] N=11	M19-972[a] N=24	Total N=73
Any AE	11 (61)	12 (60)	11 (100)	17 (71)	51 (70)
TR-AE	5 (28)	4 (20)	5 (45)	7 (29)	21 (29)
TR-AE leading to discontinuation	0	0	1 (9)	0	1 (1)
Serious AE	2 (11)	0	0	0	2 (3)
Serious TR-AE	0	0	0	0	0
Immune-related AE	0	1 (5)[b]	1 (9)[c]	1 (4)[d]	3 (4)
Death	0	0	0	0	0

All data are n (%).
[a]Stage I, 2-mg IV and 10-mg IV doses combined; Stage II, 10-mg IV dose; M19-972,10-mg SC, 20-mg SC, and 10-mg IV doses combined.
[b]10-mg IV dose, grade 1 thyroiditis (days 59–128).
[c]10-mg IV dose, grade 1 hyperthyroidism (days 14–70).
[d]20-mg SC dose, grade 2 lichenoid drug eruption (days 15–51).
AE, adverse event; TR-AE, treatment-related adverse event.

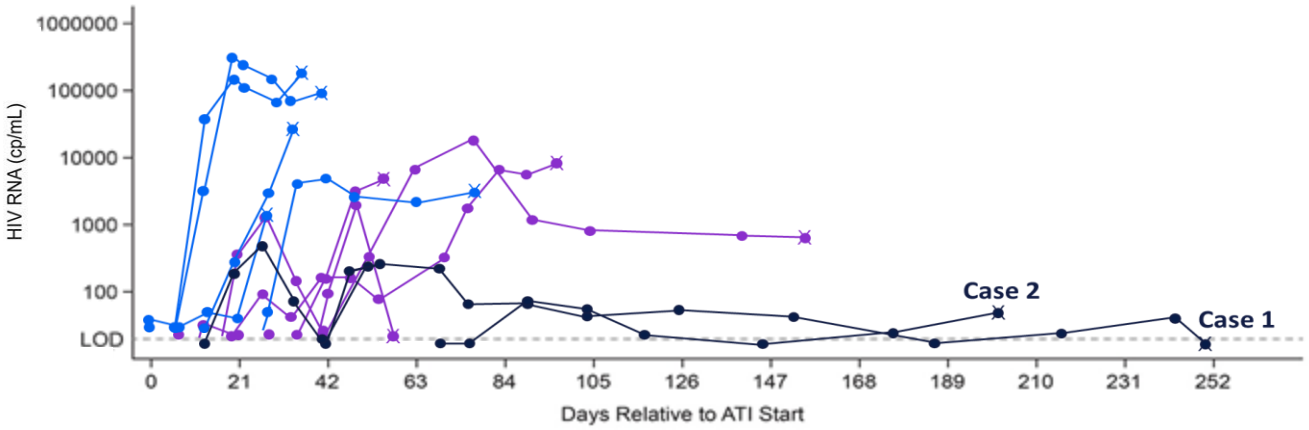
abbvie

Routy JP et a. EACS 2023; oral: abstract 1077

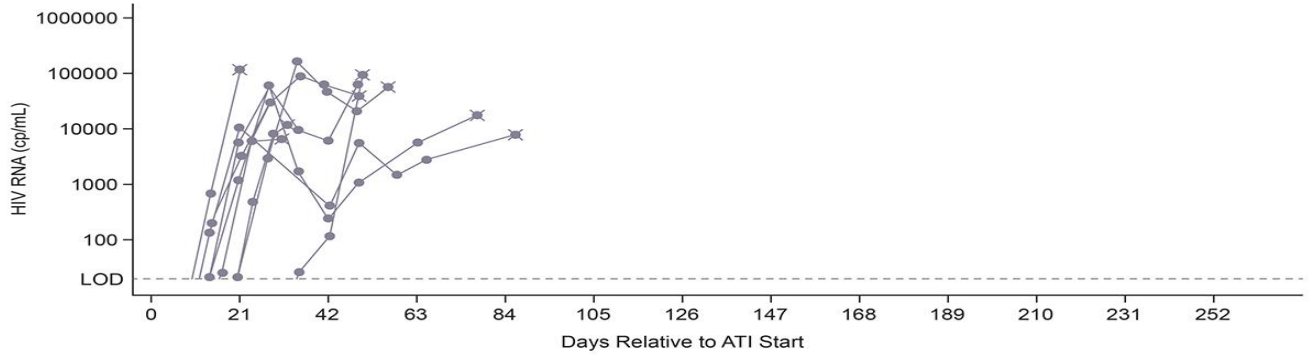
Information on investigational product (off label data)

Exploratory efficacy: Viral load kinetics during ATI (M19-939)

10-mg Q2W×4 Budigalimab (n=11)



Pooled Placebo (n=9)



Legend

- Case 1 and 2
- With delayed viral rebound or off-ART viral control[a]
- Without delayed viral rebound or off-ART viral control[a]
- Placebo
- Last observed data point before ART restart

	Pooled Placebo (n=10)	10-mg Q2W×4 Budigalimab (n=11)
Median time to viral rebound (90% CI), days	21 (21–24)	29 (21–49)

Left graphs in log scale; day 0 corresponds to baseline; in stage II, 2 participants discontinued study drug: 1 for protocol violation (prohibited live vaccination); 1 for AE (grade 1 reversible hyperthyroidism).
[a]Defined as experiencing delayed viral rebound (>21 days) and/or off-ART viral control (<1000 cp/mL).
ART, antiretroviral therapy; ATI, analytical treatment interruption; LOD, limit of detection (20 cp/mL); Q2W, every 2 weeks.

Routy JP et a. EACS 2023; oral: abstract 1077

abbvie

Conclusions

Budigalimab administered for finite duration at very low doses was well tolerated in phase 1b studies of PLWH

Near-complete PD-1 receptor saturation was achieved for ~10 weeks post-ATI with four 10-mg biweekly IV doses

Biweekly administration of budigalimab 10 mg IV for 4 doses led to delayed viral rebound and/or ART-free viral control in 6 of 9 participants completing treatment, with 2 participants remaining off ART until the end of the study

Phase 2 studies examining ART-free viral control with budigalimab 10 mg are warranted

ART, antiretroviral therapy; ATI, analytical treatment interruption; IV, intravenous; PD-1, programmed cell death protein; PLWH, people living with HIV.

abbvie

Routy JP et a. EACS 2023; oral: abstract 1077

Abbvie HIV viral control proposed clinical program

Completed

Anti-PD-1 and Anti-α4β7 Phase 1 studies[1–3]

Anti-PD-1 and Anti- α4β7 were evaluated in Phase 1 trials for safety, PK/PD, and exploratory biomarkers. The data support further evaluation in a Phase 2 study

Ongoing

Anti-PD-1 + Anti-α4β7 Phase 2 POC study[4]

A Phase 2, Multicenter, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate Efficacy, Safety, Tolerability, and Pharmacokinetics of Budigalimab and/or ABBV-382 in People Living with HIV on Stable Antiretroviral Therapy Undergoing Analytical Treatment Interruption

If Phase 2 data are positive

Anti-PD-1 + Anti-α4β7 Phase 3 studies

Phase 2 milestone	Date (lastest)
First site activated	10-Oct-23
First Participant Screened	12-Oct-23
First Participant First Dose	02-Nov-23
Last Participant Last Dose	*24-Feb-2025*
Last Participant Last Visit	*Mar-2027*
Final Analysis	*Apr-2027*

ATI, analytical treatment interruption; POC, proof of concept.

abbvie

ClinicalTrials.gov identifier: NCT04799353. Available at: https://clinicaltrials.gov/ct2/show/NCT04799353 (accessedJan 2025).

Collaborators and Investigators: Countries and site selection

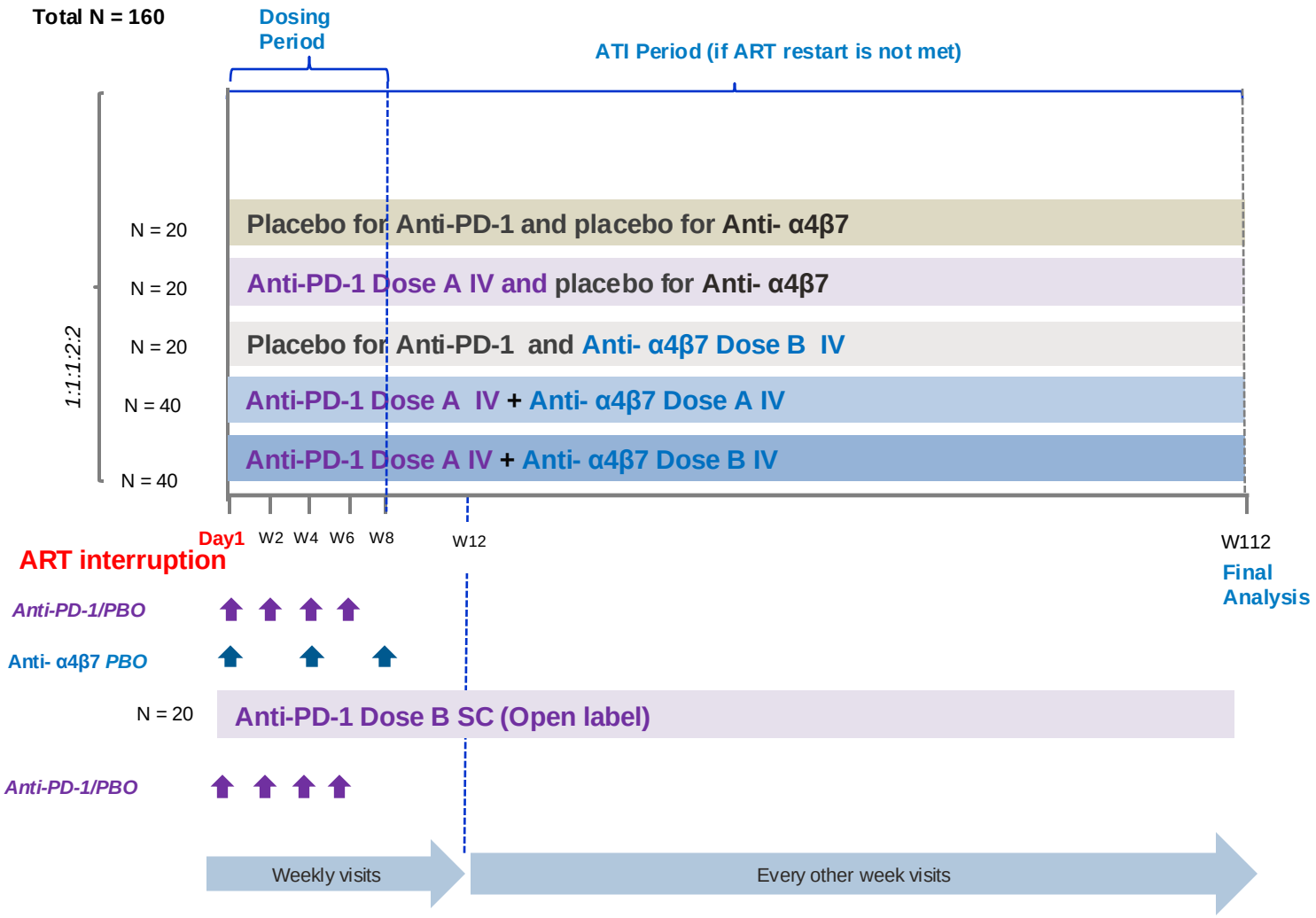
Countries	Number of Sites
United States	43
Puerto Rico	2
Brazil	1
Canada	6
United Kingdom	2
Spain	4
South Africa	4
France	2
Germany	3
Italy	4
Belgium	4
Poland	2
Japan	3
Total	80

- Sites were selected based on:
  - Experience with HIV Clinical Trials that includes an Analytical Treatment Interruption
  - Diversity
  - Site staff experience and structure to support study participants during the study
  - Site structure for drug infusions and PK collection
  - Enrollment expectations
- Sites were allowed/encouraged to share and discuss study/protocol/ICF with their local community representatives or local community boards.

abbvie

ClinicalTrials.gov identifier: NCT04799353. Available at: https://clinicaltrials.gov/ct2/show/NCT04799353 (accessedJan 2025).

How is the study designed?



Study DMC/DSMB

- Study has a DMC/DSMB (Composed of: Clinicians; Independent Statisticians; Community Representative) overseeing study safety

Study Drug Administration

- Anti-PD-1 (or placebo) given as an IV infusion for 30 minutes
- Anti- α4β7 (or placebo) given as an IV infusion for 1.5 hours
- For the combination arms Anti-PD-1 is given first followed by a 1 hour wait then Anti- α4β7 is given

Flexibility for reduce burden to participants:

- From week 11: On-site; virtual visits with local labs or home-visits are offered (PI/Participant choice)
- At anytime additional HIV RNA and CD4 can be collected per PI/Participant request.
- Participants back on ART and have already reached re-suppression have the option to collect HIV RNA/CD4 on site less frequent visits only

abbvie

ClinicalTrials.gov identifier: NCT04799353. Available at: https://clinicaltrials.gov/ct2/show/NCT04799353 (accessedJan 2025).

Participation criteria

Inclusion Criteria:

- Adults from 18 to 70 years old of any sex or gender
- A condition of general good health in the opinion of the investigator, based upon the results of a medical history, physical examination, vital signs, laboratory profile, and a 12-lead electrocardiogram (ECG).
- Must be on antiretroviral therapy (ART) for at least 12 months prior to screening and on a stable ART regimen for at least 8 weeks prior to screening (current ART regimen cannot include Non-nucleoside reverse transcriptase inhibitor [NNRTI] or long-acting ART).
- Negative human immuno-deficiency virus (HIV)-2 antibody (Ab)
- Cluster of differentiation 4 (CD4+) T cell count >= 500 cells/µL at screening and no known evidence of CD4+ T cell count < 500 cells/µL in the last 12 months prior to screening
- Participant must have plasma HIV-1 ribonucleic acid (RNA) below the lower limit of quantitation (LLOQ) at screening and for at least 12 months prior to screening

Exclusion Criteria:

- Prior exposure to long acting antiretrovirals within 24 weeks or within a period defined by 5 half-lives, whichever is longer, prior to randomization and prior to the first dose of study drug.
- History of CD4+ T cell nadir of <= 200 cells/µL during chronic HIV infection.
- History of medical disorders (other than HIV-1 infection) that, in the opinion of the investigator, might expose the participant to undue risk of harm, confound study outcomes or prevent the participant from completing the study.

abbvie

ClinicalTrials.gov identifier: NCT04799353. Available at: https://clinicaltrials.gov/ct2/show/NCT04799353 (accessedJan 2025).

What is the study measuring?

Safety

Outcome Measure	Measure Description	Time Frame
Number of participants with adverse events (AEs)	An AE is defined as any untoward medical occurrence in a patient or clinical investigation in which a participant is administered a pharmaceutical product which does not necessarily have a causal relationship with this treatment	Up to approximately week 112

Efficacy

Outcome Measure	Measure Description	Time Frame
Primary Outcome Measure		
Percentage of participants with viral control without antiretroviral (ART) restart	Percentage of participants who achieve viral control (viral load <1000 copies/mL) without ART restart at week 24	Week 24
Secondary Outcome Measures		
Median Peak Viral Load (At Rebound) prior to restarting ART	The median peak viral load (at rebound) before re-starting ART	Up to 112 weeks
Median Time to First Rebound to ≥1000 copies/mL during ART Interruption	The median time to rebound to ≥1000 copies/mL during ART interruption	Up to 112 weeks

abbvie

ClinicalTrials.gov identifier: NCT04799353. Available at: https://clinicaltrials.gov/ct2/show/NCT04799353 (accessedJan 2025).

ART Restart Criteria for the study aligned with recommendations, regulatory requests and community feedback

1. Confirmed HIV-1 viral load ≥ 100,000 copies/mL, defined as 2 or more consecutive measurements*
2. HIV-1 viral load ≥ 10,000 copies/mL, confirmed over a 4-week period *
3. HIV-1 viral load ≥ 1,000 copies/mL, confirmed over a 6-week period *
4. Confirmed absolute CD4 count < 350 cells/µL, defined as 2 consecutive measurements.
5. Pregnancy
6. Grade ≥ 3 RRS during ATI (any RRS symptom grade 3 or higher)
7. Any AE which, in the judgment of the investigator, presents a substantial clinical risk to the participant to continue ATI
8. Any social or behavioral condition which, in the judgment of the investigator, presents a substantial clinical risk to the participant to continue ATI, including **participant's request**

*To meet this criteria, participant must have multiple lab results confirming the HIV-1 viral load over the specified length of time.

abbvie

Abbvie HIV viral control proposed clinical program

Completed

Anti-PD-1 and Anti-α4β7 Phase 1 studies[1–3]

Anti-PD-1 and Anti- α4β7 were evaluated in Phase 1 trials for safety, PK/PD, and exploratory biomarkers. The data support further evaluation in a Phase 2 study

Ongoing

Anti-PD-1 + Anti-α4β7 Phase 2 POC study[4]

A Phase 2, Multicenter, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate Efficacy, Safety, Tolerability, and Pharmacokinetics of Budigalimab and/or ABBV-382 in People Living with HIV on Stable Antiretroviral Therapy Undergoing Analytical Treatment Interruption

If Phase 2 data are positive

Anti-PD-1 + Anti-α4β7 Phase 3 studies

Possible expansion to brother PLWH population according to risk:benefit profile

ATI, analytical treatment interruption; POC, proof of concept.

abbvie

ClinicalTrials.gov identifier: NCT04799353. Available at: https://clinicaltrials.gov/ct2/show/NCT04799353 (accessedJan 2025).

It takes a village …

HIV community

Study sites staff

Study participants and their families!