HHSC: Texas HIV Medication Advisory Committee, July 31, 2020

The Texas HIV Medication Advisory Committee advises in the development of procedures and guidelines for the Texas HIV Medication Program, reviews program's goals and aims, evaluates ongoing efforts, and recommends short-range and long-range goals and objectives.

Texas began distributing HIV medications in late 1987 as temporary pilot program; the THMP was officially established in 1989 in Senate Bill 959. The statute that created the HIV Medication Advisory Committee is found in Texas Health & Safety Code, Chapter 85, Sections 85.044 and 85.271-85.282. Rules related to this Committee may be found in Texas Administrative Code, Title 25, Part 1, Chapter 98, Subchapter C, Division 2, Rule 98.121. Committee members are appointed by the Commissioner of the Texas Department of State Health Services.

Natalie Vanek - Committee Chair
Houston, Texas
Term expires 2020

Frank Rosas - Committee Vice-Chair
San Antonio, Texas
Term expires 2022

Margaret Adjei
San Antonio, Texas
Term expires 2022

Ogechika Karl Alozie
El Paso, Texas
Term expires 2022

Gloria Heresi
Houston, Texas
Term expires 2024

Lionel Hillard
Dallas, Texas
Term expires 2022

Susana Lazarte
Dallas, Texas
Term expires 2020

Nancy Miertschin
Houston, Texas
Term expires 2024

Ray Moore
Granbury, Texas
Term expires 2024

Yolanda Rodriguez-Escobar
San Antonio, Texas
Term expires 2024

Demetra Tennison
Austin, Texas
Term expires 2024

Call to Order and Welcome. The meeting was called to order by Dr. Natalie Vanek, M.D., Committee Chair. A quorum was established.

Logistical Announcement and Roll Call. Sallie Allen, Advisory Committee Coordination Office, HHSC provided the logistic announcements.
Review and Approval of January 24, 2020, Meeting Minutes. The minutes were approved with minor, non-substantive change.

Commissioner's Updates. Imelda Garcia, Associate Commissioner, DSHS. The HIV program relocated to the Howard Lane location, resulting in new phone numbers. The first COVID-19 case was travel-related and now there is a whole agency response along with the Department of Emergency Management. DSHS COVID-19 numbers were presented to the Committee. *See Texas Insight's regular COVID-19 reports.*

There are increases in the number of hospitalizations and the state is rising to support hospitals across the state. They have been involved with the distribution of Remdesivir and they will be involved with the vaccine distribution once developed and approved.

The HIV program did receive additional federal funds during COVID-19 to assist with the response for the people they serve. Ninety-day refills are being provided and the application has been simplified.

Budget Update. Felipe Rocha, MSSW Director TB/HIV/STD Section stated that this is a snapshot in time and is already a month old.

Funding and Collected Revenues

Funding and Collected Revenues	2019 Projected	FY2019 YTD	FY20 Projected	FY2020 YTD	FY 2021 Projected
1. General Revenue	30,504,191	23,497,040	23,497,040	23,497,040	23,497,040
2. Federal Ryan White ADAP Funding (converted to State Fiscal Year)	80,836,014	75,221,330	86,261,491	88,761,068	87,701,609
3. Part A Donations	0	350,668	0	118,882	0
4. HIV Rebates Earmarked for THMP	10,000,000	6,747,822	2,030,913	780,914	3,274,153
4a. HIV Rebates Earmarked for Other HIV Projects (Other approved HIV projects, such as service expansion and contract increases)	16,000,000	12,572,232	13,284,767	12,123,433	12,152,105
5. Total Funding and Revenue Allocated to THMP (Does not include rebate funds for other HIV projects)	$121,340,205	$105,816,860	$111,789,444	$113,522,572	$114,472,802

Expenditures

Expenditures	2019 Projected	FY2019 YTD	FY20 Projected	FY 2020 YTD	FY 2021 Projected
1. Non Medication Expenditures	$2,290,532	2,341,750	2,500,331	2,102,728	2,341,750
2. Medication Expenditures (ALL funding sources)	95,434,747	67,492,327	100,683,658	57,382,164	71,204,405
3. Medication Co-payment, Insurance Deductible, & COBRA Expenditures (SPAP & TIAP)	11,058,448	10,042,239	10,594,562	8,336,075	10,594,562
4. Total Expenditures	$108,783,727	$79,876,316	$113,778,551	$67,820,967	$84,140,717

ADAP Medication Dispensed and Inventory

ADAP Medication Dispensed	2019 Projected	FY2019 YTD	FY20 Projected	FY 2020 YTD	FY 2021 Projected
1. ADAP Medications Dispensed	NA	101,858,225	105,630,227	105,694,614	107,460,427
ADAP Medication Inventory	**2019 Projected**	**FY2019 YTD**	**FY20 Projected**	**FY 2020 YTD**	**FY 2021 Projected**
1. ADAP Medications Inventory	NA	36,176,416	36,176,416	34,286,116	9,153,398

Mr. Rocha stated that this information means we have to fortify our financial health, especially in generating more revenue related to rebates. COVID-19 has generated more cost than anticipated (90-day fills).

Questions/Answers/Comments

What about continuing the 90-day fills past the COVID-19 period? Mr. Roche stated that because of COVID-19, the 90-day supply has been extended to many individuals. We were

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not experienced with 90-day refills when COVID-19 hit, so we do not know all the factors that could limit us.

Because revenue is dropping, is it a reasonable expectation to recover some of the loss with rebates? Mr. Roche stated they have been discussing options and it could take some program changes.

THMP Update and COVID-19 public health response (ADAP Report ADR). Rachel Sanor, THMP Manager.

The ADR is a Performance Report required by HRSA, the Federal Funder for THMP and as such, some information of the THMP application is requested because of what must be reported on the ADR. In the most recent HRSA site visit, ADR data quality was a concern.

2019 ADR Response For the 2019 ADR submission, the number of clients who received ADAP-Funded medications in 2019 increased to 17,577 compared to 2018 (n=13,937) and 2017 (n=17,043) clients. In addition, the 2019 ADR (17%) reported less clients with no services than the 2018 ADR (26%).

Due to issues with legacy systems, recertification dates have been difficult to report; however, for this year's ADR submission there were less missing recertification dates reported in 2019 compared to 2018 and 2017, 27%, 39%, and 43%, respectively.

The 2019 Application approval date had 0% missing compared to 70% missing in 2018.

In the past, HIV Status was reported based on the current year's data; however, for 2019 this variable was changed to include historical lab data. This change resulted in 34% of THMP clients identified as CDC Defined AIDS compared to 8% of 2018 clients and 11% of 2017 clients. For 2019, THMP data was matched with Ryan White Care Services data and HIV Surveillance data resulting in less missing data for several questions of the 2019 ADR. The 2019 race variable (0.4%) had less missing data than the 2017 race variable (14%). CD4 date and values had 7% missing data in 2019 compared to 12% in 2018 and 16% in 2017. The VL date in 2019 had 6% missing data compared to 11% in 2018 and 8% in 2017 and the VL value in 2019 had 6% missing data compared to 20% in 2018 and 8% in 2017.

COVID-19 Response

Eligibility: A letter was sent to all existing program participants and there is an emergency application in place. This process is not requiring copies of eligibility documents and the extension of eligibility for recertification is through state of disaster declaration.

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Medications: A letter was sent to all existing program participants. 60-day fills were provided for most medications and fills can be requested 20 days early. Medication delivery is encouraged as are 90-day fills for approved medications.

The Ryan White HIV/AIDS Program AIDS Drug Assistance Program (ADAP) Data Report (ADR) is a client-level data reporting requirement for ADAPs. The HIV/AIDS Bureau uses the ADR to evaluate the national impact of ADAP, by providing client-level data on individuals being served, services being delivered, and costs associated with these services. ADAPs are required to submit the ADR annually. The 2018 ADR is due on **June 3, 2019**.
The client-level data reported by ADAP recipients is used to:

- Monitor health outcomes of clients living with HIV receiving care and treatment services through program recipients and subrecipients.
- Address the impact of HIV in communities disproportionately affected by assessing organizational capacity and service utilization.
- Monitor the use of the Ryan White HIV/AIDS Program to appropriately address HIV in the United States.
- Track progress toward achieving the goals identified in the National HIV/AIDS Strategy: Updated to 2020.

The ADR is comprised of two components:

- **The Grantee Report:** A collection of basic information about recipient characteristics and policies.
- **The Client Report (or client-level data):** A collection of records (one record for each client enrolled in the ADAP), which includes the client's encrypted unique identifier, basic demographic data, and enrollment and certification information.

The HIV/AIDS Bureau has taken every measure possible to ensure security and confidentiality of the data collected (including the use of the eUCI), and to limit data collection to only the information that is "reasonably necessary to accomplish the purpose" of the ADR.

Questions/Answers/Comments
Have you seen a change in medication requests? There has not been a significant uptick in 90-day requests. It could be a public information issue.

The limiting factor is the certification document. Doctors are writing for 90 days but the fill is only for 30.

The speed of response by this program has been amazing.

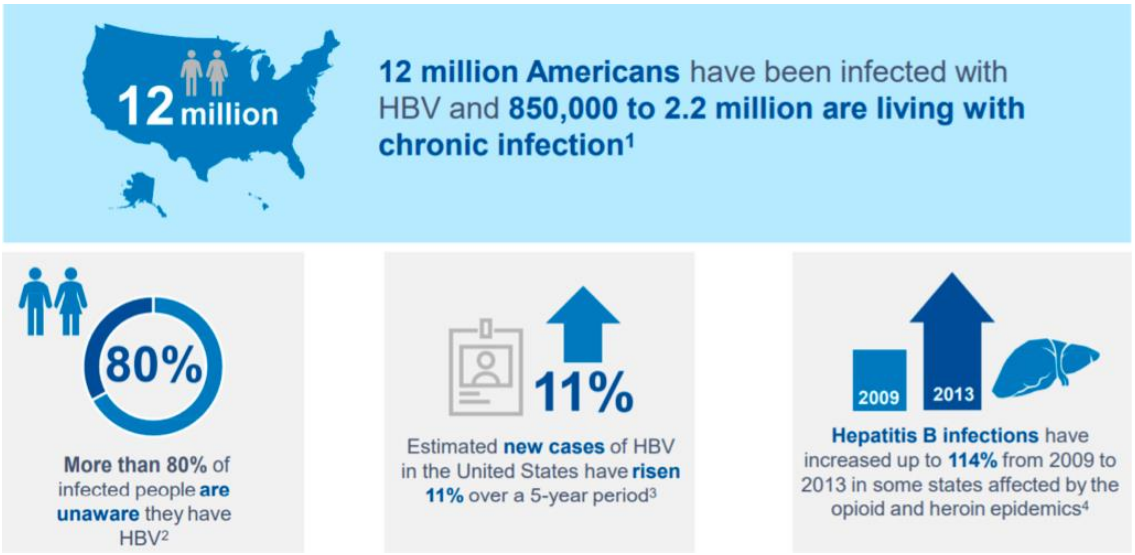
The 90-day fills required a rules change, so its continuation after COVID-19 is no longer an issue. However, in the future, there could be budgetary issues.

Patients are getting an automatic 60-day fill and it has been extended through December 31st or when the state of disaster ends.

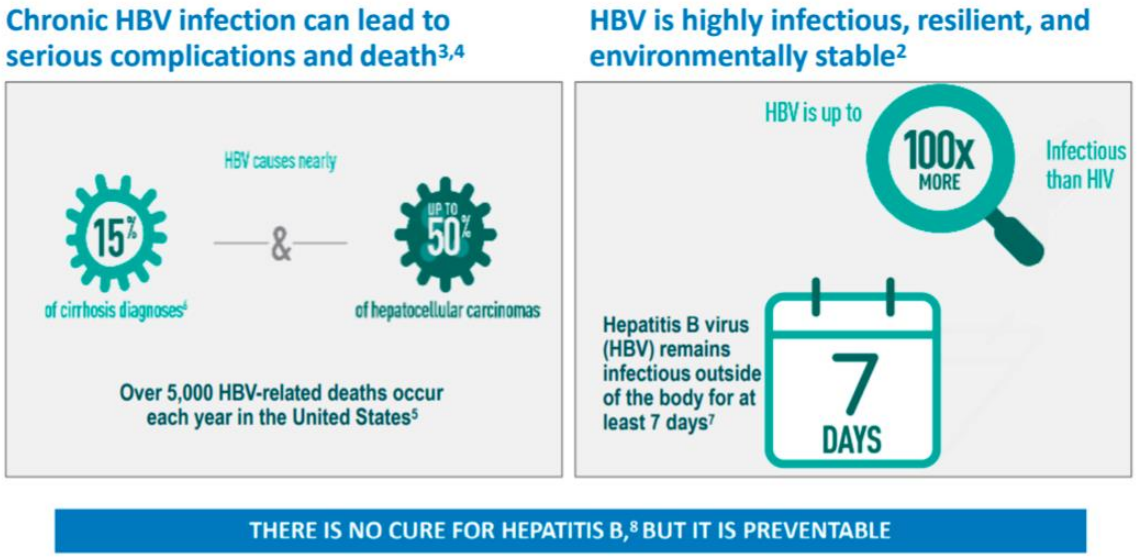
A lot of the concerns are being addressed at the Ryan White Conference

Presentation: Dynavax Technologies – HEPLISAV B. Brian Faulkner made the presentation.

Hepatitis B Is on the Rise



Hepatitis B Is an Important Public Health Concern.



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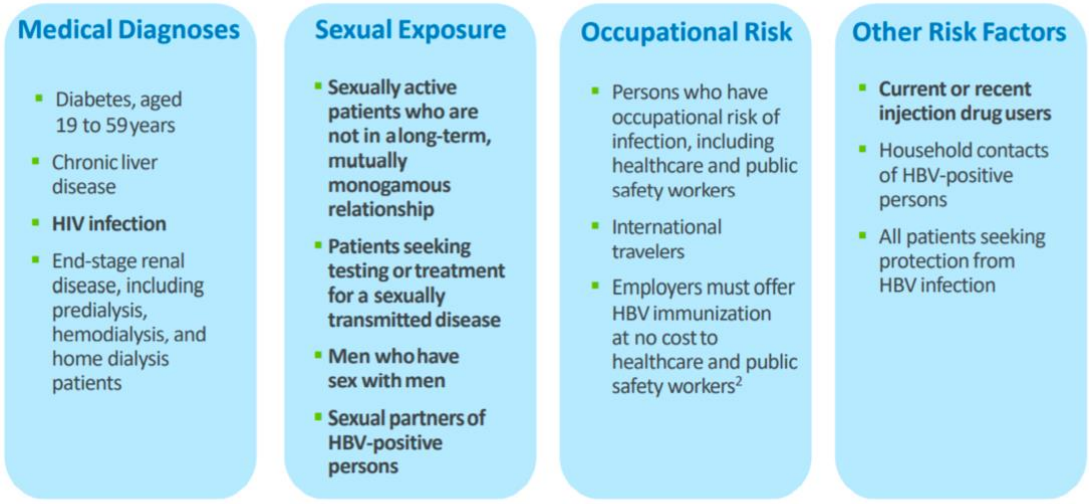
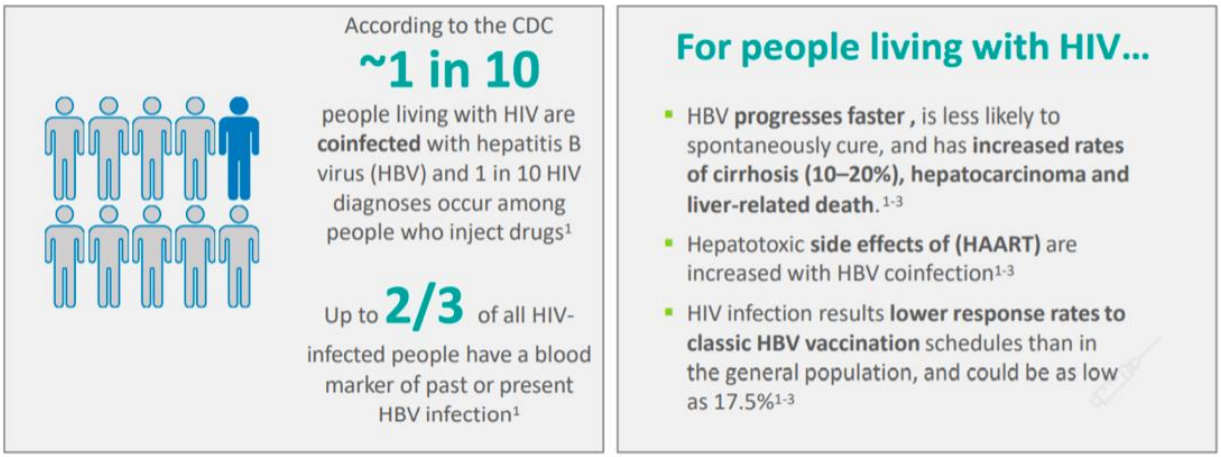
CDC Guidelines on Risk Groups Indicated for PrEP and HBV Vaccination Overlap



Co-infection with HIV and HBV is common. Both viruses share the same routes of transmission.



PROTECTION FROM HBV IS CRITICAL FOR ANYONE AT RISK OF HIV INFECTION

HEPLISAV-B® [Hepatitis B Vaccine (Recombinant),Adjuvanted]

- Indication – HEPLISAV-B is indicated for prevention of infection caused by all known subtypes of hepatitis B virus in adults 18 years of age andolder.
- Dosing & Administration – Administer 2 doses (0.5 mL each) intramuscularly 1 month apart

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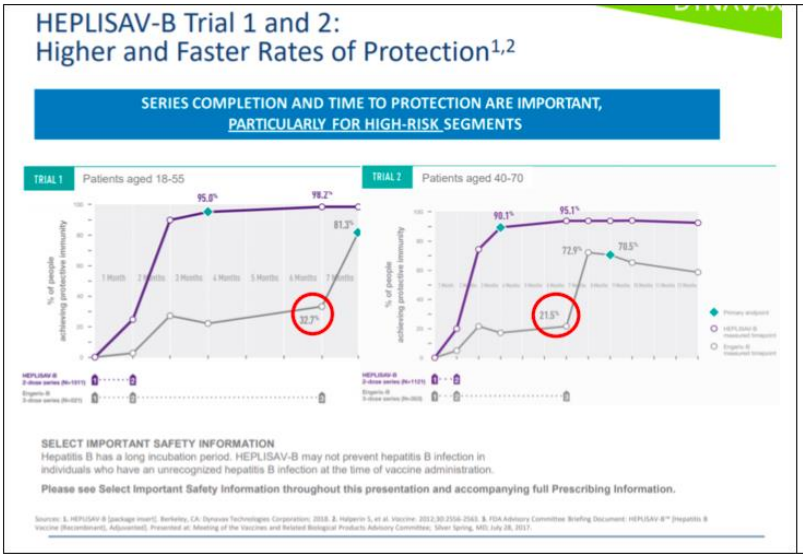
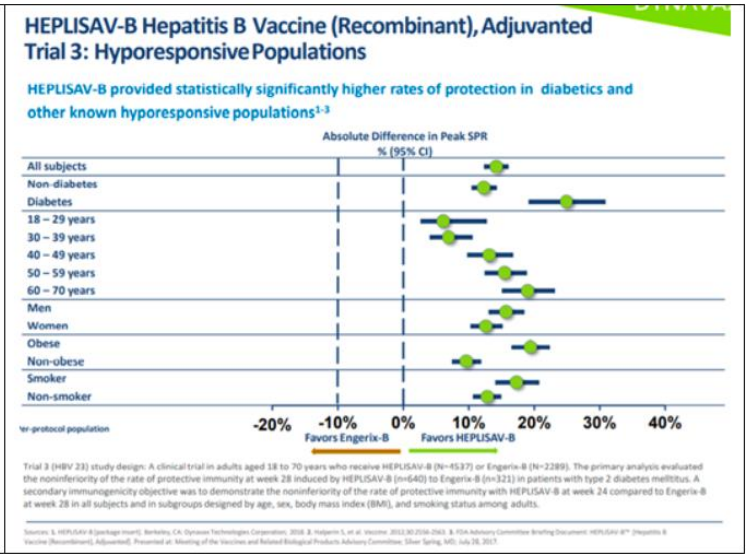
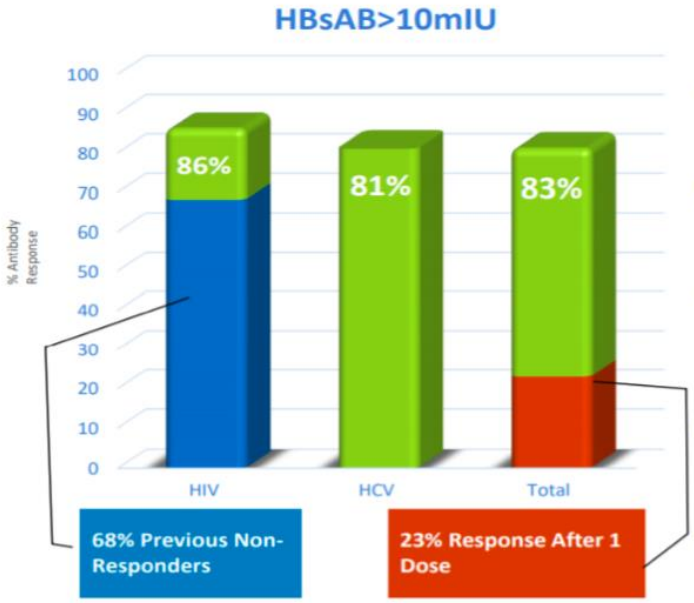
- Important Safety Information – Do not administer HEPLISAV-B to individuals with a history of severe allergic reaction (e.g., anaphylaxis) after a previous dose of any hepatitis B vaccine or to any component of HEPLISAV-B, including yeast. – Appropriate medical treatment and supervision must be available to manage possible anaphylactic reactions following administration of HEPLISAV-B. – Immunocompromised persons, including individuals receiving immunosuppressant therapy, may have a diminished immune response to HEPLISAV-B. – Hepatitis B has a long incubation period. HEPLISAV-B may not prevent hepatitis B infection in individuals who have an unrecognized hepatitis B infection at the time of vaccine administration. – The most common patient-reported adverse reactions reported within 7 days of vaccination were injection site pain (23%–39%), fatigue (11%–17%), and headache (8%–17%).





Heplisav B Demonstrates an Improved Immune Response in HIV and Hepatitis C Patients



- Retrospective analysis of 137 patients of which 71 patients were assessed for immunity
- 86% (25/29) of HIV patients were found to be immune
- 68% (17/25) immune HIV patients were non-responders to a full prior HBV vaccination series
- 81% (34/42) of HCV patients were found to be immune
- Of the total cohort tested – 23% were protected after the first dose with a total response of 83%

Brooke Kimball. Katie Garrett. Abstract (605) from the 2020 Conference on Retroviruses and Opportunistic Infections.Top Antiv Med 2020. 28(1).483

Adult Hepatitis B Vaccine Selection Considerations

Key Factors

- Time until minimum protective titer levels are achieved
- Compliance profile for completing the series
- Rates of protection for those with weaker immune systems
- Best use of existing funds towards effective seroprotection

Effective HBV vaccination is critical to achieving the CDC's goal of eliminating HBV by 2030, by protecting those with highest-risk and saving public health resources

Please see Select Important Safety Information throughout this presentation and accompanying full Prescribing Information.

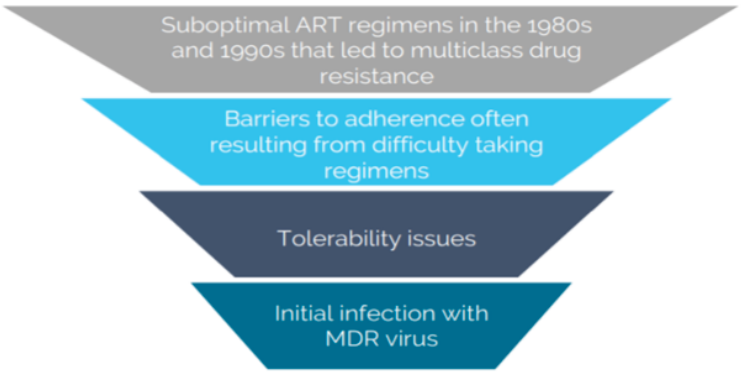
Presentation: Viiv Healthcare – Fostemsavir.

Heavily Treatment Experienced (HTE) Patients

Due largely to the development of resistance, HTE PLHIV have few remaining drug options available to them

Eventually, these patients may require highly-tailored ART regimens or may be entirely unable to construct an effective regimen[1,2]

This population includes patients with... [3,4]



RUKOBIA (fostemsavir): Indication and Mechanism of Action

INDICATION

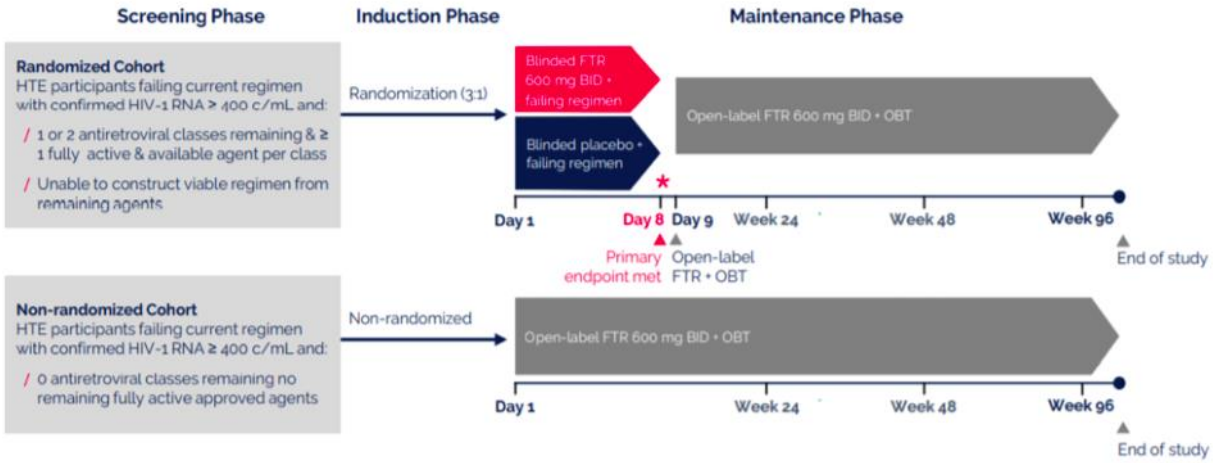
RUKOBIA, a human immunodeficiency virus type 1 (HIV-1) gp120-directed attachment inhibitor, in combination with other antiretroviral(s), is indicated for the treatment of HIV-1 infection in HTE adults with MDR HIV-1 infection failing their current antiretroviral regimen due to resistance, intolerance, or safety considerations

- **RUKOBIA is a first-in-class attachment inhibitor**
- **Prodrug metabolized to temsavir,** which directly binds the viral envelope gp120, preventing viral attachment to host CD4 T-cell receptors and subsequent entry and infection of host immune cells[1]
- **Active against CCR5-, CXCR4-, and dual-tropic (R5X4) strains** of HIV-1.[2-4]
- **Unique resistance profile** with no observed cross-resistance to other antiretroviral classes

The recommended dosage of RUKOBIA in adults is one 600 mg extended-release tablet taken twice daily with or without food. No dose adjustment required for FTR in mild-to-severe hepatic impairment or renal impairment, including hemodialysis.

Contraindications / Hypersensitivity to fostemsavir or any of the components of the formulation / Coadministration with strong cytochrome P450 (CYP)3A inducers as significant decreases in temsavir plasma concentrations may occur, which may result in loss of virologic response

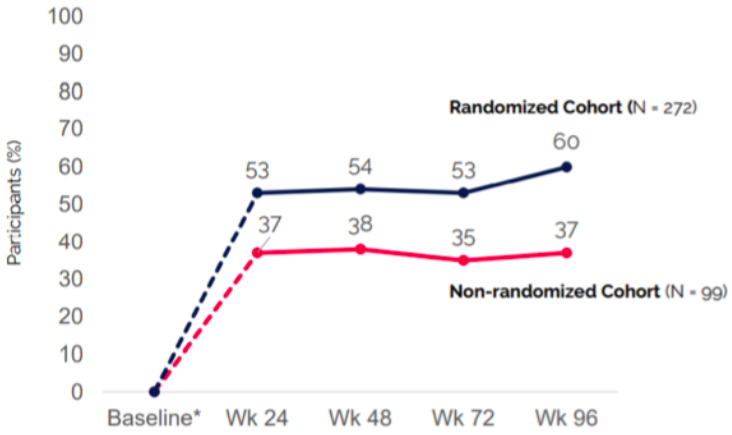
Multi-arm, Phase 3, randomized, placebo-controlled, double blind clinical trial to investigate the efficacy and safety of fostemsavir in HTE PLHIV with MDR HIV-1 who are failing their current regimen due to resistance, intolerance, or safety considerations



BRIGHTE Demographic and Baseline Characteristics of ITT-E Population

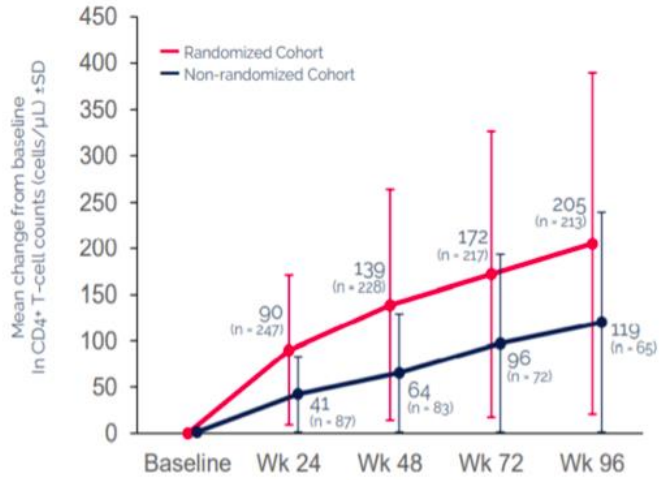
	Randomized Cohort			Non-randomized Cohort
	Placebo (N = 69)	FTR (N = 203)	Total (N = 272)	FTR (N = 99)
Age (years)				
Median (range)	45 (19-66)	48 (18-73)	48 (18-73)	50 (17-72)
Sex, n (%)				
Male	57 (83)	143 (70)	200 (74)	89 (90)
Race, n (%)				
White	48 (70)	137 (67)	185 (68)	74 (75)
Black/African American	18 (26)	42 (21)	60 (22)	23 (23)
HIV-1 RNA (log_{10} c/mL)				
Median (IQR)	4.5 (3.6-5.2)	4.7 (4.0-5.1)	4.7 (3.9-5.1)	4.3 (3.6-4.8)
HIV-1 RNA (c/mL), n (%)				
<400	7 (10)	14 (7)	21 (8)	5 (5)
400 to <1000	3 (4)	7 (3)	10 (4)	4 (4)
1000 to <100,000	35 (51)	126 (62)	161 (59)	75 (76)
≥100,000	24 (35)	56 (28)	80 (29)	15 (15)
CD4 count (cells/μL)				
Median (IQR)	100 (23-244)	99 (15-203)	99 (15-203)	41 (6-161)
<20, n (%)	17 (25)	55 (27)	72 (26)	40 (40)
20 to <50, n (%)	6 (9)	19 (9)	25 (9)	14 (14)
50 to <200, n (%)	26 (38)	76 (37)	102 (37)	25 (25)
200 to <500, n (%)	16 (23)	42 (21)	58 (21)	18 (18)
≥500, n (%)	4 (6)	11 (5)	15 (6)	2 (2)
AIDS history, n (%)				
Yes	61 (88)	170 (84)	231 (85)	89 (90)
Duration of HIV treatment (years), n (%)				
>20	22 (32)	70 (34)	92 (34)	58 (59)

HIV-1 RNA <40 copies/mL through Week 96: Snapshot Analysis, ITT-E* Secondary Endpoint



Week 96 outcome, n (%)	Randomized Cohort (N=272)
HIV-1 RNA <40 copies/mL	163 (60)
HIV-1 RNA ≥40 copies/mL	81 (30)
Data in window not below threshold	33 (12)
D/C for lack of efficacy	10 (4)
D/C for other reason while not below threshold	17 (6)
Change in ART†	21 (8)
No virologic data	28 (10)
D/C study due to AE or death	15 (6)
D/C study for other reasons	8 (3)
Missing data during window	5 (2)

Mean Change from Baseline in CD4+ T-cell Count Through Week 96 Secondary Endpoint



CD4+ T-cell counts increased steadily over time in both cohorts

Among randomized participants with CD4+ T-cell count <50 cells/mm³ at baseline (n=71), 56% had ≥200 cells/mm³ at Week 96

Safety Results – AEs through Week 96

	Week 24		Week 96	
	Randomized Cohort (N = 270)* n (%)	Non-randomized Cohort (N = 99) n (%)	Randomized Cohort (N = 272) n (%)	Non-randomized Cohort (N = 99) n (%)
Any AE	243 (90)	93 (94)	249 (92)	98 (99)
Any Grade 2-4 AE	187 (69)	76 (77)	216 (79)	87 (88)
Any Grade 2-4 drug-related AE	49 (18)	19 (19)	57 (21)	22 (22)
Any Grade 3-4 AE	66 (24)	41 (41)	78 (29)	49 (49)
Any SAE	73 (27)	37 (37)	92 (34)	48 (48)
Any drug-related SAE	6 (2)	3 (3)	9 (3)	3 (3)
Any AE leading to discontinuation	12 (4)	9 (9)	14 (5)	12 (12)
Any CDC Class C event	23 (9)	12 (12)	23 (8)	15 (15)
Death	8 (3)	9 (9)	12 (4)	17 (17)

Drug related SAE's were low at 3% and the majority of SAE's and deaths were due to severity of disease and disease progression or AIDS-related comorbidities

In the BRIGHTE study, evaluating FTR in HTE participants through Week 96, Conclusions:

- Virologic response continued to improve over time despite continued attrition in this difficult-to-treat population
- Virologic response in the ITT population continued to improve over time, including amongst participants with high baseline viral load and low baseline CD4+ count
- FTR-containing regimens remained generally safe and well tolerated through Week 96 with no new safety signals and few AE-related discontinuations (7%)

Formulary Subcommittee report. Dr. Natalie Vanek, M.D. stated they have met three times since the last full meeting. They discussed the 90-day medication scenario; Biktarvy is the most dispensed drug in the 90-day category, but even that is low uptake. They will be coming back to the committee with education/outreach ideas regarding the availability of 90-day fills. Tamexis (spelling could not be verified) was discussed, and was added to the formulary because it is a generic of a drug already on the formulary. The Subcommittee discussed **Heplisav B,** noting that the addition of the vaccine to the formulary breaks precedent for the Medication Advisory Committee. Since there is already a vaccine program within DSHS that is able to pay for vaccines, it was unclear to the subcommittee why this vaccine was not covered under that program. After significant discussion over several meetings, the subcommittee voted not to recommend the vaccine. **Fostemsavir** was discussed and is being brought to the full committee for a vote. The recommendation was to approve the medication.

Committee to Vote on Addition of the Following Medications to THMP Formulary.

HEPLISAV B (Discussion and vote)

- Concurrence with what the committee recommended
- We should provide access to the vaccines through the appropriate program
- We should clarify that there is a vaccine section within DSHS and so this was seen as outside the scope of this committee

MOTION: *Do not add to the formulary (follow the recommendation of the subcommittee) - prevailed.*

Fostemsavir (no discussion)

MOTION: *Add to the formulary contingent on pricing - prevailed.*

Subcommittee Reports

Governance/Data – Nancy Miertschin stated there were three meetings since the last full committee meeting:

- Member attendance and membership issues to be resolved
- Setting goals for subcommittee
- Baseline eligibility data for Texas
- Aligning acceptable documentation
- One page infographic for Ryan White
- Application process for being on the committee
- Data needs were discussed
- Hurricane preparedness report
- Removal of members for poor attendance
- Historical budget information for presentations
- Analysis over time for viral suppression
- No action items

Eligibility – Frank Rosas stated they met five times:

- FPL guidelines should be uniform
- Getting consumers on ADAP through Rapid Start
- COVID-19 impacted focus
- HRAR project is still on track

Public Comment. No public comment was offered.

Committee to vote on Summer and Fall meeting dates of 2021 – future meeting format will be determined by HHSC Executive leadership

- October 16th, 2020
- January 29th, 2021

- April 30th, 2021
- July 30th, 2021
- October 5th,2021

Adjourn. There being no further business, the meeting was adjourned.

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