Minutes of the meeting of representatives of Gilead and the EECA community

December 5, 2024

Organization: **Gilead**

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Start of the meeting. Introduction of participants.

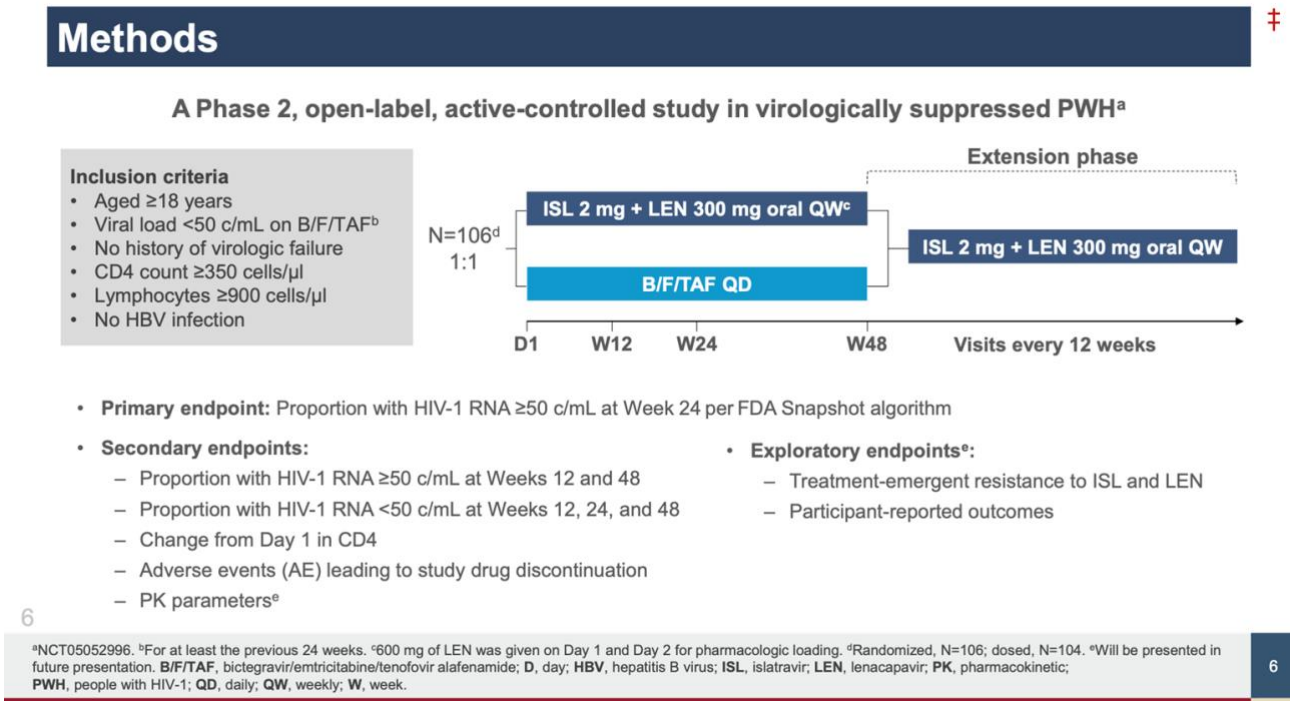
Presentation of Gilead.

We used your questions and prepared this presentation. We will start with the clinical questions.

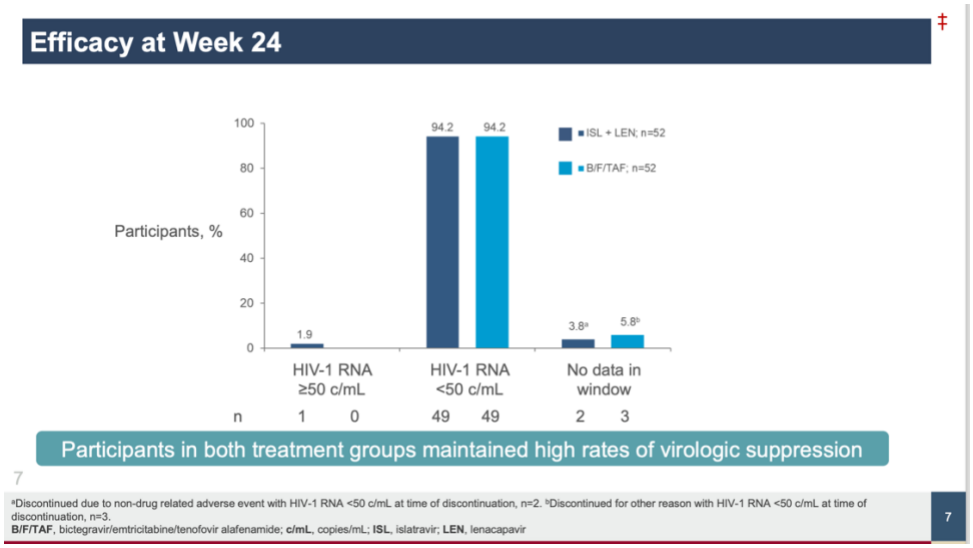
Question: Please share study plans for new HIV, hepatitis and TB drugs that are in phases II and III of clinical trials. In particular, what are the plans for lenacapavir and lenacapavir/islatravir combination trials?

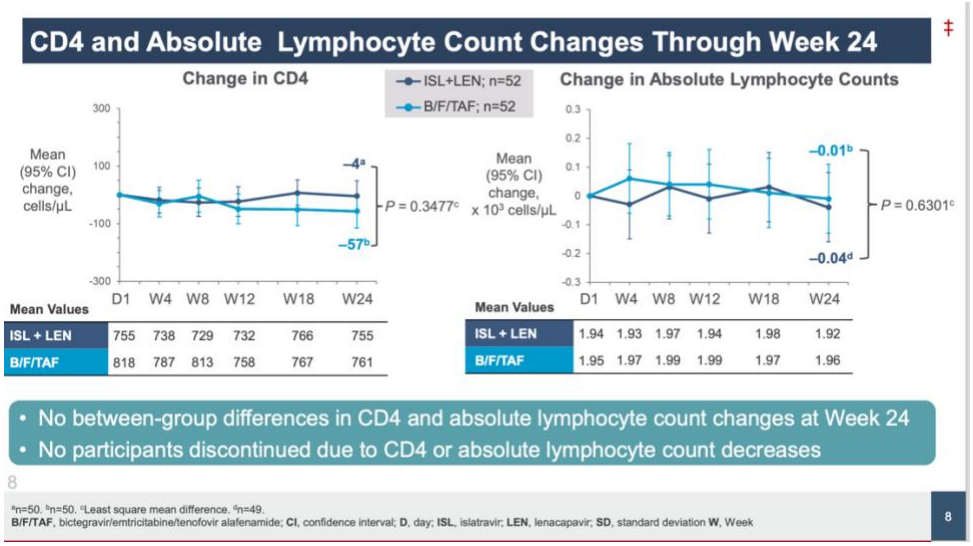
Answer: Tuberculosis is not a priority disease for our company. We are interested in and support clinical trials aimed at studying drug-drug interactions between our products and TB drugs. But at the moment the company has no plans to participate in the development of new molecules for TB. As for HIV and hepatitis, I would like to mention a few studies that are now in phase II. This is a very early stage and what we will talk about is that these studies are focused on dose selection and looking at the safety profile of the drug. It's a long time away from the release date, but I'll tell you, so you know about them.

In the first study, the efficacy and safety of weekly dosing of islatravir in combination with lenacapavir in people living with HIV for 24 weeks is being studied. This is a phase II study, and on this slide, you can see the preliminary results that were presented earlier this year at the CROI conference.

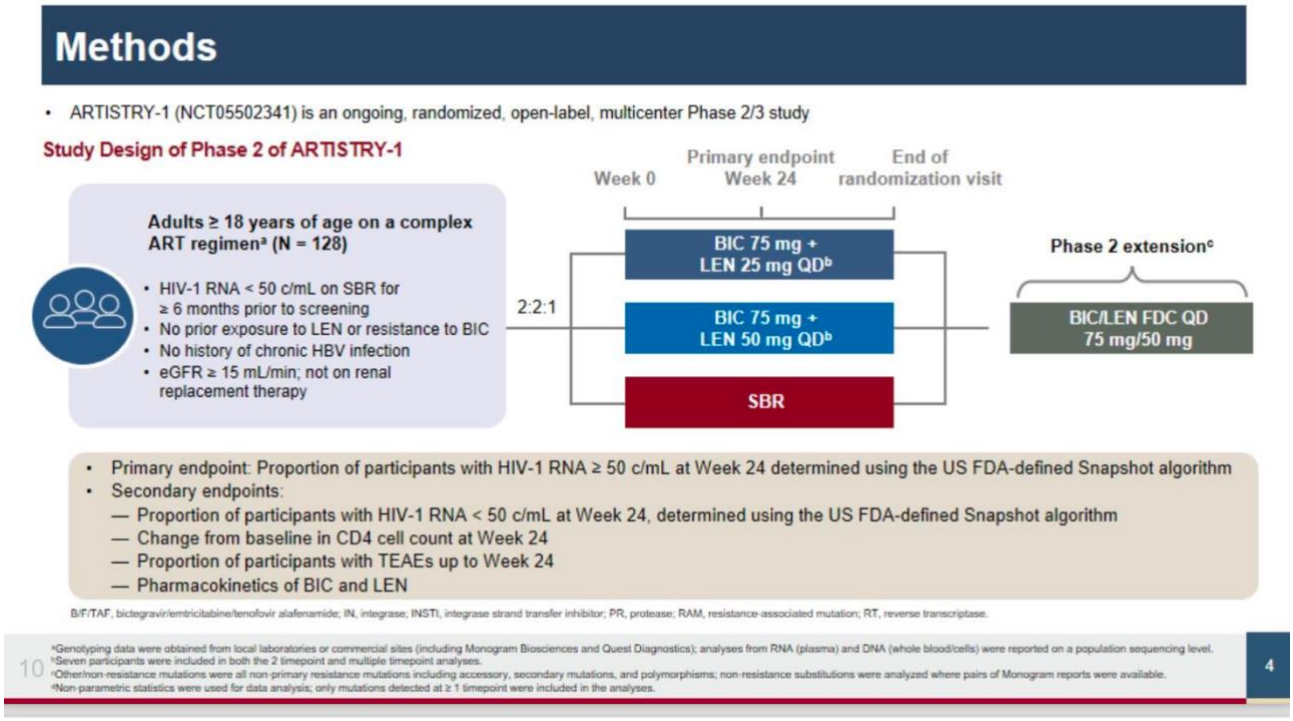


This open-label, controlled phase II study is being conducted in people living with HIV who are older than 18 years of age with a suppressed viral load of less than 50 copies without virologic failures with more than 350 CD-4 cells and 900 lymphocytes without hepatitis B infection. Study participants are divided into two groups with oral administration of the combination islatravir (2 mg)/lenacapavir (300 mg) versus the combination Biktarvy (bictegravir/emtricitabine/tenofovir alafenamide). And the endpoint of the study is the proportion of people with continued suppressed viral load at week 24. On the next two slides, you can see that both drugs showed exactly identical results in terms of efficacy in suppressing viral load. In terms of percentage of CD-4 cells and total CD-4 lymphocytes in absolute numbers, there is no significant difference either.





The next phase II study, also presented at CROI, involves switching from a conventional regimen to the oral combination of bictegravir/lenacapavir in the comprehensive treatment of HIV infection. This is not a conventional efficacy and safety study. Here we have three groups of participants, one is receiving the gold standard of treatment at the moment, the second group is receiving bictegravir 75 mg and lenacapavir 50 mg, and the third group is receiving bictegravir 75 mg and lenacapavir 25 mg.



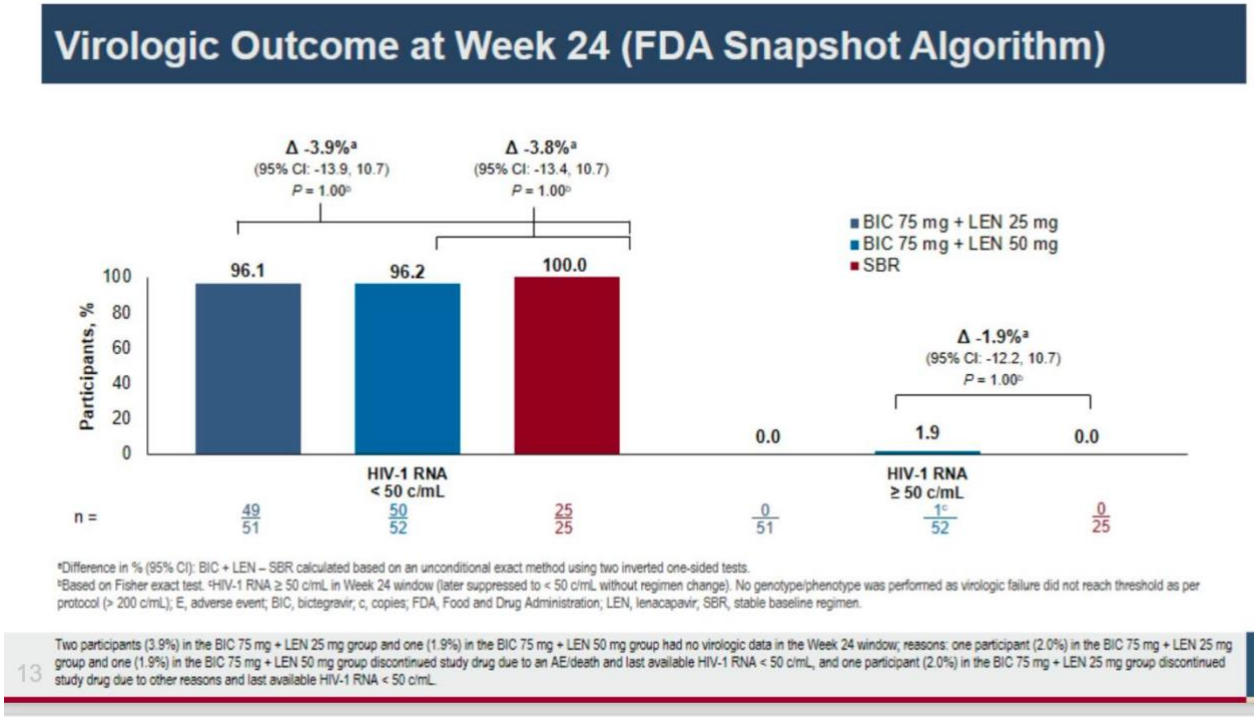
On the next slides, you can see how comprehensive HIV treatment can be as you accumulate the number of regimens that people have used for treatment that have been ineffective. Here we are talking about simplifying the treatment regimen for advanced HIV disease.

Complexity of ART Regimens at Baseline[a] in Phase 2

	BIC 75 mg + LEN 25 mg N = 51	BIC 75 mg + LEN 50 mg N = 52	SBR N = 25	Total N = 128
Number of pills/day, median (range)	2.0 (2.0, 8.0)	3.0 (2.0, 9.0)	3.0 (2.0, 8.0)	3.0 (2.0, 9.0)
Number of ARTs, median (range)	2.0 (1.0, 5.0)	2.5 (2.0, 5.0)	3.0 (2.0, 5.0)	2.0 (1.0, 5.0)
Dosing frequency of ARTs, n (%)				
Daily	47 (92.9)	46 (88.5)	22 (88.0)	115 (89.8)
Twice per day	18 (35.3)	22 (42.3)	13 (52.0)	53 (41.4)
Other	1 (2.0)	0	0	1 (0.8)

[a]ART use at baseline was defined as the ARTs taken on or up to 14 days prior to Day 1. Multiple reported ARTs were counted only once per participant for each drug name and each drug class.
ART, antiretroviral therapy; BIC, bictegravir; LEN, lenacapavir; SBR, stable baseline regimen.

11
9



Here, red color denotes more complex regimens, and when switching to simpler regimens, grey column (lenacapavir 25 mg/bictegravir), and blue column (lenacapavir 50 mg/bictegravir), the efficacy remains the same. Regarding treatment interruption during clinical trials, both groups recorded one case of interruption each, which may indicate the safety of the regimens. No serious adverse events were reported during the studies; hence the regimens are well tolerated. This study is called ARTISTRY-1, and the results showed that the regimen is highly effective in suppressing viral load during switching, is well tolerated, and has an identical safety profile at any dose of lenacapavir. The data obtained in phase II allow for further phase III studies of this combination. We chose the combination of bictegravir 75 mg and lenacapavir 50 mg. The choice of dose was based on the general data on safety, efficacy and pharmacokinetics, which were taken into account when selecting the dosage.

The next study is lenacapavir in combination with broadly neutralizing antibodies, which is studying the efficacy of this regimen in people living with HIV. Our company is working on two broadly neutralizing antibodies, which will be easier to understand in the acronym that we will use in the future: TAB (teropavimab) and ZAB (zinlirvimab).

Study Design

‡

- Adults with HIV-1
- VS ≥18 months[a]
- Chronic HBV negative
- Highly susceptible to **either** TAB or ZAB
- CD4 count:
  - At entry: ≥500 cells/μL
  - Nadir: ≥350 cells/μL

1:1

W0 — W26 — W52

LEN + TAB + ZAB 10 mg/kg

LEN + TAB + ZAB 30 mg/kg

Restart ART and Continued Follow-up

Primary endpoint W26

Participants

- After primary cohort sensitive to both bNAbs completed study, a cohort of participants with susceptibility to **either** TAB **or** ZAB was enrolled
- bNAb susceptibility defined as IC90 ≤2 μg/mL by PhenoSense mAb Assay (Monogram Biosciences)
- Randomization to treatment groups was stratified by bNAb susceptibility (TAB or ZAB)

18

[a]Previous virologic failure was allowed if participants were VS (HIV-1 RNA ≤50 copies/mL) for ≥18 months prior to screening
ART, antiretroviral therapy; **bNAb**, broadly neutralizing antibody; **HBV**, Hepatitis B virus; **IC90**, 90% inhibitory concentration; **LEN**, lenacapavir; **TAB**, teropavimab; **VS**, virologic suppression; **W**, Week; **ZAB**, zinlirvimab.

18

The goal of development is to try to further attack the different life cycles of the virus, and that's why we are working on molecular variability. These studies are at a very early stage and include only 10 participants: 4 patients in one group and 6 patients in the other. I'm showing slightly outdated data because right now the studies are in phase IIb. There are 50 patients total, and the control group is 25 patients. The advantage of these two regimens is that they are administered in the same way as lenacapavir, i.e. once every six months.

Safety and Tolerability

Event, n	LEN + TAB + ZAB 10 mg/kg (n=5)	LEN + TAB + ZAB 30 mg/kg (n=6)	Total (N=11)
Any adverse event (AE)	3	5	8
Any-grade AEs occurring in ≥2 participants			
Injection site induration	0	3	3
COVID-19	1	1	2
Injection site erythema	0	2	2
Injection site pain	0	2	2
Injection site nodule[a]	1	1	2
Injection site pruritis	0	2	2
SAE[b]	1	0	0
AEs leading to discontinuation	0	0	0

- 5 participants had treatment related AEs – all were Grade 1 injection site reactions related to LEN administration
- No infusion-related reactions occurred with bNAb administration
- There were no Grade ≥3 treatment-emergent laboratory abnormalities

21

[a]All nodules resolved by Week 26; [b]Soft tissue infection (Grade 3), not related to study drug or procedure.
LEN, lenacapavir; **SAE**, serious adverse event; **TAB**, teropavimab; **ZAB**, zinlirvimab.

10

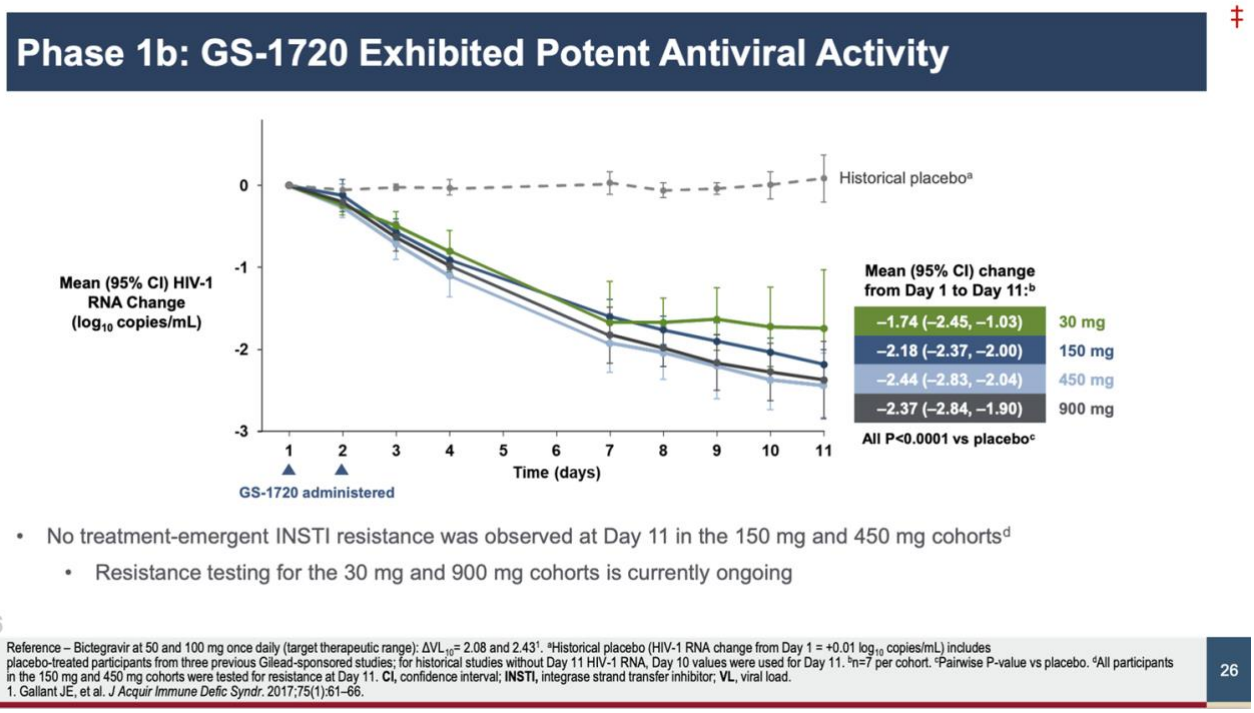
A total of 8 adverse events were observed (3 AEs in one group and 5 AEs in the other). The most frequent ones were irritation at the injection site. There were also two cases of COVID-19 (one case in each group). Based on the phase II results, we see that both TAB and ZAB are quite promising regimens. Now, based on additional criteria, we will need to decide which regimen will move into phase III clinical trials. To summarize briefly, these regimens are quite well tolerated and quite safe, and the most frequent adverse events are in the area of injection administration.

Question: I have a question about a previous study that assessed the bictegravir/lenacapavir regimen. Is this regimen going to be used for drug-resistant HIV? The second question is why did you choose bictegravir to study in combination with lenacapavir? The point is that bictegravir has the longest patent protection.

Answer: Currently, the indication for lenacapavir states that only patients with a suppressed viral load can take it. There are some trials going on right now, including bictegravir, involving patients with other parameters. But at this point, all studies include patients with undetectable viral loads. Dolutegravir is a molecule that was developed by another company, and accordingly, we can only use it as a comparison molecule in our clinical trials because we don't own it. We don't have a specific slide on access to Biktarvy, but we can discuss that later when we talk about access.

Continued presentation.

This is our new product GS-1720, a molecule that is at phase Ib. In the first stage, we are trying to find the optimal dosage. As you can see on this slide, four dosages were selected for testing: 900 mg, 450 mg, 150 mg and 30 mg. Judging from the results of the study, the pharmacokinetic profile shows that the drug can be taken once a week. It is well tolerated and shows good activity in suppressing the virus.



Question: A question about the new molecule: what class does it belong to?

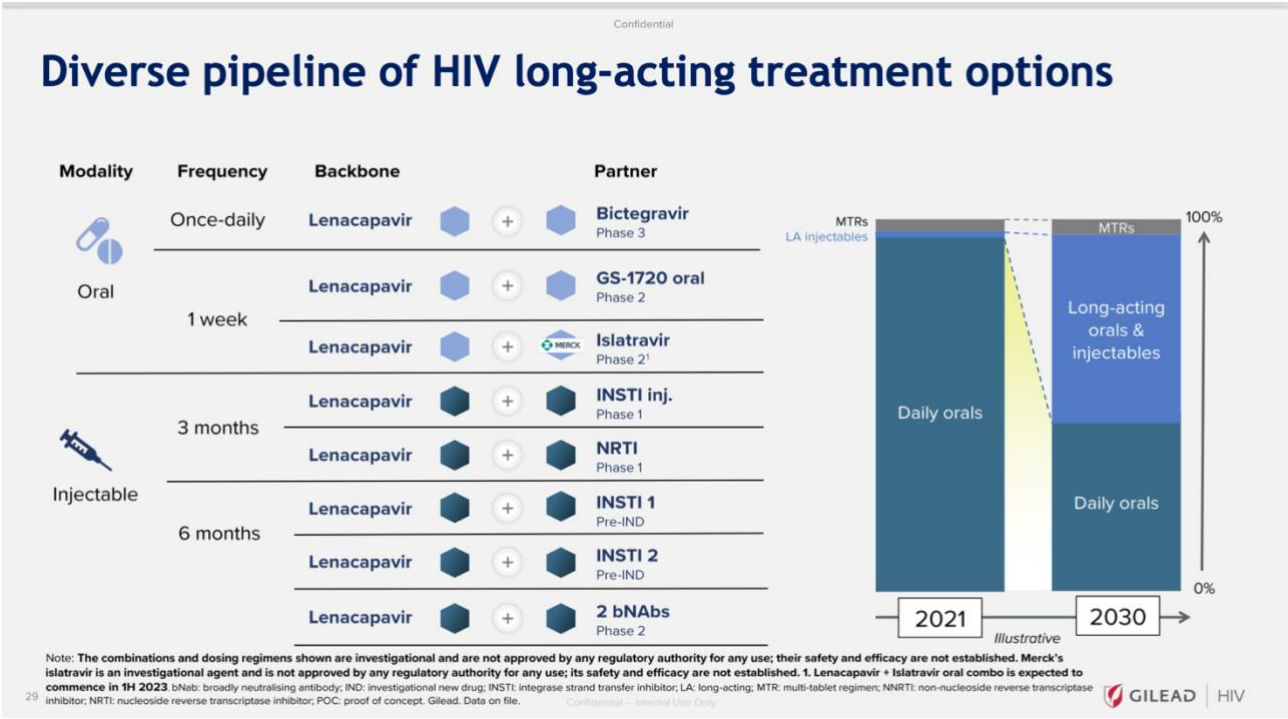
Answer: It is an integrase strand transfer inhibitor.

Question: We understand that you cannot include dolutegravir in the study because it is not your drug. But why did you choose bictegravir and not elvitegravir?

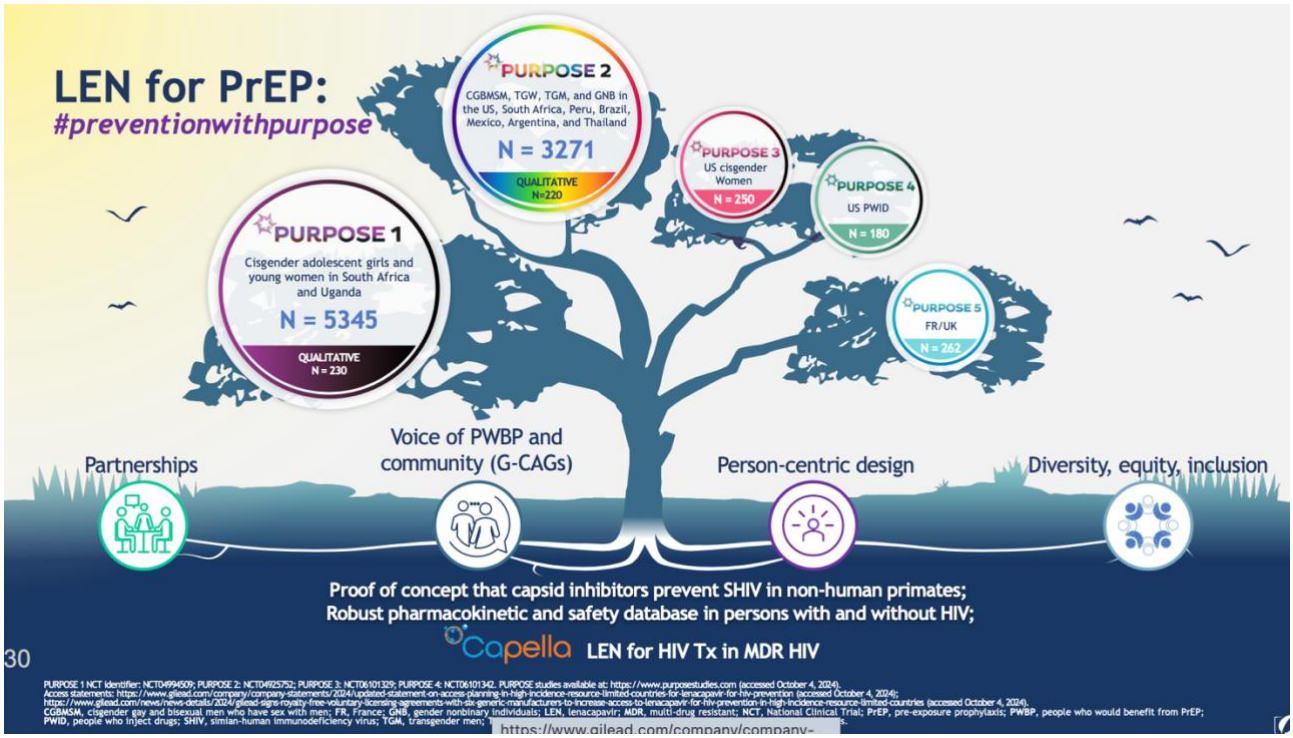
Answer: There are some clinical trials underway on elvitegravir as well, but they do not seem to be as promising. However, we do have some data, and we can send it later if there is interest in it.

Continued presentation.

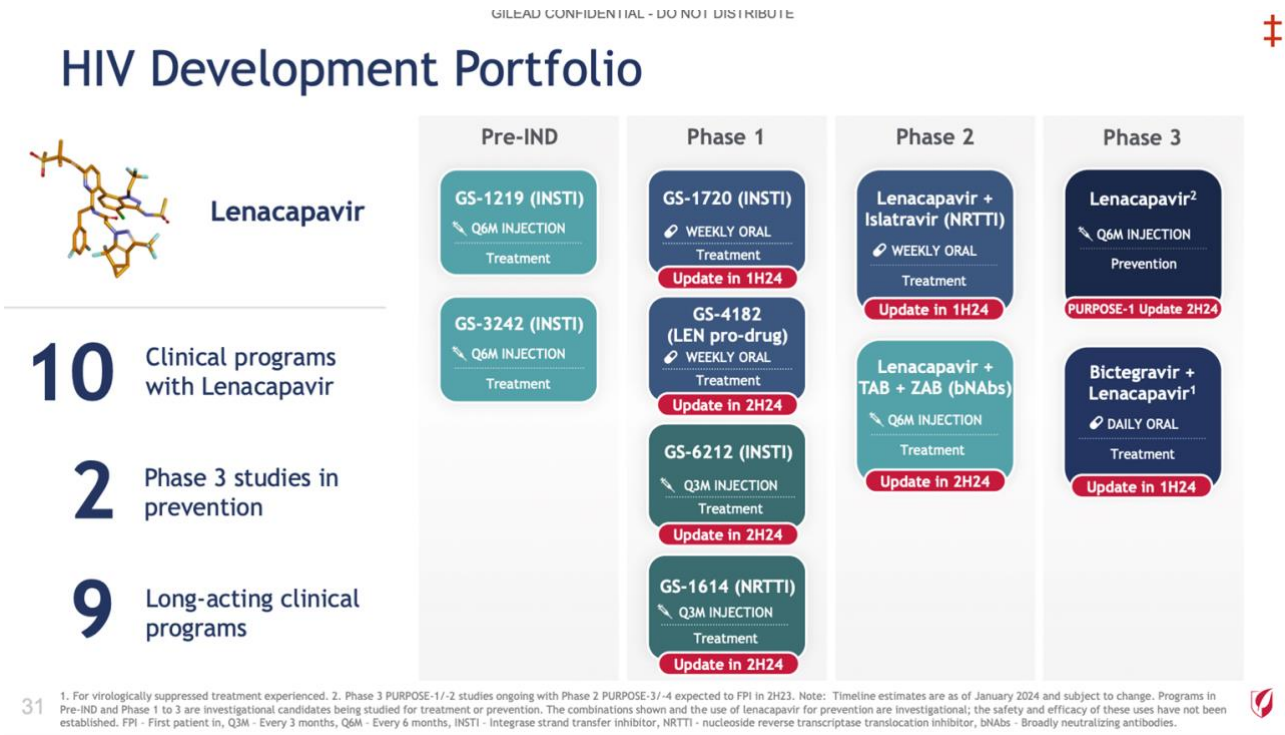
On this slide, we've compiled all of our studies based on lenacapavir as the regimen backbone that we're planning to conduct by 2030. Oral regimens, once daily lenacapavir/bictegravir combination in phase III, once weekly oral regimen, lenacapavir + GS-1720 (phase II), lenacapavir with islatravir (phase II). Injectable regimens: once every 3 months, lenacapavir and an integrase chain transfer inhibitor and also lenacapavir and a nucleoside reverse transcriptase inhibitor. Administration once every 6 months, lenacapavir and an integrase chain transfer inhibitor, lenacapavir + two broadly neutralizing antibodies.



Now I want to move on to prevention, and I hope you all know about the trials, two of which are completed and three of which are still in progress. We are working on marketing approval of the drug and bringing it to the market.



And here we have collected promising research on both prevention and treatment. Here you can see the names of our other molecules that don't have names yet, and now they are labeled with numbers. In the earliest phase, every 6 months, an integrase chain transfer inhibitor for prevention and in the same phase an integrase chain transfer inhibitor for treatment. In phase I, oral administration once a week. It should be understood that the injectable lenacapavir or its tablet form are available everywhere. Another integrase chain transfer inhibitor molecule is an injection once every three months and a nucleoside reverse translocation inhibitor once every three months. In phase II, lenacapavir and islatravir are weekly oral dosing. Lenacapavir and two broadly neutralizing antibodies, an injection every 6 months. In phase III, an injection of lenacapavir once every 6 months for prophylaxis. And bictegravir with lenacapavir, daily oral administration for treatment.



If all goes well, we could potentially add five new products to our portfolio by 2030.

Question: I would like to clarify if all the combinations and drugs presented will be used for naive patients in the first line of treatment?

Answer: Since they are in stage l, I can't comment on that yet. But we hope that they will be able to cover all patient groups.

Question: Do you plan to collaborate with ViiV on the cabotegravir/lenacapavir combination?

Answer: We currently do not have information on this topic. However, we believe that collaboration requires mutual interest from both Gilead and ViiV to agree to the terms on such research.

Question: Are there any results from PURPOSE 3 and 4 studies yet? If not, when do you expect the results?

Answer: Since PURPOSE 3 and 4 have only recently begun, we do not anticipate results until later in 2026.

Question: Are there any studies or data on injectable lenacapavir as monotherapy for HIV infection?

Answer: On prevention, yes. On treatment and in general, from what we have shown, lenacapavir is not considered as a monotherapy for HIV infection. It is only effective in combination.

Question: I have a clarifying question about lenacapavir as an HIV treatment. As far as we know, there were studies in 2021 or 2022 and based on the data, it was registered for the treatment of MDR-HIV. These are the results of CAPELLA study, which was also down on the previous slide.

Answer: I'll clarify: I said that based on the available data, lenacapavir can be used in patients with a suppressed viral load, but we can't use it as first-line treatment. It is currently indicated for the treatment of HIV-1 infection, in combination with other antiretrovirals, in heavily treatment experienced adults with multi-drug resistant HIV-1 infection, whose current antiretroviral is failing due to resistance intolerance or safety considerations.

Comment from a representative of the patient community: If injectable lenacapavir becomes available for pre-exposure prophylaxis, it may be that people living with HIV with a suppressed viral load may try this drug despite the restrictions in the instructions for use.

Question: Does lenacapavir have potential for use as post-exposure prophylaxis?

Answer: The gold standard for post-exposure prophylaxis is to use the same regimen as treatment. So based on the fact that lenacapavir is not a full treatment drug, it cannot be used as post-exposure prophylaxis because it is only one component of treatment. But this may change in the future.

Question: Are there ongoing studies on other oral medications as post-exposure prophylaxis?

Answer: As far as we know, there is no PEP study on other oral medications.

Question: What are the differences between prescribing tablets and injections? What are the differences in their effects (if any)? How do you remove the drug (injection) if it has caused adverse reactions?

Answer: The key is that oral regimens are taken by mouth, while injections are administered by injection. An important question regarding how the drug can be eliminated from the body if an adverse reaction occurs. Since the drug is deposited, it cannot be immediately eliminated from the body. The use of the drug will be stopped if serious adverse events occur, but the body will need time to eliminate the drug anyway. I want to talk about the adverse events that have occurred during all the clinical trials that are currently in place, i.e. PURPOSE 1, 2 and everything that was in Phase II. The adverse events include fairly severe swelling in 63% of patients taking lenacapavir and 39% taking placebo. As you can see, the difference is almost two times. Pain at the injection site occurred in more than half of the patients, nausea in 63% of patients, and headache in 13% of patients. Less complicated adverse events included headache, genitourinary infection, etc. But as you realize, these may not be related to taking the drug.

Question: Lenacapavir is an injectable drug, and we understand that its introduction requires specialized knowledge. Does your company plan to conduct training programs for healthcare professionals to ensure effective use of this drug in clinical practice?

Answer: When our company introduces a new product to the market, we are always involved in training medical staff. This is a part of the safe promotion of the drug. We plan to educate and do everything we have done with other drugs as well.

Question: Will you be doing this in all countries, that is, not only in countries where the original drug will be promoted, but also in countries that will be covered by generic companies under a voluntary license?

Answer: In previous years we have had training activities in Central Asia even for products that we have not directly supplied there. I assume that it is our department, which is responsible for those markets where Gilead is not directly represented, because lenacapavir is a potential solution to HIV for our countries, we will do training. But the key word is "assume". The important addition is that this is a new drug, and it is critical that it is used correctly. We will be able to give you more information on training once the product is registered and available in the countries.

Question: Do you plan to provide humanitarian supply of lenacapavir for doctors in training?

Answer: I am not authorized to make such decisions. I can only say that we will train, but I do not know how the licensees will distribute the drug. A lot of things will depend on agreements with companies.

Question: Can you share your plans for including pregnant women and children in trials of your drugs, including lenacapavir?

Answer: As far as lenacapavir is concerned, in PURPOSE-1 trial, almost 10% of the participants became pregnant during the study. Of the 5,345 participants, 510 pregnancies were recorded, of which 193 pregnancies occurred in the group that received lenacapavir, 219 among those taking Descovy, and 98 among those taking Truvada. It is important to note that the number of abortions, miscarriages and other causes of pregnancy termination in all groups observed in this clinical trial was consistent with what we observe in general population.

We have also recently started a study involving children who are already on ART. As part of the study, they will receive lenacapavir and an optimized treatment regimen. There will be a small number of people in the cohort because of the small population. The study started in the third quarter of this year. When we have the results, we'll be sure to share.

Question: Why is the company not conducting clinical trials in the Eastern Europe and Central Asia regions? Do you plan to change your approach?

Answer: Actually, we are conducting trials of drugs in your region, but not for the treatment of HIV infection and hepatitis, but for oncology and other diseases. In general, we are ready to expand nosologies. If we talk about trials of drugs for HIV and hepatitis C treatment, we usually support either some associations that deal with grants or already in post-marketing stage 4 trials, where we collect real-world data from the region on our products that are available there. We are proud to partner with the Elton John AIDS Foundation on the RADIAN program, which we support. We also support the programs of the Hepatitis Center.

Question: I have a question about studies of lenacapavir as a PrEP in individuals from 12 or 14 years of age. Do you include adolescents in these studies?

Answer: In order to have any opinion on the inclusion of children in studies, we need to see data from our studies. At the moment there is no such data. When I do see it, I will be able to have some scientifically based opinion. As for adolescents, there were adolescent girls in PURPOSE-1 (the youngest age was 16), data from this study was presented at CROI, March 2025, the excerpt is below:

New study population data from PURPOSE 1 show comparable pharmacokinetic and safety profiles for both adolescent and adult trial participants.

Additional adolescent-related data from the PURPOSE 1 trial were also presented at CROI yesterday during an oral abstract session and press conference. PURPOSE 1 is the first adult Phase 3 HIV prevention trial to intentionally include adolescents aged 16 and 17 years, and trial enrollment was much higher than in typical adolescent-dedicated studies (124 adolescents, 56 of whom were assigned to the lenacapavir group). The data showed that observed lenacapavir plasma concentrations were comparable between adolescent and adult trial groups, with participants in both groups experiencing the same most common adverse events. There were zero incident HIV infections across the adolescent and adult groups receiving lenacapavir. Given these results, data submitted to regulatory authorities support the potential use of twice-yearly lenacapavir for adolescents who need or want PrEP.

Question: How do you plan to register new drugs in EAEU countries, given that there are no clinical trials in these countries?

Answer: In countries where Gilead does not have subsidiaries, we work through distributors, such as Delta Medical Ltd., that sell the product in the countries they cover on behalf of Gilead. We also work with voluntary licensing companies and generic manufacturers to ensure that our medicines are available in low- and middle-income countries.

Question: For example, when it comes to cabotegravir, it is registered under two trade names: one is a treatment drug and the other is a prophylaxis drug. Do you plan to register lenacapavir under two trade names using the same approach?

Answer: Yes, there will be two different trade names. Right now, we already have a name for lenacapavir, which is used for treatment, which is Sunlenca. We have not come up with a name for lenacapavir for PrEP yet. Once we have one, we will share it. For countries that do not allow two trade names, we are extending the Sunlenca registration to include PrEP in addition to the HTE indication. This is being addressed on a case-by-case basis and is the exception to our global strategy, and only explored if mandated by legislation.

Question: Could you share your plans for registration of lenacapavir in the EECA region, as well as your pricing strategy for this drug?

Answer: The global strategy is that we begin filing regulatory dossiers starting at the end of this year, and we expect the first results as early as 2025. Once lenacapavir for PrEP is approved by the regulatory agencies, we will be able to update you on how the registration process is going. For countries with high HIV prevalence and limited resources, we are considering a collaborative approach to expedite national regulatory procedures as well as obtain WHO prequalification for licensees. Discussions about price are premature as the drug is not yet approved. The price will be in the interest of patients around the world and is based on the need to achieve the common good. We plan to have a special price for low- and middle-income countries, but we are not able to determine that yet.

Question: Who will submit dossiers for registration in the countries of the EECA region? Your company or generic manufacturers?

Answer: There are 18 priority countries with higher prevalence, these countries are mainly based in Africa and South-East Asia. In these 18 countries where the need is greatest, Gilead is prioritizing registering lenacapavir for PrEP. We will work together with EU-M4all initiative, WHO prequalification programs, etc. to accelerate registration. Our voluntary licensing agreements cover 120 countries. Gilead will provide Gilead-supplied product at no-profit price in the countries covered by the voluntary license agreements until voluntary licensing partners are able to fully support demand for high-quality, low-cost generic versions of lenacapavir. Some of the countries within Eastern Europe and Central Asia who are part of the voluntary licensing agreements include: Armenia, Azerbaijan. Belarus, Georgia, Kazakhstan, Kyrgyzstan, Republic of Moldova, Mongolia, Tajikistan, Turkmenistan, Ukraine and Uzbekistan. Please see copy of the 120 countries in the appendix The generic manufacturers will be responsible for submitting the dossiers for registration in EECA countries. Early access or compassionate use program is not provided for PrEP, so there are no plans to supply the drug under these programs.

Question: As far as we know, the four countries in Latin America where people received the drug during PURPOSE studies were excluded from the license?

Answer: First, people who were enrolled in studies in those four countries that were not voluntarily licensed continue to receive the drug directly from Gilead. Second, in these and other middle-income countries, the company plans to supply the drug directly and to come out with a price proposal that is in the interest of the healthcare system and the common good.

Question: What plans does Gilead have for access to lenacapavir in the Russian market?

Answer: Russia is not on the list of countries that are included in the voluntary license. We are studying the possibility of using the EAEU mechanism to ensure registration of the drug in Russia. We will submit the drug for registration under the EAEU procedure, but we don't know yet in which country we will do it. We are ready to work with various community organizations throughout the EECA region through the RADIAN program and through grants directly to increase community literacy.

Question: Currently, there is data from the University of Liverpool suggesting that lenacapavir could be marketed at $40 to $100 per patient per year for high volumes. Is this correct?

Answer: To be clear, pricing for Len for PrEP has not been set yet. What's more, the US list price for lenacapavir for the treatment of persons with multi-class-resistant HIV will not be the reference point for lenacapavir for PrEP pricing.

For high-incidence, resource-limited countries, our voluntary licensing (VL) partners set their prices independently. Our VL strategy encourages market-based competition which, in turn, drives down prices over time and supports broader access to medicines.

Gilead will provide Gilead-supplied product at no-profit price in the countries covered by the VL agreements until voluntary licensing partners are able to fully support demand for high-quality, low-

cost generic versions of lenacapavir.

In 18 countries where the need is greatest, Gilead is prioritizing registering lenacapavir for PrEP. The price for this has not yet been determined because we are still working internally and with partners around the world, to optimize the costs of manufacturing, delivering and supporting access to LEN for PrEP, if approved.

Question: One clarifying question regarding the non-profit price. Will the non-profit price be provided only to the 18 prioritized countries or to all countries before the generic enters the market?

Answer: The no-profit price will apply to all 120 countries in the VL agreement. Gilead will provide Gilead-supplied product at no-profit price in the 120 countries covered by the VL agreements until voluntary licensing partners are able to fully supply demand for high-quality, low-cost generic versions of LEN for PrEP, if approved. In 18 countries where the need is greatest, Gilead is prioritizing registering LEN for PrEP.

Question: If 6 generic manufacturers are going to set the price, why does your company need monthly reporting on the volume of product sold?

Answer: The monthly reporting will enable us to see the impact of the VL company efforts to address the HIV epidemic. The data will show the number of treatments delivered.

Question: And will your company exercise control over the prices that licensees will set? Today, using the dolutegravir license as an example, we see that every year the community controls the prices by itself, and no one else does it.

Answer: Generic manufacturers set their own prices for their own approved generic versions of Lenacapavir. Gilead will not be involved in the prices set by the generic manufacturers. The generic companies are also solely responsible for marketing and registration of their products.

Question: Then I have a clarifying question: are you going to expand the list of licensees in the near future with companies that have the appropriate potential to produce lenacapavir? In our opinion, more companies will be able to provide real competition.

Answer: We have selected 6 voluntary license partners because we believe they will be able to obtain regulatory approval and supply lenacapavir in volumes sufficient to meet demand and with sufficient competition to lower the cost of generics. Too many licensees may deter the business investment required to support broad access. Gilead will work closely with licensees to ensure they get up to speed quickly, helping to realize our goal of creating a robust network of manufacturers capable of producing high volumes at competitive prices. As with all of our voluntary licensing programs, we will assess demand and supply capacity over time to determine if more partners will be needed in the future. After consulting with about a hundred different people working in the field of HIV and access to treatment, we have concluded that 6 is the optimal number. We are open to discussing the inclusion of other companies if such proposals come forward.

Question: Are there any negotiations with the Global Fund, USAID or other donors through whom access to the drug could be expanded?

Answer: There are negotiations with the Global Fund, PEPFAR/USAID and other important donors. We cannot share more information yet.

Question: You said that your company will not affect the price. Is there a royalty spelled out in the voluntary license that will influence the price? And if so, how is it calculated?

Answer: The licenses granted are all royalty-free.

Question: Will the agreements remain royalty-free once you scale up production and begin large-scale release?

Answer: The voluntary license agreements are unconditionally royalty free for now and the duration of their existence.

Comment from a representative of the patient community: I want to go back to the issue of licensees. We know that there must be more than 6 companies to ensure access. It seems that the number "6" was chosen on purpose.

Answer: We selected the voluntary licensing partners based on rigorous criteria, given the challenges of manufacturing a complex injectable medicine. It was critical to ensure all partners were well equipped to produce sterile injectable medicines at sufficient volume. All these partners have successfully collaborated with Gilead to produce high-quality generic versions of medicines for HIV or other infectious diseases. We assessed many potential partners and made a decision to work with six manufacturers who have capabilities to provide volumes, coverage and speed of production required to bring the product to market.

Comment from a representative of the patient community: I don't know who the hundred people were who were talking about the 6 companies, but nobody approached us, the people who work in the region on access to treatment, with such a request. For the future, when you make decisions like this, please reach out to us.

Answer: I will pass this on to members of our team because I know you are in direct contact. Some of the consultation went through our community advisory board (CAB). I will advise the team that you would like to be consulted with in the future.

Question: You said that Gilead will have two trade names: for treatment and for prevention. Will the licensees also produce two drugs?

Answer: The license agreements cover both prevention and treatment. We do not require our voluntary license partners to produce two drugs under different brand names. If they wish, they can market the product for both prevention and treatment, under one brand name.

Question: Does Gilead have any plans for subsidy programs or partnerships to increase access to innovative medicines in the EECA region (e.g. lenacapavir pilot programs, PrEP programs or lenacapavir HIV elimination programs)?

Answer: No, we plan to work together with the EU-M4all initiative and with WHO on prequalification. Lenacapavir for countries outside the European Union that are awaiting product

approval will be available through the compassionate use program. But, it's important to note that this is only about lenacapavir for treatment, not for prevention.

Question: Does Gilead plan to launch a comprehensive pilot project or program to provide access to lenacapavir for pre-exposure prophylaxis in Ukraine, as ViiV is doing with cabotegravir? Is Gilead considering donating lenacapavir for Ukraine, including to military medics in emergency departments on the front line?

Answer: No such projects and programs are planned at the moment. Donations are not planned yet either, because the drug is investigational until it is registered. We are ready to support any initiatives in the EECA region through RADIAN projects and our grant programs.

Question: According to your estimates, when will lenacapavir be included in WHO recommendations (prevention, treatment)? Does your company and licensees plan to submit the drug for WHO prequalification?

Answer: We plan to cooperate with the WHO prequalification program. We hope that lenacapavir will be included in the prevention recommendations by the end of 2025. As soon as there is more information, we will share it.

Question: What special conditions (in terms of registration, market launch, price limits) have you set for generic companies under the license for lenacapavir?

Answer: The license states that licensees can only manufacture and distribute lenacapavir for prevention and treatment in the 120 countries specified in the agreement. Also, as we mentioned, this license is royalty-free.

Question: It appears that there is no clause in the lenacapavir license agreement that allows licensees to supply the drug to countries outside the licensed territory if a compulsory license is granted there. Do we understand correctly that according to section 2.5(b), licensees cannot supply generics of lenacapavir outside the license territory, even under a compulsory license?

Answer: No, licensees may not supply lenacapavir outside those 120 countries, even if someone issues a compulsory license. Our position is that issuing compulsory licenses does not increase access to drugs or improve other public healthcare goals.

Question: I have a question about removing patent barriers in other ways. If, for example, a patent is challenged in some country, can these 6 generic companies supply the drug to the country where the patent is challenged?

Answer: No, they will not be able to supply.

Question: Are there lower and upper price limits for lenacapavir under the voluntary license? If so, what are they?

Answer: The license does not specify any price limits. Once each generic version of lenacapavir is approved by regulators, the licensee manufacturing that product will set their own prices entirely independently from Gilead.

Question: We know that the Medical Patent Pool (MPP) approached you with a proposal for a license agreement for lenacapavir, but you turned them down. Do we understand correctly that you declined because an agreement with MPP would have been more lenient than the one you entered into?

Answer: We believe that the direct license strategy is more efficient and faster, while it would have taken longer through MPP. We stay in touch with the MPP and maintain contact. Also, we do not believe that too many licensees are an effective option to motivate the business, because the market from which to profit would become smaller.

Question: At the moment there are 6 licensees, including producers from Pakistan and Egypt. Will everyone have equal rights or will these two countries work only for their own market? And second question: does the license include distributors, dealers, etc. or only the manufacturers?

Answer: Any of these 6 manufacturers can supply to all 120 countries, and have the right to register and distribute their product (including via sub-distributors), wherever they want in those 120 countries. Distributors and dealers are not required a license to manufacture generic versions of lenacapavir, as they would receive the product through the voluntary license company who selects them to distribute it.

Question: Will the prices of Gilead and generic manufacturers for lenacapavir at which they will sell the drug be made public?

Answer: At this point, the price announcement is under discussion. But as you know, most companies and governments tend not to disclose the prices at which procurements are made.

Question: At what stage are the generic companies now in the production of the drug? Are they ready to produce the active pharmaceutical ingredient themselves? Perhaps the license should include additional companies that would be ready to produce the active pharmaceutical ingredient faster?

Answer: All the 6 generic manufacturers have received Gilead's technology to produce the product, including the active pharmaceutical ingredient. All the companies are already moving fast to produce generic lenacapavir.

Question: Back to the issue of competition, will there be any control over licensees submitting documents for registration of a drug in the country? This is due to the fact that today we see a tendency for companies to submit dossiers for registration at different times. Sometimes this time difference is counted in years, and in this case, there is no question of any competition.

Answer: All the 6 generic manufacturers are working at speed to make generic lenacapavir available as soon as possible.

Question: Given the high rates of HIV and hepatitis B coinfection in the EECA region, how does Gilead plan to support patients with these combinations of diseases? Are there initiatives to make Biktarvy and Genvoya more accessible to this group?

Answer: Access to these drugs in the EECA region is through voluntary license partners. At the moment we have no medical initiatives on this topic, but we are ready to consider specific requests.

Question: What are the company's plans on registration of Biktarvy and Genvoya in Kazakhstan?

Answer: Delta Medical is our authorized distributor in Kazakhstan. We do not currently plan to register our drugs in Kazakhstan. But under a voluntary license both drugs can be registered and supplied to the country by licensees.

Comment from a representative of the patient community: Yes, as far as we know Hetero already registers drugs in Kazakhstan.

Question: Is tenofovir alafenamide (TAF) included in the WHO guidelines for HIV treatment?

Answer: Tenofovir alafenamide has indications for the treatment of HIV infection. You can read more about it in the WHO guidelines.

Question: Does the company collect data on resistance to its medicines as part of pharmacovigilance?

Answer: Yes, we collect data on adverse events and emergence of resistance through the pharmacovigilance system.

Question: How long will licenses for sofosbuvir and other hepatitis C medicines be valid?

Answer: All license agreements entered into, whether voluntary or bilateral, will remain in place as long as there is a need for the drugs. We have no plans to cancel the agreements.

Question: Is Gilead going to sell drugs for viral hepatitis treatment in retail in pharmacies in Ukraine? Back in 2019, your company representatives said that the drugs will become available for purchase in pharmacies.

Answer: Viread is sold in the pharmacy network. We do not plan to supply other drugs, because there is no demand for them.

Question: What are your plans to ensure access to hepatitis treatment in Tajikistan?

Answer: This country is covered by the voluntary license, but our company does not plan to market the drug on its own because there has been no demand for our branded product from Tajikistan.

Question: What is Gilead's access plan for bulevirtide for low- and middle-income countries, especially given the current cost of Hepcludex?

Answer: Our company is working directly with the Mongolian Ministry of Health to provide access to bulevirtide (Hepcludex) for hepatitis D patients in Mongolia. In 2024, we introduced a commercial access program with the Mongolian Ministry of healthcare, which has treated approximately 137 patients as of October 2024. Under this program, bulevirtide is provided at a reduced price to meet the tremendous need of hepatitis D patients in Mongolia. This program was made possible by the willingness of the Mongolian government to invest in hepatitis D treatment. Speaking about the entire EECA region, Gilead does not have marketing rights for bulevirtide. The holder of marketing authorization in these countries (Azerbaijan, Belarus, Kazakhstan, Kyrgyzstan, Moldova, Russia, Tajikistan, Turkmenistan, Ukraine and Uzbekistan) is Hepatera. Please contact them with any questions.

Comment from a representative of the patient community: We talked with Hepatera and their representatives told us that they are only responsible for the EAEU countries (Russia, Armenia, Kazakhstan, Kyrgyzstan and Belarus). Last year, your company responded to our letter where you shared information that Hepatera will also be responsible for Uzbekistan, while Gilead is responsible for all other countries in our region.

Answer: In your region, we are only responsible for Georgia, but we do not commercialize it. When did Hepatera tell you about this geographic coverage?

Comment from a representative of the patient community: At the end of last year.

Answer: Hepatera has the commercial rights to develop and manufacture bulevirtide in Armenia, Azerbaijan, Belarus, Kazakhstan, Kyrgyzstan, Moldova, Russia, Tajikistan, Turkmenistan, Ukraine and Uzbekistan. Gilead holds commercial rights in Georgia, but we do not have regulatory approval to market the product in Georgia at this time. Bulevirtide can be accessed through a shortened regulatory process, 'Regime of Recognition,' which enables a product registered in another country to be supplied to Georgia. We are open to discussing the HDV burden in Georgia with you to assess this further.

Answer: For our part, we can only officially confirm what we have in our possession. Based on this, you will be able to talk to Hepatera about what they own.

Comment from a representative of the patient community: But you need to understand that you need to own the rights in Ukraine, because the country will not be able to buy from the Russian company because of the military conflict.

Question: Can we get bulevirtide as a humanitarian aid for compassionate use in a country where Hepatera owns the rights to the drug?

Answer: If we have commercial rights in a specific country, we can provide evaluate the possibility of providing compassionate and humanitarian supplies. If Hepatera owns the rights to the drug in those countries, they are responsible for providing such supplies.

Question: Do you plan to conduct clinical trials of bulevirtide in Kyrgyzstan?

Answer: At the moment there are no clinical trials planned for bulevirtide. But you should ask Hepatera.

Question: Do you plan to expand the license for sofosbuvir/velpatasvir/voxilaprevir? Do you plan to include Kazakhstan?

Answer: We have no plans to expand this license.

Comment from a representative of the patient community: We ask you to include Kazakhstan in this license.

Question: Are there any studies on the duration of treatment with bulevirtide? Who should I contact to get this data?

Answer: There is no formal guidance on duration of treatment. The SmPC outlines that treatment should be continued "as long as there is clinical benefit". There are several studies with bulevirtide evaluated for off-treatment response, and currently only MYR204 and MYR301 has a long enough follow up to assess this. None of those results have been reviewed and approved by any regulatory body. Please contact Gilead Medical Information for further information (https://www.global.askgileadmedical.com/)

Question: How does Gilead address the issue of access to treatment in rural, mountainous and remote areas with limited medical infrastructure?

Answer: We support patient advocacy groups and community organizations through sponsorships and grants programs (e.g. RADIAN program; ZeroingIn HIV grants; Rainbow grants). Gilead also works to promote HIV medical education for healthcare providers. Our company partners with providers and healthcare systems to support access initiatives in communities most affected by HIV as part of a comprehensive strategy to improve access to medicines. We actively listen to stakeholders to understand the opportunities and barriers to accessing treatment and care they face.

Question: Do you have plans to expand local ART production in regions with high HIV prevalence to improve logistics and accessibility?

Answer: We are assessing the capacity of our global production network as needed based on global demand. Where demand is met by our existing network, we are unlikely to initiate changes.

Question: Please share information on grant programs in the EECA region. What are the main priorities of these programs?

Answer: Besides RADIAN, we have our own grant portal through which applications can be submitted. We also support programs aimed at supporting LGBTQ people and eliminating stigma and discrimination.

Question: Does Gilead plan to launch large projects in Armenia in the coming years aimed at improving access to treatment for key populations and which areas will be prioritized?

Answer: We are not planning to launch a large project to improve access to treatment. Armenia can apply through the RADIAN program. There is a link to apply.

Question: When do you expect generic companies to be able to produce lenacapavir and put it on the market?

Answer: We will be able to announce a more precise date when the product is registered in at least a couple of countries. In our experience, it can be estimated after the drug is registered in the first countries. One of the licensees from North Africa suggested, based on his experience, that it will be late 2026 or early 2027.

Question: Do you track adverse events and resistance data for your drugs? Where can we see this data?

Answer: As far as I know, our company regularly sends data to the Food and Drug Administration (FDA) and the European Medicines Agency (EMA) to update their documents and so on. We send to these agencies all the data we receive from countries.

Question: I would like to clarify about the hepatitis C elimination program in Georgia. What results have been obtained? And what plans do you have for the future?

Answer: We believe that the program is good. There are difficulties in finding patients and recruiting them. But you are creative, and I'm sure you can do it. The contract for free drugs will be valid till the end of 2025. But we cannot say whether the contract will be extended.

Question: Do you have any molecules in development that will be targeted at curing HIV?

Answer: We are very interested in curing hepatitis B and HIV. Everything we are currently researching is at extremely early stages, so I can't tell you anything. This is a guiding star for us, and at the next meeting we may include a section in our agenda to talk about how we see the potential for achieving a cure for HIV.

End of the meeting.

APPENDIX

120 high-incidence, resource-limited countries included in the voluntary licenses for generic lenacapavir

1. Afghanistan
2. Angola
3. Anguilla
4. Antigua and Barbuda
5. Armenia
6. Aruba
7. Azerbaijan
8. Bahamas
9. Bangladesh
10. Barbados
11. Belarus
12. Belize
13. Benin
14. Bhutan
15. Bolivia
16. Botswana
17. British Virgin Islands
18. Burkina Faso
19. Burundi
20. Cabo Verde
21. Cambodia
22. Cameroon
23. Central African Republic
24. Chad
25. Comoros
26. Congo, Dem. Rep. of the
27. Congo, Rep. of the
28. Cote d'Ivoire
29. Cuba
30. Djibouti
31. Dominica
32. Dominican Republic
33. Egypt
34. Equatorial Guinea
35. Eritrea
36. Eswatini
37. Ethiopia
38. Fiji
39. Gabon
40. Gambia
41. Georgia
42. Ghana
43. Grenada
44. Guinea
45. Guinea-Bissau
46. Guyana
47. Haiti
48. Honduras
49. India
50. Indonesia
51. Jamaica
52. Kazakhstan
53. Kenya
54. Kiribati
55. Kyrgyzstan
56. Lao, People's Dem. Rep
57. Lesotho
58. Liberia
59. Libya
60. Madagascar
61. Malawi
62. Maldives
63. Mali
64. Marshall Islands
65. Mauritania
66. Mauritius
67. Micronesia, Fed. States
68. Moldova, Rep. of
69. Mongolia
70. Montserrat
71. Morocco
72. Mozambique
73. Myanmar
74. Namibia
75. Nauru
76. Nepal
77. Nicaragua
78. Niger
79. Nigeria
80. North Korea - DPR
81. Pakistan
82. Palau
83. Papua New Guinea
84. Philippines
85. Rwanda
86. Saint Kitts and Nevis
87. Saint Lucia
88. Saint Vincent and the Grenadines
89. Samoa
90. Sao Tome and Principe
91. Senegal
92. Seychelles
93. Sierra Leone
94. Solomon Islands
95. Somalia
96. South Africa
97. South Sudan
98. Sri Lanka
99. Sudan
100. Suriname
101. Syrian Arab Republic
102. Tajikistan
103. Tanzania
104. Thailand
105. Timor-Leste
106. Togo
107. Tonga
108. Trinidad and Tobago
109. Tunisia
110. Turkmenistan
111. Turks and Caicos Islands
112. Tuvalu
113. Uganda
114. Ukraine
115. Uzbekistan
116. Vanuatu
117. Vietnam
118. Yemen
119. Zambia
120. Zimbabwe