

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

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Organization: ViiV Healthcare

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Start of the meeting. Introduction of participants.

Question: What are the current results of the clinical study of ultra-long-acting cabotegravir (CAB-ULA), and what stage of development is the product currently at? According to preliminary data from the Phase I open-label crossover CLARITY study presented at EACS 2025 (assessment of clinically meaningful differences in acceptability and tolerability of long-acting injectable products for HIV prevention - lenacapavir and cabotegravir), most participants preferred cabotegravir injections after a single administration due to less pronounced adverse reactions (side effects), both at the injection site and in the post-injection period. In this regard, the question arises: will ultra-long-acting cabotegravir (CAB-ULA) retain a more favorable tolerability profile during and after injection, or, given its ultra-long mechanism of action, could the severity of post-injection adverse reactions increase?

Answer: The study of CAB three times a year for HIV prevention is called EXTEND4M. The first view of results related to the product's safety and pharmacokinetics will be available in the first quarter of 2026. The main results will be published in the third quarter of 2026. Put simply, we do not have results at this time, but we expect to be able to share all data with you in 2026. It is important to note that the pharmacokinetic data will be very important for regulators from the perspective of the product's registration. We can already see that the study is progressing well. In addition, studies of CAB three times a year for treatment have not yet started, but they are planned, and we will certainly share information as soon as we are ready.

It is important to note that the Phase I CLARITY study compared one dose of cabotegravir with one dose of lenacapavir. This means that one dose of cabotegravir (one injection, the first shot) was compared with one dose of lenacapavir (two injections). Based on the results of this study, people would prefer cabotegravir over lenacapavir. It should be understood that, in the real world, the choice will be between either a dose given once every two months (cabotegravir) or a dose given once every six months (lenacapavir). We expect that all the attributes of cabotegravir will be preserved in its three times a year form, as it is also an intramuscular injection at the same volume of injection. Unlike

lenacapavir, which is administered subcutaneously, cabotegravir is administered intramuscularly. In any case, we are awaiting the study results.

Question: Have you considered developing a prolonged oral (tablet) form of cabotegravir? In our view, it may have advantages over the injectable form because it does not require additional involvement of medical staff.

Answer: I assume your question is related to the fact that MSD/Merck recently announced results of studies of an oral PrEP regimen taken once a month. In my view, in the near term the PrEP market will be well represented by the following options: cabotegravir dosed once 6 times per year, cabotegravir dosed three times per year, lenacapavir dosed twice a year, and an oral form dosed 12 times per year. It is important to say that the best PrEP option is the one that people who can benefit from PrEP actually use. Accordingly, we already see a large number of people using daily oral PrEP, and it works for them. We are glad that health systems will have different PrEP options. We think the CAB-three times per year option may be of interest to health systems from the perspective of regular visits to medical centers, where screening for other sexually transmitted infections can also be carried out. We think an interval of once every four months may be convenient. At the same time, it is important to note that we are not currently considering self-injection. Looking at the market, it seemed to us that, at this stage, there are no advantages to launching such a form.

Question: How are the studies and clinical trials conducted by ViiV to improve the pharmacokinetic profile of cabotegravir progressing, and what stage are they at now? In particular, what is the current status of Opera, Trio and other related studies?

Answer: As for the dosing regimen of CAB 6 times per year, we are currently not working on pharmacokinetic optimization. The main research activity is focused on CAB dosed three times per year. This is a transitional program. It will be available for prevention, and it is also planned to study this form for treatment - the cabotegravir/rilpivirine regimen. Accordingly, this combination will use a different form of rilpivirine.

Regarding the Opera and Trio studies: these are not pharmacokinetic studies; they are real-world clinical practice studies - specifically, cohort studies of the effectiveness and safety of using the product for PrEP and for treatment. Data are presented every year, and we plan to present data from these studies at upcoming scientific conferences. As for pharmacokinetics, as I mentioned, there are two studies. The first we have already discussed – EXTAND4M - and the second study is Two to Four. This study examines switching to an injection once every 4 months instead of every two months. We also plan to conduct a treatment study. Most likely, it will launch next year and will be called QUATRO.

Question: Are there any new data on interactions between cabotegravir and rifampicin, and other anti-tuberculosis medicines?

Answer: At the moment we do not have new data. As you know, rifampicin is a strong enzyme inducer. We conducted modeling studies and there is no easy way to overcome this drug-drug interaction. Rifampicin will reduce cabotegravir concentrations. This problem does not exist with other anti-tuberculosis medicines, including rifabutin, which has low availability due to its high

cost. There is a potential to dose adjust when taking Rifabutin, but it is not commonly used or easily accessible and thus not practical. From a research perspective, we are looking at the possibility of modifying cabotegravir doses, but this will most likely require more frequent administration - possibly once a month - and it is still unclear how useful this would be in clinical practice if there are other options.

Question: At the previous meeting you showed us a large number of molecules under development. Are there any that currently look the most promising and are closest to market entry?

Answer: If we look at the current pipeline of investigational products that offer additional value, in our view the more promising molecule is VH184. This is a next-generation integrase inhibitor. This molecule will be moving into Phase 3 studies. You may have seen results from earlier studies at conferences. Its advantages include a strong resistance profile, and we expect it to be effective even in the presence of mutations to other integrase inhibitors such as cabotegravir, dolutegravir and bictegravir.

Another promising molecule we are currently developing is called N6LS - a broadly neutralizing antibody. As you understand, this is a new mechanism of action. Strategically, we are currently targeting a new treatment regimen - once every 6 months. We consider this a very promising direction. Among the molecules that can help us achieve this goal are VH184 and other integrase inhibitors in the list, as well as N6LS. There is also a new capsid assembly inhibitor - molecule number 499.

As for timelines, the launch of CAB-3 times per year will most likely be in 2027 - first for prevention, then for treatment with dosing regimens once every 4 months and once every 6 months. As for the new molecules I mentioned, that would be 2028-2029.

Question: Which countries will be included in HIV treatment studies? Will countries from the EECA region be included?

Answer: The pharmacokinetic study is conducted only in the United States and at a single site, but it is not an efficacy study. As for treatment studies, they have not yet started. I am not on the team that runs clinical trials, but I can try to find out information on this. (To be clarified during finalization of the minutes.) The countries have not yet been decided for the pipeline studies and there are ongoing discussions.

Question: In mid-2025, ViiV expanded its voluntary license via the MPP for long-acting cabotegravir (CAB-LA), extending it beyond prevention (PrEP) to include HIV treatment as well. At the same time, the number of licensees remained unchanged - three generic manufacturers. Is ViiV considering starting negotiations to expand the number of licensees, taking into account that, in the case of lenacapavir, there are already at least six such manufacturers?

Answer: We are not currently considering increasing the number of generic manufacturers. We believe the product needs a sustainable market. If there are too many manufacturers, generics will not have enough incentive to invest in manufacturing capacity and in the product. We believe that three manufacturers will be sufficient for now.

Regarding readiness to manufacture cabotegravir, there is no new information. We still expect generic versions of the product to file for regulatory approval in 2027.

Question: Does your company plan to include Azerbaijan, Belarus and Kazakhstan in the main voluntary license for dolutegravir in order to ensure an affordable price for the product in these countries?

Answer: We believe that countries that have the ability to partially cover the cost of product development should do so. At this time, we have no plans to include these three countries in the main license. I would again emphasize that since this voluntary license was concluded, the price of dolutegravir has fallen by almost 90% and access to it has improved significantly. Governments of countries covered by the license (for example, Kazakhstan) have publicly noted how much this license helped to increase access.

Question: Last year we asked whether you would introduce additional price-reduction thresholds under the special dolutegravir license. You said you had received this request and that once the 60-70% coverage threshold is reached - and that threshold has already been reached in Kazakhstan and Belarus - the price would be reduced. What are your thoughts on this request to introduce another threshold? You said you would decide this next year. Have you introduced another reduction threshold?

Answer: I would like to emphasize that we do not set the final price. Generic manufacturers set it. As for price thresholds, we have not yet made a decision, but we are considering this option.

Question: If, at the beginning of next year, civil society in the EECA region were to proactively approach the company with an open letter stating that this needs to be done because these countries have good coverage of the products, would that help speed up the decision-making process?

Answer: At the company we take the views of civil society seriously, listen to them and consider proposals we receive, although we cannot always agree with them. It will be harder for us to advocate for changes if all our leadership hears is criticism. What can really help is recognition of progress while also noting what community would like to see change. If there is a public letter, of course we will review it, but the tone of the letter will play an important role.

Question: I analyzed purchases of antiretroviral (ARV) medicines in Belarus for 2026 and found that around 80% of all products are dolutegravir.

Answer: This is within the remit of generic manufacturers. As for communication with them, we interact regularly and have quarterly check-ins where we analyze what has been done. Regarding technology transfer, if direct technical support is required, we have the ability to provide support to generics in the form of regular technical visits. The main communication with generics goes through the patent pool. If you have any difficulties communicating with generics, let us and the Patent Pool know, and we will try to help resolve this.

Question: This year we met only with one generic company. With the other companies there are major problems even in correspondence: they either do not respond or respond very slowly. Often companies like ViiV, Gilead, etc. delegate all this to their licensees, who are responsible for

registration, product promotion, etc. But we cannot get this information from generics because they do not engage. We are asking for help in terms of you influencing them somehow so that communication improves.

Answer: We are happy to speak again with the Patent Pool so that they convey to generic manufacturers the importance of interacting with the community in the region.

Question: In Russia, a Russian generic company won the tender for dolutegravir, but in the end the originator product was purchased. Could you explain this situation in more detail? Also, do you see any prerequisites now for a compulsory license for dolutegravir to be issued in Russia in the near future?

Answer: Our view of the situation in Russia is as follows. Indeed, the Government announced a tender in which a generic company won, but the tender was then withdrawn. A new tender was announced again, in which GSK was the only participant, as our representative in Russia. We believe these actions comply with the law, because our patent in Russia has not yet expired.

As for the second part of the question about a compulsory license, as far as we know, under the law a compulsory license can be issued in two cases. The first is a shortage of the product on the market, which does not correspond to the situation because, according to our data, confirmed by the Ministry of Health, there is a sufficient quantity of the product on the market. A compulsory license can also be issued if a so-called technological innovation emerges from a generic company. I cannot comment on this because there is currently a court case in Russia. When there will be a result is unknown.

Question: Did the 'blackmail' by the generic manufacturer, with the support of the procurement organizer, ultimately affect the price reduction?

Answer: This partly relates to the answer to the next question as well. We look at a combination of factors when deciding on price. This combination includes World Bank data, procurement volumes communicated by governments, and procurement patterns in terms of the trend we observe for our products. I can say that for Russia it was crucial for us that people who receive dolutegravir and need this product continue to have access to it in the current conditions. That was probably the key argument we considered during our engagement with the Ministry of Health, and which we plan to continue.

Comment by a patient community representative: Given that in Russia there is an informal 'confrontation' between two products - dolutegravir and elsofavirine, which is significantly increasing its production volumes. According to our data, more than 100,000 courses of this product are planned for procurement in 2026. Our appeal is that you reduce the price a bit more so that the Ministry of Health purchases more dolutegravir.

Answer: Thank you, I will pass this information on to colleagues who work on Russia.

Question: Does ViiV plan to begin considering (or developing) alternative approaches to determining territorial jurisdiction for providing access to its medicines under voluntary licenses, in addition to the World Bank classification? Is ViiV ready to work with civil society on this issue?

Answer: For us as a company, externally defined criteria are extremely important - criteria that make it possible to understand in advance which category a given country will fall into in terms of its development and access to various services, etc. As you know from many years of communication with me, I am ready to consider any ideas and work with civil society. I cannot promise that if you propose something we will immediately adopt the proposal. But we will definitely review it.

Question: Can you help facilitate a meeting with GSK? Perhaps you can share contacts of people we can reach out to?

Answer: I have already sent you the contact of Andrew Garvey, and I informed him that you would be getting in touch. He is quite an open person and is ready to keep in contact.

Question: Do you currently have any active support programs for NGOs? Given the withdrawal of many donors, do you plan to launch additional support measures for NGOs in countries?

Answer: As you know, we have the 'Positive Action' program, which works with non-profit organizations primarily across low- and middle-income countries. Also, today at the ICASA conference 'Positive Action' is announcing its new NGO support strategy. I encourage everyone to visit their website and social media and look into this. I do not know all the details myself, because their strategy development took place independently.

The second type of support is through the government affairs team and our advocacy initiatives, which, for example, can be aimed at ensuring that HIV continues to remain an important political priority on the health agenda.

In connection with the change in the financial landscape that occurred earlier this year, we took certain actions. First, we allowed all grantees to make changes to their projects and adjust them so that, using our funds that we provided, they could cover any gaps that emerged due to the fact that the United States cut its funding.

We also provided funding to the Elizabeth Glaser Pediatric AIDS Foundation to support our collaboration specifically in the area of pediatrics. We also provided funds to the Robert Carr Fund, which should distribute them among regional networks and organizations. In addition, 'Positive Action' has Rapid Response Funds, to which we also directed resources for current grantees so that they could ensure they meet their project goals.

Of course, we continue to monitor how the situation develops. Although I have not yet seen the new 'Positive Action' strategy, I would be surprised if they did not take the current situation into account in their new strategy, so I encourage everyone to review their resources.

Question: What are the approximate timelines for the appearance of generic cabotegravir for treatment, and not only for PrEP, given that the license was expanded to include treatment this year as well?

Answer: I cannot answer this question right away, but we will check and get back to you with an answer

Question: Given that injectable and oral cabotegravir and rilpivirine are registered and available in Russia, what prevents the start of use of the product? What barriers exist today?

Answer: At this time I can say that we have difficulties launching new products. Our priority has been to ensure the continuity of supply of Tivicay for people living with HIV in Russia. In consideration of MOH practice not to recommend the treatment for inclusion in the EDL we are re-evaluating timelines. GSK has not received any requests to supply V&R. Since this product is promoted in partnership with Janssen, that may also have some impact on the launch situation in Russia.

Question: But you are still continuing clinical trials in Russia?

Answer: We will complete the clinical studies that are currently ongoing. We have said that we will not start new ones.

Question: Are there any discussions about whether next year you will in any way change your policy on funding and support not only for civil society programs, but also for improving access to products? I understand that, as with Gilead, many organizations come to you with requests for support, and that this demand has increased this year. Are you considering increasing support overall given this funding situation?

Answer: Regarding the first question, I have just received the slides for the 'Positive Action' program. I cannot answer this question in detail and precisely. I can only say that we are now looking very carefully at how to ensure funding in the new political environment and how to advocate for HIV to remain a political priority. As you can see, the United States did not mark the importance of World AIDS Day. The direction we are currently looking at supporting advocacy activities related to HIV, including for example supporting the training of young activists. We also want to invest in obtaining data generated by civil society in order to show governments the importance of investing in HIV. Also, within 'Positive Action' we want to ensure support for grassroots organizations within 'Positive Action'. These are the areas that currently seem important to us.

Question: We see that, for example, with Gilead products - in particular lenacapavir - there are regular announcements of not-for-profit prices and agreements between UNITAID, Dr. Reddy's, etc., where they announce that they will supply the product for \$40. Are there similar steps by your company regarding cabotegravir?

Answer: We are closely watching Gilead's policy regarding lenacapavir and believe that having a choice is important; and since lenacapavir may not be suitable for everyone, we are considering working with PEPFAR and the Global Fund so that cabotegravir is also available as an option. We are looking at what access programs can be used and what partnerships can be established to meet current needs. A creative approach may be required. I cannot provide precise information, but we are considering this direction.

Question: I would like to ask a follow-up question about our region. Are there already any implementation and scale-up programs for cabotegravir for PrEP for the EECA region? Perhaps you can share additional information.

Answer: There is no specific information at the moment.

Question: Beyond what we discussed earlier, are there any new challenges or specific features you face in our region in connection with harmonization of legislation within the Eurasian Economic Union - both for product registration and the mutual recognition procedure, and in terms of patent law?

Answer: We have already discussed regulatory aspects with you, and we mentioned that there were difficulties in communicating with regulators when trying to clarify certain issues. But as for specific technical information, I will need to clarify it. As for patents, I also have no information about any additional barriers.

Question: I have a question about training programs for medical staff on cabotegravir. Is the company developing such programs? Perhaps you are developing training programs jointly with the World Health Organization so that the medical community will already be prepared for the introduction of cabotegravir in countries?

Answer: We can respond regarding programs on the use of cabotegravir as PrEP. This was mainly within implementation studies and in resource-limited settings. Some of these programs are currently partially on hold due to ongoing discussions with PEPFAR. With regard to treatment, I cannot say for sure. As you know, cabotegravir was added as a treatment option in the World Health Organization guidelines. But there is no specific information on this.

Question: This would be very important, because often the medical community is not trained within countries, but in the case of cabotegravir, qualified work by medical staff is very important.

Answer: We are currently experimenting with digital training tools. In particular, a digital training on injectable formulations with virtual reality elements was developed and presented at one of the conferences. I know that this cannot be implemented in all settings. Nevertheless, I can say that this training was very well received by mid-level and senior medical staff. We are exploring the use of artificial intelligence for training. Perhaps later I will try to provide more detailed information. But overall, these digital programs may be easier to implement in settings where the product has not yet been introduced into clinical practice.

End of the meeting.