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.

Presentation of ViiV Healthcare.

We have prepared a presentation in which we took into account the questions on clinical aspects that we have received from you.

Of course, you are aware of the current situation we are in now in terms of the number of new infections, of which there are 1.3 million per year and 360,000 new cases that appear every day. As you know, the current standard ARV regimens suppress HIV in more than 90% of the people who take them. Our company has developed two prolonged antiretroviral regimens that are available in many countries. As many companies, we are now focused on developing long-acting forms of drugs, including a focus on those that can be self-administered to improve people's life expectancy and quality of life.

If you look at our developments that are presented in the presentation, you will see both dolutegravir-based regimens and cabotegravir-based regimens, including injectable cabotegravir for PrEP. Our focus areas of development have also emerged here: an ultra-prolonged drug for injection and a prolonged treatment that can be self-administered. And also, a whole set of drugs: fusion inhibitors, 3 molecules, broadly neutralizing antibodies, 3 molecules, as well as capsid inhibitors and maturation inhibitors. If you look at this slide, this is where the numbers signify the different stages of the life cycle of the virus in terms of its entry into the CD-4 cell, and which drug belongs to which point in the life of the virus and at which point is designed to have an effect on it.

The stages of clinical trials at which a particular drug is in are also shown here. For example, drugs that affect fusion and adherence are in stage IIb, broadly neutralizing antibodies are in preclinical research, and a capsid inhibitor is in stage IIa. In terms of virus introduction and integration into the cell, it's ultra-long-acting cabotegravir in stage I, and two new molecules in the same class, VH-184 in stage II and VH-310 in preclinical studies. If we are talking about the assembly and cell exit stage, it is a capsid inhibitor at stage IIa and the last drug at stage IIa.

In terms of the regimen of the injectable treatment and prophylaxis, we are targeting dosing, three or two times a year. And for self-injectable treatment, we are targeting an injection every two months. We may be able to increase the time interval between injections, but it's too early to tell at this point.

At the bottom of the slide, you can see that integrase inhibitors are the basis for all of these regimens, and potential combination partners are non-nucleoside reverse transcriptase inhibitors, broadly neutralizing antibodies, capsid inhibitors, and dual-specific broadly neutralizing antibodies.

Question: Which of the molecules presented is in a more advanced stage of clinical trials?

Answer: I would like to draw your attention to ultra-prolonged cabotegravir. Although this is technically a phase I study, since we don't need to collect efficacy data, it will go faster than normal. Essentially, this is a study about frequency of administration. We plan for this drug to be administered three times a year. You may have already seen preliminary data. We expect more data next year.

Question: Is it planned to be used only for prevention, or for treatment as well?

Answer: What you are seeing now is cabotegravir-only data, but that data will be used to support and advance regimens for both prophylaxis and treatment together with rilpivirine. We will use the data from this study.

Continued presentation.

On this slide, you see molecule VH-184, which is a new class of integrase inhibitors, i.e. 2nd generation. Its fundamental difference is that the resistance profile is different from the 2nd generation integrase inhibitors that are already available. If resistance has developed to past 2nd generation integrase inhibitors, this one can be used. We are also aiming to have a prolonged form of this drug, but which second component we will use for the combination will be determined in further studies.

As for broadly neutralizing antibodies, I would like to tell you about the N6LS molecule. This molecule showed a very good tolerability profile and very few adverse events at different dosages per kilogram of weight in the first and second stages of the study. The dosages were as follows: 40, 70, 280, 700 mg. In all cases, the number of serious adverse events is practically zero. The drug is good with both intravenous and subcutaneous administration. Another important point with broadly neutralizing antibodies is that *in vitro* studies have shown fairly high efficacy against 9 or 6 viral chains. This allowed the drug to move into phase III trials.

In the first part of the CINNAMON studies, VH-280 and VH-499 were compared. Based on the results obtained, we anticipate that we will continue to study the VH-499 molecule, which belongs to the class of capsid inhibitors. The inclusion criteria for the study were as follows: no history of ARVs from 18 to 65 years of age HIV-1: CD-4 level greater than 200 cells and body mass index from 18.5 to 31 kg.

I also would like to talk about a maturation inhibitor that targets HIV-1. A maturation inhibitor is an investigational class of drugs that targets the very final stages of the virus life cycle and blocks a protease-related process between the capsid and one of the proteins. The point is that we have been doing development on several molecules in this class of maturation inhibitors and generally previous

development on this class has shown that this approach has efficacy. But the VH-937 molecule is a next-generation maturation inhibitor within our pipeline of drugs because it has the potential to be a long-acting drug. All previous molecules in this class have been short-acting, so we dropped out of development. Now we want to focus on the VH-937 molecule, which has the potential to be a long-acting molecule.

And the last slide shows our plans to work towards a complete cure of HIV. We haven't stopped thinking about it and we plan to use a combination approach that combines the reduction of HIV infection in cellular reservoirs once HIV transmission is suppressed. There are three circles here. First: HIV transmission must be in latently infected cells and must disappear. Second: the reservoirs that are filled with viral proteins must be cleared. We had fostemsavir in our portfolio, and now we have a new drug called temsavir. We are planning that this particular drug will be at the core of this approach. It will be a combination of temsavir, which is the active form of the adherence inhibitor fostemsavir, combined with broadly neutralizing antibodies and then purification of CD-4 cells. We also have an N-6 molecule, and we are trying to combine these three molecules to achieve a functional and complete cure of HIV.

The last slide says that we don't plan to stop until we get results, both in terms of improving the quality of life of people through long-acting regimens and in terms of preventing and curing HIV infection. Our slogan states that we will not stop until the day we end the HIV and AIDS epidemic.

Question: We understand that if there is resistance to a group of drugs, there will be no resistance to this new molecule, because it is 2nd generation. Can you say now how high the resistance profile of this molecule will be?

Answer: Judging by the preliminary data on the resistance profile of this drug, it shows efficacy in cases where dolutegravir and cabotegravir are no longer working. But at this stage we cannot yet say what the drug's resistance threshold will be. VH184 is an INSTI in development which has very similar potency as DTG, with a different barrier to resistance profile to existing INSTIs with a broader coverage of RAMs. We have not fully finished characterising the profile, but we hope that it could play a role where 2nd Gen INSTIs are insensitive to INSTI RAMs. On this slide, you see information that shows that when dolutegravir and cabotegravir are taken, when resistance occurs, the viral load remains un-suppressed, whereas this new drug suppresses the viral load and shows efficacy.

Question: We had a session with WHO where we were shown a slide about cabotegravir staying in a person's body for a very long time after the last injection is administered. This can lead to resistance later on if the person gets HIV. Is the company considering any strategies to rapidly remove cabotegravir from the body?

Answer: We are not currently working on the neutralization issue. In terms of the occurrence of potential side effects and the need for neutralization, we initially worked on oral cabotegravir so that we could assess its full safety when used in a broader population. Only then did we move to injectable solutions to have a greater degree of confidence that the drug would be safe in the long term in different situations. To date, we do not have any data that anyone has developed resistance at a stage when this so-called pharmacokinetic "tail" is still active in the body. We know that there was a case of acute HIV infection with cabotegravir.

I think this is a very good question, and it is important, because at the moment we do not have such developments, and a potential solution could be in the form of an implant, which could then be removed in case of a problem. If you want, I can pass on the feedback to our core large clinical team.

Question: What strategic partnerships or collaborations are you considering to accelerate development?

Answer: We are constantly collaborating with research institutes in terms of new developments. As you know, we had a collaboration with Jonson & Jonson on a prolonged-release injectable. We also have a collaboration with Halozyme Therapeutics, which has a product called PH-20. It's a drug injected subcutaneously that we are developing together.

Question: Do you work in partnership with Gilead?

Answer: We don't partner directly with Gilead. But there are various third parties that are interested in conducting various studies related to cabotegravir and lenacapavir. We are willing to work with non-profit organizations and research institutes and provide them with product for such studies.

Question: Why do you not want to work directly? Are you willing to work directly? As we understand it, it has to be an initiative from both sides.

Answer: At this stage for us it is a proof-of-concept issue because, firstly, it is important for us to first prove the efficacy of the concept on our own molecules. Secondly, it is no secret that Gilead is a competitor. We are willing to work, and we work with a variety of partners. For example, we work with a network of HIV prevention and treatment research institutes that promote modern approaches related to treatment.

Question: Are you working on developing a vaccine?

Answer: As I said, we are looking at different options for finding a cure for HIV. We also continue to look at the possibility of developing a vaccine. Also, next year we plan to present studies on cabotegravir with a regimen of administration every four months.

Question: We have received reports of patients withdrawing from cabotegravir because of pain at the injection site. Are there any statistics on how often patients withdraw from treatment?

Answer: Discontinuations of CAB+RPV LA due to adverse effects in our clinical studies was 4-6%. Injection site reactions are the most frequently reported adverse event for CAB+RPV LA (up to 84%) in our clinical studies. Up to 1% of people in the CAB+RPV LA clinical studies discontinued treatment because of injection site reactions. There have been occasional reports of a post-injection, drug-related fever, occasionally with mild flu-like symptoms. These cases reported to date have been mild, lasted for only a few days.

Question: Does your company have any plans to increase efforts against possible cabotegravir resistance, especially given the long period of exposure to the drug in the blood after stopping injections?

Answer: We think the approach should be as follows: if a person stops taking cabotegravir but wants to continue taking PrEP, they should be switched to another appropriate oral regimen in a timely manner. From a treatment perspective, we don't have information that someone got HIV infection during the pharmacokinetic "tail" period. But if that happens, the person has to adjust the treatment regimen based on the fact that a drug of that class should not be included in the regimen.

Question: Are there any studies to improve the situation with the pharmacokinetic "tail"?

Answer: Yes. Among them are Opera, Trio and a number of other post-marketing studies, which allow us to observe patients and collect information about what happens in reality, including the presence of pharmacokinetic "tail".

Question: How does your company plan to reduce or control side effects, such as depressive disorders, that have been reported in cabotegravir users?

Answer: We continue to collect information from all the post-marketing study groups on the incidence of these events. As you know, a number of patients are experiencing these adverse events and everything that we are getting from different studies shows us that according to the pharmacovigilance data we do not need to make changes to the labelling yet. At the moment, the frequency of occurrence of the events is in line with the labelling.

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

Answer: As you know, the only country in the region that uses cabotegravir for PrEP is Ukraine, because a pilot project has been launched there. In general, we are working with all supranational organizations that are involved in training and supporting medical personnel. We also have grants available where you can get support aimed at national training of healthcare workers. But due to the fact that the product is not registered anywhere, we are not actively involved in training and promotion among other things because it is an ethical conflict since we cannot train on something that is not yet on the market. But if there is a request that some specific training is needed, we are ready to respond and consider it.

Question: Does your company collect resistance data on its drugs, including dolutegravir, as part of pharmacovigilance? Please share the latest data.

Answer: We routinely collect all data as part of pharmacovigilance and post-marketing studies. The data that we have now is that less than 3% of people develop resistance to dolutegravir-based regimens. I'm very interested in the reason why this question was asked. If this question is based on the studies that were presented in Glasgow, please note that they took data from the so-called Rosetta registry, which takes into account specifically a group of people who have already had treatment failure on a whole range of drugs, including integrase inhibitors. Rosetta Registry (HIV Glasgow, November 2024): This interim analysis focused on a case series of individuals on second-generation integrase inhibitors who experienced virological failure. It highlighted prevalence and resistance patterns following second-generation integrase inhibitor (INSTI) failure. The case series did not

provide denominators and did not account for the millions of people on DTG-based regimens worldwide, compared to other second generation INSTIs. Due to the widespread use of DTG, and recommendation as a first and second-line treatment in WHO guidelines, most individuals in the case series are expected to be on a DTG-based regimen. Dolutegravir, unlike other second generation INSTIs, is indicated for individuals with prior INSTI resistance. In this case series, 19% of individuals had prior first-generation INSTI exposure, but it is unclear how many had prior resistance. Accordingly, this is a group in which the initial level of resistance specifically to this class is higher. But, in general, no more than 3% fail to achieve a virologic response. And they can fail to achieve virologic response for a variety of reasons, and it may not necessarily be due to having resistance.

Question: Are these data for the original dolutegravir or do they also include generics?

Answer: The data includes other generic options and this is based, among other things, on those data on epidemiological surveillance that are implemented by different countries, WHO and other organizations.

Comment from a representative of the patient community: I would also like to add that the company should supplement the study with its data on dolutegravir resistance, which is broadcast in Russia. Patients are already reluctant to take dolutegravir because they believe they are developing resistance to it.

Answer: Thank you for the information. I will pass this information on to our team.

Question: Is there any new data on the interaction of dolutegravir with methadone? Or maybe there is data on the incidence of lipodystrophy while taking dolutegravir?

Answer: Yes, according to updated data from the Liverpool DDI resource and the prescribing information for dolutegravir, dolutegravir has no clinically significant effect on the pharmacokinetics of methadone. Methadone and dolutegravir can be safely taken together — the changes in methadone levels in the blood are so minor (1–2%) that they have no clinical relevance. No dose adjustment is needed for either medication.

ViiV is not aware of any data about dolutegravir and lipodystrophy. However we are actively studying fat distribution in a number of our studies particularly in relation to weight gain and the impact of integrases and other ART agents and will report out on the data once available.

Question: Do you already have any data on drug-drug interactions with cabotegravir that you received from Ukraine?

Answer: As far as cabotegravir is concerned, it has a slightly different pharmacokinetic pathway in the body. It doesn't go through cytochrome 3A4 (CYP3A4) and the second cytochrome. It goes through UGT1A1, if that tells you anything. Cabotegravir does not affect the active ingredient concentration of other drugs. But other drugs can affect its concentration, such as rifampicin and a number of antiepileptic drugs. But there is nothing new compared to what is already stated in the instructions.

Question: In case a person has injected cabotegravir and has some very severe side effects immediately, what is the solution for emergency removal of this drug or any other mechanisms?

Answer: Serious AEs have been rare. While there is an optional oral lead in which can be used, most initiations of CAB LA have been direct to injection. We have seen allergic reactions or a drop in blood pressure when the person received the injection. In this situation, as with any medical procedure, supportive treatment is recommended. We need to correct the blood pressure and immediately give fast-acting antihistamines. This is the standard set of actions for dealing with an allergic reaction.

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

Answer: No, because is the adult DTG voluntary licence was designed for low- and middle-income countries, and these countries are not among them. We believe that high- and middle-income countries should contribute to the global development of innovation. So, our approach to voluntary licenses on these countries is different from low-income countries. But I think it's important for us to take a step back and look at what we've achieved with this license, which is that the price has dropped by over 90%, the coverage has increased by over 60%. It may not be the model you wanted, but it has allowed us to achieve a lot.

Comment from a representative of the patient community: Yes, we don't quite agree with you. And this time we disagree even more. In the previous two days, we discussed the World Bank classification a lot. If you look at this classification, Ukraine has already become an upper-middle-income country, and soon all our non-wealthy countries will also become upper-middle-income countries according to the classification. We propose to meet and discuss changes in these classifications, so that countries would be included in licenses on a different principle.

Answer: Yes, we too were extremely surprised to see Ukraine on the updated list of upper-middle income countries, and this also provoked certain discussion processes in our company. So, we will be very interested to hear your suggestions on alternative ways of defining territories for access.

Question: Your company proposed the following scheme: the more access to treatment (coverage), the lower the price. We agreed with your scheme, and today in Kazakhstan dolutegravir is not provided only to those patients who have contraindications to this drug. But unfortunately, we do not see a decrease in the price. For the last two years the price has been kept at the same level, i.e. $17 dollars, which is much higher than in other countries of the EECA region. Will ViiV fulfill the promise you made: the more coverage, the lower the price?

Answer: The price has fallen by more than 90% over the entire time. We still believe that upper-middle-income countries should contribute to the development of global innovation. Certainly, the price that we have now is not even close to the prices that high-income countries pay, because they pay much more. Last year we introduced two additional intermediate royalty levels at which there is some reduction. We have received a request to introduce another threshold when the 60–70% coverage threshold is reached, and we are still thinking about that request. We will address that issue next year.

Question: At some point, will you provide an answer next year? We hope you will not do so after the 2026 tenders are announced.

Answer: We are taking that into account in the schedule, so we will do before then.

Question: If we propose new criteria for inclusion of countries in licenses, who will decide on the relevance of the criteria? Your company or the Medical Patent Pool (MPP)? Or will it be a joint decision to transfer/include countries in another license?

Answer: If such a model is found and we are satisfied with it, the final process will look like a negotiation process between our company and MPP. Yes, our team plays a very important role as the access team in this process. But here we also need colleagues from the commercial department. So, the final process of translating or implementing such a license will look like a negotiation between ViiVand the MPP.

Question: The existence of a scheme in which the price reduction depends on the volume of procurement leads patients to certain risks. Today the country has hit the ceiling and is paying a certain price, but let's suppose that side effects and resistance appear, and we need to procure other drugs. In this case, the buyers will look at it this way: the price is increasing, we cannot afford it. Or will your company keep this price, even if the volume of procurement decreases in the future?

Answer: That's a good question that I myself have never thought about. We will discuss it within the team as well. Right now, we have the following process: we have the total number of people on treatment according to the countries' official data, and from that we calculate the percentage of people taking dolutegravir. Our assumption is that the number of people now who will have treatment failure and so on will not be very high. And soon the patent will expire, and so this issue will be eliminated. But we will discuss this issue.

Comment from a representative of the patient community: There is another aspect to this issue. They are trying to switch all people to dolutegravir, while reducing the procurement of other drugs, and therefore reducing the number of possible options for people.

Answer: We will discuss these issues. Thank you for your feedback.

Comment from a representative of the patient community: This year we have already communicated with the licensees on this issue, and they told us that in case of a decrease in the volume of procurement, the price will be reconsidered.

Question: Not long ago, your company announced that it is committed to providing at least two million doses of long-acting cabotegravir for pre-exposure prophylaxis of HIV for procurement in low- and middle-income countries during 2025–2026. Is this announcement related to Gilead's recent press release on lenacapavir license agreements? How do you assess the risks that lenacapavir could displace cabotegravir in the market?

Answer: No, it's not related. We have always wanted to increase the coverage of long-acting cabotegravir until our generic licensees scale up their own production. The situation is that in September 2024, we announced that our production capacity will now be increased. We welcome the

release of new prophylaxis options and believe that people should have a choice. The more different prophylaxis options there are, the better. We are not afraid of competition. The patent and pricing strategy for cabotegravir has not changed due to the recent news, and we will follow the same path we announced earlier.

Question: Given that lenacapavir shows high efficacy in clinical trials and the recent issuance of a voluntary license by the manufacturer, how does ViiV see the situation with cabotegravir developing? Will the price be reduced in this regard?

Answer: I am not at liberty to comment on country-specific pricing, other than the general comment I have already mentioned. Regarding cabotegravir, we will follow the same flexible pricing pathway that we have had with other products. This pathway takes into account World Bank classification which we understand that you do not like, health procurement patterns, national investment, etc.

Question: At what stage is the generic release of cabotegravir? Do you control this process?

Answer: We are in constant contact with the generic companies and provide them with technical support. The last thing that was done was to provide technical packages aimed at starting production to all three licensees (Aurobindo, Mylan and Cipla). There are also ongoing discussions between the technical teams on an ongoing basis. We remain in active and continuous contact for the early release of cabotegravir for PrEP. Given our previous experience with dolutegravir development and technology transfer, as well as the technical challenges associated with the different technologies of prolonged cabotegravir, we expect the first shipments of generic drugs from our licensees to low-income countries to begin in 2027.

Question: How many people in the world are on the injectable cabotegravir/rilpivirine regimen?

Answer: 62,000 people in total.

Question: Ukraine is the only country in the whole EECA region, where cabotegravir for PrEP (TN Apretude) is registered. In all other countries of the region, the registration dossier for Apretude has not even been submitted to the national regulatory authorities. When does ViiV plan to start registration processes in the rest of the EECA region?

Answer: We adopted the approach that we prioritize registration in countries where the national government prioritizes HIV prevention and make it one of the national health priorities. We are working with a variety of policy-makers, including national health agencies, organizations and communities, international organizations, to make new HIV prevention options available to as many people as possible. We would like to work together with you and encourage you to give feedback to your governments on why this is important. We say this because we keep getting information and we keep hearing about governments saying that they don't see benefits from using prolonged prophylaxis compared to regular HIV prevention. So, we encourage you to work with your governments.

Comment from a representative of the patient community: At the moment, oral prophylaxis is thousands of times cheaper than the prolonged form.

Question: I would like to ask you to consider including Kazakhstan in the license for cabotegravir. There is also a question regarding licensees. There are three companies, Aurobindo, Mylan and Cipla. Based on the experience of dolutegravir procurement, we see that for the third year dolutegravir is supplied to Kazakhstan, but Mylan does not participate in tenders. We often say that there should be competition, but there is no competition today. Also, among your licensees there is no Hetero company, but it is the main player in cost reduction, for example, for dolutegravir. I do not understand why your company chose these licensees. For Kazakhstan, these three companies are absolutely not players when it comes to reducing the price of the drug.

Answer: At the moment we are not considering the possibility of expanding the cabotegravir license to Kazakhstan for the reasons I have already mentioned. But we are continuously thinking about how we can evolve the access mechanisms that were used in previous years.

As for licensees, MPP uses an anonymized process in which there are quite clear and transparent criteria that interested companies can apply to get licenses. Our company has no influence on the selection of licensees. The only thing we are involved in is the development of the criteria by which these licensees can be selected, for example production capacity, etc.

Comment from a representative of the patient community: I don't understand why Hetero can't fall under these criteria. I mean, they qualify for a dolutegravir license, but not for cabotegravir.

Answer: We are talking about how many licensees there should be. Three is the optimal number, because from our point of view, the level of demand for the product at the time of launch was unclear. A larger number of licensees would have led to unnecessary fragmentation of the market, which would not have allowed licensees to implement a stable business model for the release of the drug. This would not be very cost-effective. As we estimated at the beginning, three was enough to start the production process and at the same time have competition to lower the price.

Comment from a representative of the patient community: If we talk about the license for dolutegravir, judging by what is happening in Kazakhstan now, three companies do not provide sufficient competition. I would like to emphasize once again that Mylan is still not participating in tenders, so we cannot talk about any competition among the three companies. We also need to take into account the timing of filing a drug for registration, and usually it happens 3–5 years after the license is granted.

Answer: We will pass this information on to our colleagues.

Question: Do I understand correctly that it is now necessary to negotiate with MPP to increase the number of pharmaceutical companies to be included in the cabotegravir license?

Answer: The final decision will be up to us, but we have an open dialogue with MPP on these issues.

Question: The strategy that the government should prioritize PrEP sounds like blackmailing. But with ViiV no longer having a monopoly on the prolonged release drug, such a blackmailing could result in losing out on the market. Also, slow scaling up of production with restriction of licenses, countries, licensees etc. may also push the government to decide to wait for lenacapavir to enter the market. Is your company not afraid of losing budgets invested in marketing and development?

Answer: Gilead is certainly a competitor, but I believe two products are better than one; two prophylactic options are better than one. Having more options is better. Overall, our position is that we need to advocate that countries value innovation and investment in innovation. We are not afraid of competition. We have a good product and we will do everything we can to ensure access to it.

Comment from a representative of the patient community: What choice of drugs can we talk about if, for example, Armenia is not included in the license for cabotegravir? How can we choose?

Question: Your organization has added a clause to the contract with Kazakhstan which allows the procurement price of the abacavir/lamivudine/dolutegravir (Triumeq) regimen to be concealed. Can you disclose this data?

Answer: As far as we know, Kazakhstan is included in the voluntary license for this combination. I think a generic drug is being procured by your country.

Comment from a representative of the patient community: No, we definitely have the original drug. We have a contract with GSK.

Answer: I believe that branded Triumeq is being purchased for the paediatric population because under Kazakhstan law generics cannot be procured for paediatric use. I understand that the government does purchase generic ALD in addition for adult use.

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

Answer: We look at health technology transfer as a complex and rather complicated investment that must take into account the demands, volumes and ability of companies to produce a quality product. We have local manufacturing facilities in Brazil and Russia. We are not planning to launch new production facilities in the EECA region.

Question: At the moment cabotegravir for treatment is not included in the WHO guidelines. How do you plan to ensure the availability of the drug in the region?

Answer: The product release is now at a very early stage. Those countries that we have prioritized for registration globally are listed on our website. We will prioritize those countries that are publicly talking about prioritizing HIV investments in their national healthcare system.

Question: A two-year pilot program for cabotegravir for PrEP is currently underway in Ukraine. Do you plan to continue to increase supply through PEPFAR and are additional donations planned?

Answer: As you know, PrEP in Ukraine is procured through PEPFAR. We are happy to hear that the project was launched in August. We have determined the number of doses we give to PEPFAR and they decide how they will distribute. According to our data, as of October 2024, there are 102 people in Ukraine receiving cabotegravir. The question should be addressed to PEPFAR and the Global Fund as to whether they will provide the drug in the future. At the moment we are not planning to provide any more donations.

Comment from a representative of the patient community: We would very much like to ask you to come to our next meeting in person, where we will dedicate more time to discuss all the issues that have accumulated.

Comment from a representative of the patient community: We wish Kazakhstan inclusion in the cabotegravir license as a New Year's gift.

Meeting Wrap-Up.