Meeting Minutes

between EECA CAB and J&J

July 2, 2014, St. Petersburg, Russia

Meeting Participants

Janssen:

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3	Aibar Sultangaziev	Partners' network	Kyrgyzstan
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5	Anahit Harutunian	Сеть позитивных людей Армении	Armenia
6	Artem Esse	Patients in control	Russia
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9	Aleksandrs Molokovskis	Association HIV.LV	Latvia
10	Dmitriy Sherembey	Patients of Ukraine	Ukraine
11	Mari Chokheli	OSF Georgia	Georgia
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13	Natalia Khilko	E.V.A.	Russia
14	Olga Aleksandrova	ECUO	Ukraine
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Moderators: Sergey Golovin, Tatyana Khan.

Presentation 1. Portfolio of Antiretroviral Drugs

Introduction

The main goal of antiretroviral therapy is to suppress viral replication. This also reduces the risk of transmission. One of the major trends is to initiate treatment as early as possible. Currently, the recommended threshold is 500 CD4 cells.

Factors influencing the choice of first-line drugs are related, among other things, to the safety of the drug (including risks associated with the onset of fast, medium and long term adverse events). Motivation of the patient is also important.

The combination drug Eviplera[1] (tenofovir/emtricitabine/rilpivirine) is indicated for the treatment of HIV-1 as a first-line therapy in patients with the viral load of less than 100,000 copies. Regimen: 1 tablet 1 time per day. In Russia, the drug is registered since December of 2013.

The main toxic effects associated with first-line drugs used in Russia and the CIS include lipodystrophy, anemia, and skin lesions. In case of intolerance to first-line drugs, switching to other drugs is recommended. No dose reduction or temporary therapy discontinuation (the so-called "drug holiday") is recommended.

The preferred regimen should include fewer than 3 tablets. Increased pill burden and dosage frequency is associated with an increased risk of error. Adherence is the key factor when it comes to the success of antiretroviral therapy.

Various studies have demonstrated that reduced pill burden and less frequent dosage is better for the patient (laboratory and clinical manifestations). In one study, the authors concluded that the barriers associated with the dosage amount and frequency are the most important ones when it comes to compliance and treatment efficacy.

Tenofovir/emtricitabine/rilpivirine is a good alternative for patients intolerant to first-line drugs, including efavirenz.

Combination products available in Russia include abacavir/lamivudine, emtricitabine/tenovofir, tenofovir/emtricitabine/rilpivirine (zidovudine/lamivudine, zidovudine/lamivudine/abacavir – *comment by CAB*).

The studies suggest that tenofovir/emtricitabine/rilpivirine is proven to be more effective than an efavirenz-based combination. Tenofovir/emtricitabine/rilpivirine is also a good option for patients co-infected with HIV/HBV and HCV.

Question: The fact that the drug is registered in a country, unfortunately, does not mean its availability. In Latvia, neither Eviplera nor Edurant is accessible, despite the European registration. The Company has not submitted these products for price registration and has not presented them for inclusion in the reimbursement system. When do you plan to do it, and what causes such delays?

Answer: Concerning Russia, the drug is registered and is physically available. The dossier for the inclusion of Edurant and Eviplera in the Essential Drug list has been submitted. Regarding the EU, we will promptly contact our colleagues responsible for this region. The colleagues

[1] Hereinafter, the trade name is used for convenience and brevity only – comment by the company. The trade name "Eviplera" refers to a combination of tenofovir / emtricitabine/rilpivirine.

were originally supposed to take part in the meeting, but they could not come due to technical reasons. *The question will be forwarded to the respective department*.

Comment: There is a patient who has moved from Germany to Latvia. In Germany, he used to receive Eviplera. In Latvia, he is not able to receive the drug. In our opinion, for ethical reasons, the Company should provide access to the drug, especially as it concerns the EU area. We have sent a request to the Swedish office regarding this matter. The patient was forced to take only tenofovir/emtricitabine on an irregular basis; the drug was provided by patient organizations from emergency stocks. Currently, he is buying the drug for his own money in Germany.

Answer: From a medical point of view, switching from one drug to another is not very good. Moreover, switching from Eviplera is a complex process. From a clinical point of view, it is preferable that the patient remains on Eviplera. From an ethical point of view, the Company should make efforts to ensure that the patient does not change the regimen; such precedents had already taken place both in Russia and in the EU. It also has to be noted that in EU the company responsible for marketing tenofovir/emtricitabine/rilpivirine is Gilead (marketed under the trademark "Complera").

Comment: However, the rights to rilpivirine (Edurant) in this region are owned by J&J. So, it should be possible for your company to provide Edurant.

Answer: In this case, on the one hand, the clinical benefits of taking the combination drug would have been lost; however, on the other hand, you are right in that the patient would not have to switch from the regimen which he received.

Question: Which groups of patients participated in the study that examined the relationship between treatment efficacy and pill burden?

Answer: The groups were standardized by the duration of infection; all patients received first-line agents. The primary method of measurement was a questionnaire filled in by patients. Accordingly, in their responses to questions, including those about the reasons for therapy discontinuation, there is certain subjectivity. This subjectivity was partially balanced by the fact that those who received first-line treatment and those who received second-line therapy were analyzed separately.

Question: Concerning Eviplera, there is information that resistance to this drug develops quite rapidly, and requires compliance of more than 95% in order to ensure efficacy. Is it true? Can Eviplera be used in experienced patients?

Answer: There are no special requirements for Eviplera regarding compliance. Also, I can not agree with the statement that resistance to Eviplera develops rapidly. In the Russian Federation and the EU, Eviplera is indicated as a first-line therapy, as well as for switching from first-line therapy. The drug is preferred for use in patients co-infected with HIV and hepatitis C.

Question: Are there clinically significant interactions with pegylated interferon and ribavirin?

Answer: No. It is important to note that the preferred treatment option for hepatitis C genotype 1 is currently triple therapy with antiviral drugs.

Question: Is there any interaction between tenofovir/emtricitabine/rilpivirine and TB drugs?

Answer: According to the current drug label, concomitant use with anti-TB drugs is contraindicated, as this may lead to decreased concentration of rilpivirine. At present, the drug label is being amended to enable concomitant use provided that dosage of rilpivirine is increased.

Question: Was there a statistically significant difference relating to discontinuation of the treatment between the group treated with mono-components and with combination drugs? The question relates to the fact that currently there is a discussion with the Federal Antimonopoly Service, which does not consider the issue of convenience of dosing a significant factor.

Answer: It is possible that some cases of therapy discontinuation were due to inconvenience, but this parameter was not considered separately in the study. Combination drugs are used not only for the sake of convenience, but also for the sake of efficacy and resistance prevention. Pharmacoeconomic benefits can be calculated. It is planned to conduct a study on pharmacoeconomics, the results of which will be published in December 2014. Tenofovir/emtricitabine/rilpivirine will be compared with other drugs that are used in clinical practice.

Question: What are the recommendations for tenofovir/emtricitabine/rilpivirine and rilpivirine alone with respect to missing doses?

Answer: Instructions for administration of Eviplera and Edurant in case of missed doses are the same. If the delay in receiving the drug was less than 12 hours, the patient should take the tablet as soon as possible with food. The next tablet should be taken at the usual time. If the delay in dosing was more than 12 hours, the missed dose should not be taken; the next tablet is taken at the usual time.

Question: What actions to improve access to the drug, in addition to inclusion in the EDL, are being planned in Russia now?

Answer: The starting point for ensuring the availability of the drug is its registration in the country. If the drug is not on the EDL, its procurement in Russia is possible only using the funds of the regional programs. The EDL dossier was filed in June. The price is currently not fixed; much depends on the commercial policy of the distributor. The estimated price starts from 45 thousand rubles per pack. If the drug is included in the EDL, the price will be determined based on the reference prices.

Question: Is the dosing of the drug affected by food intake? Are there interactions with alcohol, narcotic drugs? Are there DDI studies with substitution therapy drugs?

Answer: The drug is taken with food (rilpivirine, Eviplera). There is no data in the label regarding alcohol; neither is there data on interaction with ST drugs.

Effect of food on absorption, Edurant: Exposure of rilpivirine was approximately 40% lower when taken in fasting condition than concomitantly with a normal caloric diet meal (533 kcal) or with a high fat meal (928 kcal). When the drug was followed by a drink rich in proteins, the drug exposure was 50% lower as compared to the situation when it was taken concomitantly with food.

The following table summarizes data on the concomitant use with methadone

Methadone * 60-100 mg per day Individually tailored dose	AUC of methadone R(-) ↓0,84 (0,74-0,95) C_{min} of methadone R(-) ↓0,78 (0,67-0,91) C_{max} of methadone R(-) ↓ 0,86 (0,78-0,95) AUC of rilpivirine ↔* C_{min} of rilpivirine ↔* C_{max} of rilpivirine ↔* * Based on data from historical control groups	In case of simultaneous administration of methadone with Edurant®, no dose adjustment is required. However, clinical monitoring is recommended due to the necessity of adjustment of the methadone maintenance therapy regimen in some patients.

No information on the concomitant administration of Edurant and alcohol is presented in the label.

Question: Is there interaction with hormonal contraceptives?

Answer: There is no significant interaction. The drug is a preferred choice for women of childbearing age and women planning pregnancy.

Question: Are there international guidelines mentioning Eviplera as a preferred first-line regimen? What drugs are recommended for switching from Eviplera?

Answer: The use of Eviplera as a preferred first-line drug is recommended in several national guidelines, including the French guidelines. In the Russian Federation, it is still an alternative regimen. There are no special recommendations on switching; the choice of the subsequent drugs depends on the resistance profile.

Part 2: Access to HIV medicines

Introduction

In the Russian Federation, the minimum price for tenofovir/emtricitabine/rilpivirine is currently approximately RUB45,000 per pack. This is the starting price; the Company hopes that the price will go down during the tendering process.

In December 2013, darunavir 800 mg was registered in RF. Because of bureaucratic issues, the drug is not yet available for patients. Once the new EDL list is approved, the drug will become available. The price of 800 mg will be comparable to the price of 400 mg.

Etravirine 200 mg has also been registered in RF. It will become available after the EDL is revised.

Question: Is the Company intending to register darunavir 800 mg in Europe? So far, this product is not available in Latvia, and the price is not registered.

Answer: As far as we know, in some countries, darunavir 800 mg was registered earlier than in Russia. *We will check and provide this information later*.

Question: When is the Company going to amend the label to include the recommendation to take 800 mg once daily? At the moment, in order to avoid taking 600 mg twice daily, patients must break tablets.

Answer: *We will check and provide information regarding changes in the EU countries;* in Russia this amendment has already been included.

Question: A generic version of darunavir is currently being launched in Russia. To what extent is the Company going to reduce the price given this situation?

Answer: At the moment, we have no information about the price and quality of the drug, so we can not say for sure. As far as we know, the 800 mg dosage has not been registered, only 600 mg and 400 mg. Most likely, we will do everything possible to ensure patients receive the original drug.

Question: As far as we know, the generic darunavir has a slightly different structure. Have the generic manufacturers bypassed the patent?

Answer: We would like to wait for the drug to be used in clinical practice. We would not want to “strangle” the generics, but one needs to look at the quality of the drug.

Question: Are there any plans to localize the manufacturing?

Answer: Currently, the local manufacturer is "Pharmstandart"; so far, it is not a full cycle, but the full cycle is planned. The tentative date is early 2016.

Question: Does the Company cooperate with GF in terms of pricing and price reductions?

Answer: In Russia, there are no drug procurement programmes within GF grants. GF programs in the region will be covered in the EECA presentation.

Access in EECA

The Company is currently represented in 6 countries of the region, besides Russia: Armenia, Ukraine, Kazakhstan, Belarus; operations in Azerbaijan and Moldova have began this year.

At the moment, access policies for ARV drugs are being developed for each country; they will require further internal and external approval. So far, this part is confidential. However, the fundamental decision to expand access programs has already been taken, and the contact person on this issue will be Alexei Kuznetsov.

In Kazakhstan, negotiations are being conducted on reduction of prices and increasing the number of patients receiving treatment. Programs to improve patient adherence are being implemented. An early access program for rilpivirine is planned in Kazakhstan and Belarus.

Question: In Kazakhstan, a problem has occurred with ritonavir, which is used in combination with darunavir. Patient organizations had to look for ritonavir outside of Kazakhstan.

Answer: In this particular case, we provided ritonavir for free.

Question: Do you plan to develop and market darunavir/booster as a combination drug?

Answer: Indeed, a boosting agent is needed when taking darunavir, so we are working on eliminating our dependence on ritonavir.

Question: In Ukraine, the price of the drugs is very high, and the drugs are not affordable for public programs, with the exception of several humanitarian initiatives. The main purpose of registering drugs in Ukraine is to provide information about reference prices for Russia. We have a suggestion: you should either reduce the price for the government program taking into account the disease burden, or change the name of the product, as it has been done by AbbVie for lopinavir/ritonavir (changing the name "Kaletra" to "Aluvia"), to solve the problem with reference prices.

Answer: In Ukraine, we have offered a program, under which 50% of darunavir will be provided as a donation. At the moment, we are ready for negotiations in Russia in terms of providing discounts and price reductions. We have no plans to change the name yet, but we understand your point of view, and we will convey it to our colleagues. This can be a good way to solve the issue. At the moment, negotiations are underway with the Ministry of Public Health to gradually provide access to third-line therapy for all patients in need by 2016. There is also a project on adherence being implemented in Ukraine in collaboration with the Red Cross.

Question: How long will it approximately take to consult with your colleagues about the possibility of changing the name of the product in Ukraine? Technically, this is a simple solution.

Answer: A year ago, we already discussed that issue at the meeting which was attended by our colleagues from the head office; so far, no decision has been taken. We will send the request to the head office; perhaps, the policy at the global level has changed since the last meeting.

Question: Are there any plans to work with the Global Fund in Kyrgyzstan?

Answer: Currently, GF buys darunavir for some EECA countries (Moldova, Georgia). In Kyrgyzstan, this is not the case yet, but theoretically it is possible. The list of drugs approved by GF includes both darunavir and etravirine.

Comment: Most likely, making second-line drugs available through GF programs requires work on the national level.

Presentation continued:

There are plans to set a special price for rilpivirine ($5 per pack) for a number of countries in the region, including Moldova, Armenia, Georgia, and Azerbaijan.

Question: Why is Ukraine not on this list? The drug price issue is very serious; there are 260,000 HIV-positive people registered in Ukraine.

Answer: We will convey your point of view to our colleagues.

Question: When are you planning to complete the registration process in Moldova?

Answer: Darunavir has already been registered; there will likely be supplies later this year. Etravirine and rilpivirine are likely to be registered in the second half of 2015.

Comment: As far as we know, there is an office of Janssen in Moldova; we would like to get their contacts.

Answer: We will provide them (*contacts have been provided to Tatiana Khan and sent to the meeting participants*).

Question: Are there negotiations with the Ministry of Health of Armenia about procurement?

Answer: In Armenia, at the moment the drugs are only supplied through the GF program.

Question: I would like to get a little more information about the project in Ukraine involving the Red Cross.

Answer: This is a program to improve adherence, under which the Red Cross staff works directly with the patients.

Comment: In Ukraine, there are already programs on adherence being implemented by other organizations; you could also consider the possibility of working with them.

Question: J&J has a program for donating pediatric formulations for countries in sub-Saharan Africa. We ask you to consider the possibility of implementing similar programs for the countries of Central Asia.

Answer: We are considering opportunities for expanding this program; we can keep in touch on this subject.

Question: Are there plans for registering pediatric formulations of darunavir in Ukraine?

Answer: Such work is underway.

Question: Why was rilpivirine selected for special pricing programs?

Answer: We prefer to offer a special price for a new drug rather than an old drug. Also, the rights for this drug are fully owned by Janssen, and we do not have to pay royalties to anyone.

Question: On the one hand, the budget funds for ARVs in the Russian Federation remain at the same level as before. On the other hand, the HIV epidemic is growing. The J&J drugs for a

number of reasons are expensive. Do you plan to revise the pricing policy in Russia in view of the procurement decentralization and the current epidemiological situation?

Answer: In our opinion, there is a tendency in Russia to increase the total budget funds by expanding regional programs; however, in terms of the federal budget the amount indeed stays the same. Once tenofovir/emtricitabine rilpivirine is available under the federal program, the price, based on our experience, will be reduced by about 25-30%.

Comment: In some cases, we see that since the drug procurement became decentralized, the prices for J&J drugs have increased rather than decreased.

Answer: Formally, the producer in Russia is Pharmstandart, but we monitor the sales of our products and cases of treatment cessation/stock-outs. In a number of Russian regions, the price was reduced or retained at the level of 2012.

Question: Have there been any purchases of tenofovir/emtricitabine/rilpivirine under regional programs?

Answer: Not yet, negotiations are underway.

Question: How can the drug be available in Moscow? Are these drugs leftovers from clinical trials? We have information about patients who are taking tenofovir/emtricitabine/rilpivirine.

Answer: Negotiations regarding procurement are underway; however, Eviplera has not been sold in Russia yet. The drugs you are referring to have most likely been purchased in Europe. These could not be leftovers from registration trials as Eviplera was registered based on separate dossiers for tenofovir/emtricitabine and rilpivirine.

Question: Were there any trials involving only women? What was the approximate number of women in the trials of rilpivirine and tenofovir/emtricitabine/rilpivirine?

Answer: There is data from the study of rilpivirine in women of childbearing age involving about 700 people; the study has demonstrated its efficacy and safety.

Part 3: Viral Hepatitis C

Introduction

International studies of the telaprevir-based triple therapy demonstrated the efficacy of 63-79% (genotype 1). Based on the results of the clinical trials, the efficacy in Russia is likely to be significantly higher, since in Russia (this is also true for the CIS countries) the dominant subtype is 1b, which responds to the treatment better. In addition, the patient population in our countries has fewer patients with African roots whose treatment response is worse. Also, on average, patients in our region are younger than in UE (younger age also being a predictor of success). The average efficacy of the triple therapy in our country may be up to 90%.

The results of international clinical trials of simeprevir as part of the triple therapy demonstrate the efficacy of 80% (studies QUEST-1 and QUEST-2, PROMISE, ASPIRE). Both naïve and experienced patients were enrolled.

The efficacy of the regimen comprising sofosbuvir (polymerase inhibitor) in combination with simeprevir is over 90% (data from COSMOS study, the study is in the public domain, this

regimen is included in the international guidelines). Sofosbuvir is not currently available in the EECA region. Once it is registered, the simeprevir label will be modified accordingly. The cost of the regimen will be an important issue.

Simeprevir is a protease inhibitor, administered orally. It is registered in Russia since February 2014 only as part of the triple therapy (in combination with pegylated interferon and ribavirin). In the foreseeable future, additions to the label will be made to include the possibility of its use as part of an oral therapy in combination with sofosbuvir.

The duration of the "triple" period is 12 weeks for all categories of patients (including co-infected patients). The duration of the dual therapy is 12 weeks. For patients with partial/null response, the dual therapy should be continued for 36 weeks.

If by week 4 of the triple therapy the RNA concentration is above 25, the therapy should be stopped. The second control point is week 24. If at this point the concentration is above 25 IU, therapy with pegylated interferon and ribavirin should be stopped.

Accordingly, access to highly sensitive RNA tests is required, which are currently not always available. There is also a big problem with the infrastructure.

The most difficult group of patients are nonresponders to the dual therapy. In this group of patients, the efficacy is 50%. Previously, according to international guidelines, repeated dual therapy was not indicated in non-responders due to extremely low efficacy. With the advent of antiviral drugs, these patients have a chance for a cure.

Another problem is the stage of the disease. Patients with early stages of fibrosis respond much better than patients with advanced fibrosis. ForF4 stage, the efficacy of the triple therapy is about 70%. Patients at stages 0 to 2 are usually recommended to wait.

Head-to-head comparative trial of telaprevir and simeprevir

The advantages of simeprevir over telaprevir are mainly related to safety. The efficacy of these drugs is roughly comparable. Telaprevir is associated with cutaneous and anorectal pruritus (severe manifestations). The use of boceprevir is associated with toxic anemia. The adverse effects of the triple therapy comprising simeprevir are only related to pegylated interferon and ribavirin. In other words, there are no additional adverse events due to the use of simeprevir only.

An additional advantage of simeprevir as compared to telaprevir is administration once daily, with no account taken to meals.

Question: What do you do with the 10-20% patients who do not respond to the triple therapy?

Answer: If you consider the Russian Federation, we are most likely talking about 12% of "non-responders". There is no sense in treating them again with protease inhibitors. They will have to wait for regimens based on either polymerase inhibitors or NS5A inhibitors.

Question: Is it worth offering simeprevir to patients who have not responded to the triple therapy with boceprevir or telaprevir?

Answer: If the course has been completed, and there is no response, then it makes no sense. You also need to consider the reason for not completing the course. It could be that the patient simply ran out of money to pay for the drug.

Question: How quickly does resistance to simeprevir develop?

Answer: if we take protease inhibitors in general, this group of drugs has an average resistance profile. Sofosbuvir has the best resistance profile.

Part 4: Access to HCV drugs

In the Russian Federation, the registered products include telaprevir and simeprevir. The price at the moment is about 450,000 rubles per pack. The price for the full course of treatment is about 1 million 350 thousand rubles, not including pegylated interferon and ribavirin. This price is significantly lower than in the US.

Question: In which EECA countries are simeprevir and telaprevir registered?

Answer: Only in Russia and the EU. Simeprevir is submitted for registration in Kazakhstan and Ukraine. There are also plans to register the drugs in other countries.

Question: Are there plans to include the drugs in the EDL in the Russian Federation? Can we hope for price cuts? Now, the price is extremely high.

Answer: The dossiers of telaprevir and simeprevir have been submitted for inclusion in the EDL. As for the price, we have already considered the reference prices when setting the price; so, the price will most likely remain at the same level.

Question: To our knowledge, telaprevir is not a recommended drug in the European and American guidelines anymore. Does it make sense to continue promoting it?

Answer: Indeed, telaprevir and boceprevir are not recommended in the US and EU guidelines anymore. However, according to the position of the medical community in RF, there should be a certain transition period of telaprevir use, as simeprevir will not be available everywhere and immediately to patients even physically, not to mention the price factor. In addition, the manufacturing of telaprevir has already been localized. If we talk about medical education activities, we really want to shift the focus to simeprevir.

Comment: By significantly reducing the price, the Company can increase its market share in the long run. The HCV epidemic in the region is very intense; the standard of living in most countries is very low.

Question: Is it possible to get information on early access programs in EECA?

Answer: In RF, it is part of the pan-European program. It included approximately 100 patients. Also, such program is being implemented in Kazakhstan (10 patients). In other countries, we need to look at opportunities. Due to the specifics of registration in EECA countries, in this region we fall behind by a year or two.

Question: What is the reason for the high price of the drug?

Answer: The drug was not originally developed by Janssen. J&J acquired the rights in the first phase of the clinical trials. There are certain financial obligations that the Company must fulfill. The second factor influencing the price is that at the time of registering simeprevir, there were other drugs with comparable cost on the market. However, there is no doubt that the presence of a large number of players will contribute to lowering the price.

It is also important to note that the problem of hepatitis as a whole is not given enough attention in RF and other countries of the region.

Comment: If the problem of HCV is paid attention to, given the current prices, the government would need to spend its entire healthcare budget for hepatitis C.

Comment: In the world, about 110,000 people have been treated with telaprevir by now; it is not so much. J&J could make telaprevir more affordable. Telaprevir was submitted in Latvia for inclusion in the list of compensated medicines at the price of EUR7400. Of course, the government refused to compensate telaprevir at this price. The same thing happened with boceprevir. Latvia has already had an early access program; doctors have learned to manage the side effects. In our opinion, it is unethical and impractical for the Company to hold this price.

Answer: Besides price, there are a number of other barriers to access, including the presence of the drug in the respective lists. These factors must also be considered. In the Moscow region, where the government is planning to treat about 300 patients, the price of telaprevir may be reduced by half. There was a real dialogue there.

Question: Why do J&J refuse to cooperate with the Medicines Patent Pool?

Answer: *We will forward the question to our colleagues in the head office*.

Comment: We suggest that the Company transfers the license for simeprevir to generic companies so that they can supply the drug to the region at the lowest price. Usually, almost all the litigations take place in countries which are less interesting to the Company in terms of profits.

Answer: This may be one of the mechanisms. However, there are a number of issues that need to be solved, including those with local partners.

Comment: The market will soon have lots of antiviral drugs for the treatment of hepatitis, and the market will be won by those who offer the lowest price. Now, Gilead is the main target of anger because of their price, and your Company is at risk of sharing the same destiny if it is to pursue a similar pricing policy. In addition, we as civil society find it very difficult to advocate HCV treatment programs, when the prices for the drugs are so high.

Comment: The prices for the diagnostics are also very high; this problem also needs to be solved.

Answer: There was a screening project in Moscow covering about 70 patients. Most likely, we will continue this project. Also, there is a screening project for the general population; last year, it covered 5 cities. However, it is important to understand what happens to these patients further; infrastructure issues need to be solved.

Comment: The same argument is used by the government when they refuse to expand the testing programs. In this regard, we are a little surprised by the position of companies which refuse to reduce prices, including distributors. In Kyrgyzstan, nearly 200,000 people are infected with HCV. Many of them are willing to buy drugs for their own money. If you cut the price by a half, that would double the number of people who could be treated. The current price is in the realm of science fiction, even for Russia. If you take the volume of the HCV treatment program in Russia, treating 200-300 patients with either simeprevir or telaprevir would take the entire budget for HCV treatment.

Question: Simeprevir was registered in RF before the EU, which is quite a unique case. Can the Company share this experience of accelerated registration?

Answer: Registration depends on many various factors. The first country was actually Japan (dosage of 100 mg).

Comment: In Georgia, last year, before the initiation of the government treatment program, 100 courses of standard therapy had been provided (pegylated interferon and ribavirin). This year, this number is already 1000, and another 600 patients have purchased the drugs for their own money. As to boceprevir and telaprevir, we have no more than 10 patients, who were forced to sell their apartments. This is an example of how pricing affects the availability of drugs.

List of issues for further cooperation:

- Early access and registration programs in the EECA region;
- Plans for the revision of the pricing policy to achieve lower prices;
- Cooperation with the Patent Pool;
- Contacts in EECA countries;
- Possibility to change the trade name in Ukraine and other countries;
- Possibility of voluntary granting licenses for the manufacture and supply of the drugs at the lowest prices;
- Questions on Eviplera and darunavir in Latvia and other Baltic States;
- Selected clinical aspects.

End of Meeting