



## Meeting minutes between Eastern European and Central Asian Community Advisory Board (EECA CAB) and Gilead

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Kiev, Ukraine

### Участники:

#### From Gilead:

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#### EECA CAB Participants:

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Denis Maruha	CREDINTA, Moldavian CAB, Moldova
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Facilitator: Alexandra Volgina

Introduction of the participants. A minute of silence.

## *Gilead's Presentation*

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Gilead appreciates the chance to participate in this EECA CAB meeting.

Drugs for treating HIV. Several of these drugs have not been approved by regulatory authorities in EECA countries and in Europe.

We will discuss two drugs: Stribild and TAF. Janssen is responsible for the drug Complera (Eviplera in EE) in the EECA region.

### Stribild:

Two clinical trials: 102 (comparison with Atripla) and 103 (comparison with Atazanavir+Ritonavir). Trial 102 demonstrated that Stribild is not inferior to Atripla. In the trials, good, stable CD4 cell growth was achieved. In terms of impact on the central nervous system, Stribild was associated with less adverse events when compared to Atripla. Fewer patients on Stribild discontinued treatment.

Similar results in 103, with non-inferiority of Stribild vs. Atazanavir+Ritonavir. With Atazanavir+Ritonavir, AE related to diarrhea occurred more often. Nausea occurs at approximately the same rate. Stribild also associate with less treatment discontinuations.

In a few cases, patients taking Stribild experienced an increase in creatinine levels. This effect was observed over the course of the first weeks of Stribild treatment and occurs due to the inhibition of a renal transporter for Creatinine and is not associated with renal impairment. A similar effect is observed with ritonavir, dolutegravir and other agents.

For non-white patients and patients with cell counts above 350, Stribild's statistically significant superiority over Atripla was demonstrated in 102.

**Question:** Was there a significant statistical difference between men and women?

**Response:** The sample was too small to make a determination. A greater number of patients would be needed. There is a separate study on women; we will present the results at a later date.

CD4 cell growth– 321 cells after 144 weeks. These results correlate with results obtained earlier.

After Week 96, resistance indicators were the same for the two groups. In the third year, there were no cases of resistance in the Stribild group, and four cases in the Atripla group.

AE occurred more frequently in the Atripla group – CNS and rash. Proximal Renal tubulopathy was a rare event and reversed after discontinuation of the study drug in the 4 patients (4/352) who had laboratory criteria for it.

There is study on patients with mild to moderate renal impairment taking Stribild and Cobi boosted Atazanavir. One group consisted of naive patients taking Stribild. The second group consisted of experienced patients taking PI with ritonavir, and then switched to cobicistat. Viral suppression rates were 85% and 90%. Creatinine clearance reduces as seen in other studies, because of the inhibition of renal transporters of Creatinine

There are a number of trials for which patients are still being selected; the results will be presented at a later date. In particular, a study is being conducted with two groups: patients who are taking NNRTIs, and patients who taking boosted PI and then switched to Stribild. The data will be available next year.

There is a separate study on women: naive women received either Stribild or atazanavir+ritonavir-based regimen. Russia was one of the countries in which the study was conducted.

Data from three years of Study 103 will be presented at the European AIDS Conference.

Stribild has been approved in the EU, the USA, Canada, South Korea, Australia and Turkey

### TAF

TAF is a new form of tenofovir.

Data from a phase 2, 48 weeks evaluating naive patients receiving either Stribild or a new combination in which TAF was administered instead of tenofovir. Week 48: 90% viral suppression. Similar CD4 cell increase. Regarding AE, since the sample was not large, no major difference was observed. TAF performed better in terms of impact in estimated Creatinine clearance, the difference is statistically significant. Regarding bone demineralisation, TAF had a more favourable profile (both for spine and hip).

There are still a number of studies being conducted with TAF. In particular, 2 Phase 3 studies will be conducted comparing Stribild with E/C/F/TAF (1,700 patients overall).

There will be a study on patients with virological failure. In as much as TAF concentrates in lymphocytes, we expect it to be more effective.

Another study: TAF in patients with renal failure. According to the latest recommendations, Stribild should be prescribed for patients with creatinine clearance above 70. TAF can be prescribed for patients with creatinine clearance greater than thirty.

**Question:** Will there be study on a pediatric version of TAF? It should be a good medicine for children.

**Response:** At the moment, it is easier to test effectiveness and safety on adults, but we have plans for a pediatric version.

**Question:** Are there any interactions with opioid medications (buprenorphine, methadone)?

**Response:** Ritonavir may interact with methadone. But Cobicistat causes a more specific inhibition of CYP3A, therefore, Stribild can be prescribed to patients on substitution therapy with no problem.

**Question:** Are there any interactions with tuberculosis drugs?

**Response:** TAF has no interaction with rifampin, but there is interaction between cobicistat and rifampin, and it is not recommended to take them together. Studies are being conducted with rifabutin. There are no recommendations as of yet.

TAF is active against hepatitis B. We are now determining the appropriate dosage. There is data that shows that Stribild does not have any significant interaction with telaprevir.

**Question:** What about the interaction with alcohol and sleeping pills?

**Response:** Alcohol itself can cause problems, but not in terms of interacting with the drugs. Sleep disorder was not a common side effect in the group taking Stribild.

## **Hepatitis C**

The focus is on direct antiviral agents that block specific viral proteins (enzymes). Sofosbuvir blocks the enzyme polymerase (NS5b) that is responsible for the production of new RNA viral chains.

Another target is enzyme NS5A. Drugs are in development: ledipasvir and GS5816.

### **First wave:**

All virus genotypes, for 1, 4, 5, and 6 – simplified and shortened treatment regimen. For 2 and 3 – treatment without interferons.

Regulatory agencies are reviewing these regimens on a priority basis

### **Second wave:**

Fully oral treatment in a combination dosage only for genotype 1 (sofosbuvir and ledipasvir).

### **Third wave:**

Fully oral treatment in a combination dosage for all genotypes (sofosbuvir and GS5816).

Sofosbuvir is active with all genotypes and has a high resistance profile. Based on study results, the dose selected was 400 mg once a day. Good pharmacological profile (independent of food), no significant drug-drug interactions, a favourable safety profile (data from 3,000 patients).

Cleared primarily via the kidneys. No dose correction needed with creatinine clearance greater than 30. Patients with cirrhosis demonstrated a significant decrease in viral load within seven days.

Phase 3 results: 4 studies.

**NEUTRINO:** 1, 4, 5, 6 genotypes, naive patients, 327 patients, 17% cirrhosis of the liver.

Sofosbuvir + PEG-INF, treatment 12 weeks, after which all drugs were discontinued. Sustained virologic response (SVR), assessed at weeks 12 and 24 after completing treatment.

90% – SVR12 after completing treatment. Genotype 1 – 89%. SVR24 – 91%.

Genotypes 4,5,6 – SVR12 – 97%. Statistically significant difference compared to the historical control standard (60% - including studies with telaprevir and boceprevir). SVR was achieved in 80% with initial symptoms of cirrhosis. The most frequent AE – general malaise, nausea, insomnia, anemia (standard side effects of PEG-INF). 5 patients discontinued treatment due to side effects.

**FISION:** Genotypes 2 and 3, almost 500 naive patients, 20% with cirrhosis.

Sofosbuvir + ribavirin. Treatment duration 12 weeks. SVR was assessed after 12 weeks. Control group – PEG-INF. Standard treatment duration– 24 weeks.

67% – SVR12. Genotype 2 – 97%. Genotype 3 – 56%. Results are comparable with standard treatment regimens. Genotype 2 responds substantially better. There were no cases of resistance. Lower rate of discontinuation because of side effects (1% versus 11%).

**FUSION:** 2 and 3, received prior treatment, treatment failures, 34% -- cirrhosis.

Sofosbuvir + ribavirin 12 weeks, then placebo.

Second group – full treatment regimen 16 weeks.

SVR – 50%. Genotype 2 responds better. Efficacy of 16 week regimen twice that of 12 weeks. Clearly, patients with Genotype 3 require longer treatment duration. It may be worth trying 24 weeks.

**POSITRON:** Genotypes 2 and 3, pegylated interferon intolerance, 15% cirrhosis.

Sofosbuvir + ribavirin, the control group received a placebo.

Genotype 2 – 93%. Genotype 3 – 61%. Comparable with previous studies. Good tolerance and resistance profile were confirmed

In total, for Phase 3 – 1,300 patients, 20% – cirrhosis.

**Question:** Why was a duration of 16 weeks chosen, instead of, say, 18?

**Response:** Different regimens are tested in the studies. In Russia, a group of patients will be given the drug for 16 and 24 weeks.

**Question:** Given the fact that there is nonetheless the risk of resistance in vitro, will research in this area be continued?

**Response:** Resistance will be investigated separately in all upcoming studies, but we can already say that the drug has a very good resistance profile.

**Question:** Are you planning to register sofosbuvir in all countries? Atripla, for example, has not been registered in several countries in our region. We are afraid that the same thing will happen with Sofosbuvir.

**Answer:** Registration will be phased: the USA, the EU, and countries where global studies are being conducted. In some countries it will be possible to approve Sofosbuvir on the basis of FDA or EMEA approvals. But for some countries local studies will be required. A local study is conducted in Russia now, thanks to which we are planning to register the drug in the near future.

Second wave: Sofosbuvir / ledipasvir. Ledipasvir inhibits NS5a. By inhibiting this protein, it halts the development of the virus. It is effective against resistant strains. Taken once a day. At least 3,000 patients have received one dosage of this drug. Now studies are being conducted on the combination form (one tablet), third phase. The drug powerfully suppresses viral replication. Low dosage is required to suppress replication (from 10 mg to 90 mg).

Research Phase 2 – for Genotype 1 (**Ledipasvir only works against Genotype 1**).

#### **ELECTRON**

Sofosbuvir / ribavirin / ledipasvir – naive patients and null responders.

Week 4 – almost 100% of naive patients and 89% of previous null responders responded to treatment.

SVR12 – patients, receiving ledipasvir in both groups had viral load below limit of detection.

The drug and the regimen as a whole was well tolerated over the course of 12 weeks.

#### **LONESTAR**

5 subgroups, 3 – naive patients, 8 weeks, 2 – did not respond to PI for hepatitis C treatment (50% of patients with cirrhosis), 12 weeks.

100% – naive patients without cirrhosis.

95%, including the subgroup of patients with cirrhosis that were prior non-responders.

Phase 3 Studies: ION1 – naive, ION2 – experienced, ION3 – naive, shorter treatment regimen in comparison with Study 1.

There are Phase 2 results for co-infection (sofosbuvir + ribavirin, plus interaction with ARV). Efficacy results are comparable with mono-infection. No clinically significant interactions were observed.

**Question:** Is it necessary to lengthen the duration of sofosbuvir treatment if there is HIV/HCV co-infection, as is the case in the current standard?

**Response:** No, it isn't.

**Question:** Is it possible to improve communications with regard to clinical protocols that are taking place in Russia? ECAB requests to analyse the protocols for Gilead studies, including those which are being conducted in Russia, but it is difficult for ECAB to comment for the Russian patient community.

**Response:** We will make a note of this. We can hold a conference call every three months.

**Question:** Are there any plans for clinical studies in other countries in the region, in particular, in Ukraine? In particular, representatives from the Ukraine Presidential Administration expressed interest in having similar research conducted at a recent meeting with representatives from the patient community.

**Response:** We would be happy to discuss the possibilities for conducting such research. We are now collecting information and would be glad to listen to suggestions about research centres that have the necessary capacity. We will also discuss the possibility of conducting research in other countries in the region, in addition to Ukraine. However, it is important to mention that in as much as the drug sofosbuvir has been purchased by another company, many research centres have been chosen in advance.

**Comment/request:** In Uzbekistan, treatment – and it is not cheap – is only possible at the entire expense of the patient. When selecting research sites please take into account not just capacity, but also need.

**Question:** When does Gilead expect to receive approval from the FDA and the EMA and will the company apply for registration in those countries that recognize FDA and EMA registration? In Georgia, in particular, if the drug has already been approved by the FDA, then the registration process takes one week and costs 250 Euros. But Georgia isn't included in the list of countries in which Gilead plans to apply for registration in the near future. To the best of our knowledge, the registration process in Ukraine and Armenia is also simplified. In Ukraine, a programme for treating hepatitis has been adopted, funding for the next year is several hundred million dollars.

**Response:** FDA: in December, EC: during the first quarter of 2014. Thank you for the information about Georgia. It could affect the application filing time in that country.

**Question:** Are there any plans for early access programs in the region? Is there any information about the compassionate access program in France?

**Response:** The compassionate access program is a global one: 70 patients from Europe and Eastern Europe, although is open to patients from around the world. There are discussions with regard to France. Many of the countries represented do not have the appropriate regulatory mechanism. The French system, in particular, allows temporary permission for using a non-registered drug due to compassionate access.

**Comment:** This mechanism might indeed be difficult, but the humanitarian aid mechanism, for example, exists in all countries.

**Response:** A drug can be brought onto the territory of Russia in several cases: if it is registered, if it has been determined for usage in clinical trials, or is on the "named patient programme" (for specific

patients, who have exhausted all available means of treatment). The last mechanism is chiefly used for orphan diseases. Theoretically it would be possible to do this with sofosbuvir.

**Comment:** In the Baltic States, there is a very high prevalence of hepatitis C among IDU – up to 90%. It would be good to organize clinical trials for these countries as well, including this population group.

**Access:**

HIV access programmes: countries are categorised on the basis of GNI and the prevalence of HIV within the country. The access programme includes approximately 130 countries – countries with a low to mid-low income levels. The first approach is the sale of original products without profit (non-commercial price). The second approach is to give the license to generic companies. These companies pay approximately 3% compensation (royalties) to Gilead and are able to sell products in 95 countries.

4.2 million patients receive tenofovir within the framework of access programmes. Our partners (generic companies) have significantly reduced the price for tenofovir counting on an increase of the number of patients on this drug. Now their price is even lower than our «non-commercial» Access price.

In the EECA region, we are working with the company Delta Medical, whose headquarters are located in Kiev. Delta Medical is responsible for registering drugs, interacting with physicians and with patient organisations, etc (with support from Gilead).

In countries with a low level of income, the price for a package of Viread (30 tablets) is \$17 USD and \$26.25 USD for a package of Truvada. Several countries in the region fall into the mid-low income category. Their price for Truvada is \$45 and \$30 for Viread.

In our view, donations are not a sustainable mechanism, although we sometimes make use of them.

Viread and Truvada are registered in almost all countries in the region.

**Question:** What countries aren't they registered in?

**Response:** We are registered in all CIS Countries

**Question:** Do you know how much the generics in these countries cost?

**Response:** Our partners' drugs are, as a rule, cheaper. In several countries in Africa, the price for a package of tenofovir is \$4. In South Africa, the generic Atripla was set at \$12 per package in some tenders..

**Comment:** In 2008, our organisation helped Gilead register Truvada in Ukraine. But now Delta Medical is not participating in tenders. A week ago a tender ended, Truvada wasn't part of the tender, and as a result, generics were quite expensively priced. At the beginning of the year, the registration certificate for the original drug Truvada expired, but the generic was available.

**Response:** Yes. In fact, we had to change the packaging, because there were production problems, and we really weren't able to participate in the tender.

**Comment:** There are constant complaints about Delta Medical. The registration of tenofovir in Russia has become proverbial. Have you thought about the possibility of changing your partner? We sometimes get the impression that Gilead just isn't interested in our region.

**Response:** We are currently endeavouring to review Gilead's policy in the region, in particular, by establishing a Russian office. We would also like to maintain in close contact with the patient community to resolve any questions.

**Question:** Will there be a separate structure within Gilead that is responsible for the EECA region or will this be the Russian office or Delta Medical?

**Response:** In Russia, Gilead will conduct the work directly. The other CIS countries have been divided into two groups: the countries from Belarus to Kazakhstan (geographically) fall under the responsibility of the commercial team that will be based in London, but team representatives will regularly make visits to the region.

**Comment:** Given the Customs Union, it would be logical to combine Belarus, Russia and Kazakhstan into one group, taking into account, among other things, registration.

**Response:** One of the main criteria in categorising the countries is GNP.

Atripla is a combination drug. Gilead has the rights to two components. The rights to the third – efavirenz – are divided between Merck and BMS. In Ukraine, Merck is the responsible party. Gilead is responsible for Belarus, Azerbaijan, and Russia. The majority of countries in the region come under the responsibility of Merck.

**Comment:** In Uzbekistan and Tajikistan, Atripla is not available. Given that, I am sorry in advance for countries that fall under the registration sphere for Merck.

**Comment:** Based on Russia's experience, the same thing can be said about countries that fall under Gilead's responsibility.

**Response:** The contract stipulates that the partners (Merck and Gilead) can exert influence on each other in the event that inaction on the part of the other party is observed in a specific region.

**Question from Gilead:** Has there been any communication with Merck about this?

**CAB answer:** We posed this question at a EECA CAB meeting. They referred it to Gilead.

**Question:** Wouldn't you like to give permission to generics to produce and import Atripla in those countries, where they have not been registered.?

**Response:** With regard to Russia, we have decided to register Atripla. The dossier is being prepared, we will file for registration within several months from the date of this meeting.

**Question:** About Russia, patients have been asking for three years to include tenofovir on the list of vital and essential drugs (EDL) Is there any information about this?

**Response:** Tenofovir has been registered and is commercially available. We have filed a dossier for EDL. The results are not yet known. We have also filed a dossier to include Truvada on EDL. We understand the importance of including these drugs on EDL so access to them can be provided on a federal level.

**Question:** It would be nice to receive some information about registering Atripla in Azerbaijan We have the feeling that Merck is not interested in the Azerbaijanian market.

**Response:** If you think that there are countries that Merck or Gilead are not paying enough attention to, then please, provide us with this information.

**Question:** Is it possible to say that Gilead is more interested in registering Stribild than Atripla? Atripla is a priority regimen in the latest WHO guidelines.

**Response:** It will be simpler for us to register Stribild, in part because all of the components are owned by Gilead. Regarding the guidelines, they are always a little behind the clinical trial data, which show that Stribild is preferable to Atripla. In the future, Stribild will be the basis for HIV treatment. In Russia, a

study is now being organised for Stribild and the dossier is going to be prepared. This takes time. So we are now registering Atripla. The process should take a year and a half.

Gilead is the representative for the Baltic States. Questions about these countries should be address to the company.

**Request:** Provide information about the patent status of Gilead drugs in the region.

**Request:** Provide the registration schedule for drugs in the region, including Atripla.

### Russia

The company was registered in September 2012. There were a lot of questions regarding access to Viread and Truvada. Now they are registered in the RF and commercially accessible. The dossier for Atripla will be filed during the first quarter of 2014. Patients will have access to the drug in approximately the first or second quarter of 2015. We hope the fact that Atripla's components are registered and used on the territory of the RF will expedite the process. Registration is planned for sofosbuvir. At the current moment, clinical trials are under way. Registration is likewise planned for Stribild. Viread has also been approved for the treatment of hepatitis B. Any complaints about AE should be sent to Delta Medical. We hope that access to Viread and Truvada can be provided via regional programs, but it is necessary to work with each AIDS centre separately. There must be cooperation with patient organisations to improve access to treatment, including public support.

**Question:** Let's assume the positive option, and say that tenofovir is included in EDL, what will its approximate price be?

**Response:** Remember that Delta Medical is the supplier. The rough price for Truvada will be from 10,000 to 11,000 per package (month).

**Question:** Two generic versions of Truvada will more than likely be registered next year in Russia. The price for them will probably be notably cheaper. Judging by the set price, Truvada is not a priority drug for Gilead. Is this correct?

**Response:** Truvada is the basis of a treatment regimen included in all international standards. In Russia, there is a patent for a fixed combination. Based on the GNI, Russia is quite high in country ratings; The current price in Russia is lower than that in countries with higher income.

**Comment:** That being said, in Russia the analogue to Truvada, Kivexa, is two times cheaper.

**Comment:** What determined the choice of R-Pharm? This company is considered "difficult" among the patient community, given the fact that it is a monopoly, doesn't participate in auctions and has high mark-ups.

**Response:** Delta Medical selected the distributor, but we hear your concerns.

**Commentary:** Do you foresee any problems with procurements for your combination drugs in Russia given the fact that Russia now buys individual drugs instead of combinations?

**Response:** There are studies that show that superiority of combination drugs over separate ones. In particular, one study shows that taking combination drugs reduced the risk of hospitalisation by 30%. But often the interests of patients and the medical community do not coincide with what is possible within the health care system. We support combination drugs, but unfortunately, we cannot control how the procurements will be implemented. This is more likely a question of control on the part of the patient community.

**Comment:** This sort of research data is very important to us in as much as it is difficult to prove the benefits of adherence to the Ministry of Health and the FAS.

**Question:** Do you foresee any supply problems given the fact that in this year the auction regulations significantly reduced delivery times?

**Response:** We do not foresee any problems in this area. It's always possible to keep a supply of drugs on hand to ensure rapid delivery.

**Comment:** It is important to us to understand how you are going to control R-Pharm, since over the course of monitoring procurements in the RF, we've seen that 90% of the problems are connected with this company. Many auctions for combination drugs were challenged by a subsidiary of R-Pharm. It turns out that your partner hypothetically might block access to your drugs.

**Comment:** It is very hard to convince the government that combination forms are better than monotherapies as long as it is a question of price. The Global Fund, on the other hand, is inclined to take into account recommendations and guidelines. In countries, where the Global Fund does the purchasing, these should be made use of. For governments, only economic models work.

**Question from Gilead:** It is our opinion that officials now do not always understand the economic benefits of treatment. How worthwhile do you think it would be to begin "training" officials in the area of health care economics?

**Request from Gilead:** Unfortunately, the system of pharmaceutical supervision in Russia is at a very low level. There is very little documentary confirmation of various problems associated with taking drugs. Support from patient organisations is required in this area.

**Comment:** It's our impression that there will be a budget and treatment deficit next year in Russia and accordingly the issue of pricing is very important to us. Other companies have commented that they would rather destroy a portion of the drugs than offer them at a lower price, because the price, in particular, in Russia, is a referential price for Europe.

**Response:** We aren't familiar with such practices. With regard to Russia, prices there are quite a bit lower than in countries with higher income levels.

**Question:** Can you tell us the price that you offer your distributors? In Russia, the auction prices are sometimes twice as high as the cost of manufacturing.

**Response:** We aren't ready to address the question at the moment. We will answer it later.

**Question:** Could we invite representatives from Delta Medical to the next meeting?

**Response:** We don't see any obstacles to this.

**Question:** By how much are you willing to reduce the price for low income countries in this region?

**Response:** We have already announced the prices for Viread and Truvada. They will be approximately \$17 and \$26.25 and \$30 and \$45 dollars for countries with low and mid-low levels of income respectively. This is actually the cost of the product plus logistical expenses (no profit). Our programme doesn't have the goal of making a profit, but it also isn't aimed at creating a loss. At the last government tender in the Ukraine, we reduced the price on Truvada to \$21 per package. At this level, we start losing money so we can't make this a standard practice.

**Question:** Are there any plans to offer the Atripla license to the Patent Pool?

**Response:** To the best of our knowledge, all of the Atripla components that are owned by Gilead are already in the Pool. If a generic company approaches the Patent Pool for licenses on the Atripla components, then in theory, it should be able to get them. It's important to remember, however, that the Pool licenses cover specific countries.

**Comment:** We wouldn't recommend that Gilead sue generic companies over Truvada. It might increase the level of tension connected with the company's policy in the region, which many people think has complicated access to treatment.

**Response:** We appreciate your feedback in regard to our access policy. There are many factors which can influence access to drugs. We examine each case individually. In South America, for example, the pharmaceutical company Cipla violated our patent rights, but we decided not to sue them because of the severe epidemic in the country. The same thing applies to the situation in Ukraine.

**Question:** Approximately how long does it take Gilead to prepare a registration dossier? The question is related to the fact the GF is going to be leaving the region in the near future, and some countries may be left without drugs if they aren't registered.

**Response:** In Russia, we receive a list of requirements from the Ministry of Health. Our partners in London prepare the dossier, translate it, and send it to Russia to be submitted. Delta Medical handles HIV infections with its own regulatory department. Timing is largely dependent upon the capabilities of the Ministry of Health. There is always the possibility of additional requests. There can be delays associated with the workload in Gilead's regulatory department.

After approval by the FDA, about a month is spent getting the Certificate of Pharmaceutical Product (CPP), which lets us prepare the dossiers for submission in other countries. Then it all depends upon the particular circumstances in these countries, but we always use the components of the FDA dossier. Time is needed to get everything translated, and to observe the local regulations for packaging and labeling. Theoretically, the process can take anywhere from one to three months. Due to the limited capacity of the regulatory department, we have to set priorities (the prevalence of the disease, etc.)

**Question:** What sort of pricing are you ready to offer for hepatitis treatment?

**Response:** As long as the drug hasn't been registered, we cannot announce a price. We'll most likely have news on this in December.

**Question:** Can the company guarantee that it won't stop with registering the drug in the USA and the EU, selling it there at a higher price?

**Response:** It's always difficult to give promises and guarantees. The drugs will, of course, be registered in other countries. In particular, there is now a project under way in Egypt as a country that has the highest HCV prevalence in the world. We might need your help with issues related to registering drugs.

**Question:** Has Gilead been working on an HIV vaccine?

**Response:** Gilead has a few initiatives on HIV Cure, including inhibitors of HDAC and TLR7.

**Comment:** The hepatitis C market in the region is basically a private one, where people have to pay for treatment themselves. If the price is set at a level at which people can afford to purchase their own medical treatment, then this might be the best solution for the region.

**Suggestion:** The next meeting should take place over the course of a whole day.

Questions can also be sent by e-mail.

**End of the meeting**