looks like patients that got the oral agent needed more red cell intervention, so to speak, but if there were crossover patients, then that may not be so.

DR. STEMPIEN: Yes. I can't tell you to the extent that that happened, but these are independent measures. So the same patient could show up in both.

CHAIRMAN POMERANTZ: And one other question. Was the use of blood products in EPO left up to the investigator or was there a cutoff where you said below this value consider using these or use these?

DR. STEMPIEN: We had recommendations in the protocol that were consistent with ganciclovir. They were the standard recommendations that we use in ganciclovir protocols, that if ANC drops below a certain level or hemoglobin drops below a certain level, you can consider the following options, either support with a colony stimulating factor, a brief dose interruption.

So we didn't mandate it. We just set out some guidelines, and this was what actually happened would have been driven by the investigator's judgment.

CHAIRMAN POMERANTZ: I think your question is a good one because it also brings up clinically how

different people will address low red blood cell count due to whether it's AZT against cyclovir (phonetic) or valganciclovir.

There are physicians who, as you know, would rather do anything than give someone blood products, even if they're HIV infected, and there are others that are loathe to use a lot of erythropoietin.

So your question, it may confound the -- your question shows the confounding part of the analysis, which is that it wasn't mandated what everybody would do at one particular state. It was left up with some considerations at that point.

And I think it's very hard to judge that when it's left that open.

DR. BERTINO: And just what time frame was that pivotal study done over? From what year to what year?

DR. STEMPIEN: Well, it's still running. It started enrolling in early '97 and --

DR. BERTINO: The reason I asked that, I don't know if other people have found this, but I can tell you at my institution the threshold for transfusing people with packed red cells has -- the threshold has increased so that they have to get to a lower hematocrit now before they get transfused.

CHAIRMAN POMERANTZ: Absolutely. We find that I would say that's probably country-wide.

Other comments on Question 3? Chris Mathews.

DR. MATHEWS: Yeah, one thing to keep in mind also is that in the maintenance phase many patients will go off maintenance therapy, and we didn't see the follow-up CD4 counts on the patients in the pivotal trial here, but because of that phenomenon and the guidelines recommending or at least suggesting that people who get over 100 can go off maintenance therapy, you're going to be selecting for a poorer prognostic group of people, patients who will continue on maintenance therapy, who will be at risk for other infections, too, which makes the toxicity data even more difficult to interpret.

CHAIRMAN POMERANTZ: I would also add the fact that those recommendations have changed over the time of this study. A hundred is pretty new that many people are comfortable with stopping maintenance therapy. So knowing how long this trial has been moving along, I would imagine it will make it even harder to interpret it because people wouldn't have stopped at 100 even a year ago.

Other comments?

Because we're getting close to a third vote here.

(No response.)

CHAIRMAN POMERANTZ: Okay. That's what we're going to do. This time we don't have to change the question.

Do the data submitted in this NDA support the safety of valganciclovir for the treatment of CMV retinitis?

And we're going to go back to the other way and go with Dr. Wong. Yes or no?

DR. WONG: Yes.

CHAIRMAN POMERANTZ: Dr. Yogev.

DR. YOGEV: Abstain.

CHAIRMAN POMERANTZ: That's a new one. Okay. Dr. Pulido.

DR. PULIDO: Abstain.

CHAIRMAN POMERANTZ: Rodvold.

DR. RODVOLD: Yes.

CHAIRMAN POMERANTZ: Mathews.

DR. MATHEWS: Yes.

CHAIRMAN POMERANTZ: Mindel.

DR. MINDEL: Yes.

CHAIRMAN POMERANTZ: Bressler.

DR. BRESSLER: Yes.

CHAIRMAN POMERANTZ: Pomerantz votes yes.

Kumar.

DR. KUMAR: Yes.

CHAIRMAN POMERANTZ: Fong.

DR. FONG: Yes.

CHAIRMAN POMERANTZ: Hannush.

DR. HANNUSH: Yes.

CHAIRMAN POMERANTZ: Fletcher.

DR. FLETCHER: Yes.

CHAIRMAN POMERANTZ: Bertino.

DR. BERTINO: Yes.

CHAIRMAN POMERANTZ: Okay. We have 11, with two abstentions.

Okay. We're going to get to the fourth question, but I just want to recap what we have here in the three official votes for the FDA. The first question, do the data submitted in this NDA support the efficacy of valganciclovir for the induction therapy of CMV retinitis, 12 to one -- one is a no -- was the vote, 12 positive.

The second was a changed question. Do the data submitted in this NDA support the use of valganciclovir for the maintenance therapy of CMV retinitis? That was 13 positive, no, zero noes, zero abstentions.

And the last one you just heard. Did the data submitted in this NDA support the safety of valganciclovir for the treatment of CMV retinitis? Eleven vote yes, zero vote no, with two abstentions.

Okay. This one doesn't require a vote, and it just requires some discussion. Number four is if the answers to the above questions are yes, and most of us voted yes on these, are there additional clinical trials that you would recommend to the applicant conducting as Phase IV studies?

Open for discussion. Ram.

DR. YOGEV: Well, my usual on over pediatric, which I mentioned.

But on a personal note, older --

CHAIRMAN POMERANTZ: So noted.

DR. YOGEV: Yeah, and on a personal note, older than 65. I'm almost getting there. So I would like to use the drug, and they don't have data on that.

I think we need to request a longer period of follow-up on safety and toxicity, and patient with liver disease or peritoneal (phonetic) dialysis, we need to collect data on those to see how should we replenish the drug.

CHAIRMAN POMERANTZ: Other comments?

I have one actually because I think Ram brings up a couple of good points, and that is not only for this drug, but for most anti-CMV drugs, Phase IV trials that take into account age, be it at the beginning or the later half of life, is an important one. There are clear differences certainly in the very young, below two.

And now we know more and more that immune reconstitution differs greatly whether you're -- and I'm sorry, Ram. The data from Mike McCune suggests that it's age 40 when the thymus really starts going away, not at two.

If you monitor that by TREK, by thymic replication circles, 40 is where it falls off, and so there's not real clear data whether there's going to be a difference in how people on HAART, even those that do well, will do depending on whether you're less than 40 or, I'm sorry to say, greater than 40.

And so age is a clear indication for new trials as they come forward and as the epidemic expands.

I think the other point that we had brought up before is the question of what HAART does to maintenance therapy. We left it as a bit of a gamisch (phonetic) here in the maintenance therapy,

allowing people to change their regimen. I would like to see a Phase IV or whatever you want to call it trial where HAART is at least segregated in some ways based on changes in a trial so that you could figure out whether there truly is efficacy in the HAART era, whether it's IV ganciclovir, valganciclovir, and what it is because a lot of alterations in HAART will change the efficacy. Anti-HIV medications are anti-CMV indirectly, but there.

So that would be something for the company to think about I would hope for both this and for a variety of other drugs that affect CMV.

DR. FLETCHER: Two things for me. One, drug interactions. We kind of gave a pass on any kind of drug interactions. The background briefing says, you know, anything that is there for ganciclovir will be there for valganciclovir, and as a place to start, I think that's fine.

But ganciclovir clearly hasn't been studied in this new era of HAART, and as Dr. Pomerantz has mentioned now, there will be additional drugs as we treat hepatitis and so on. So there really does need to be an active program to look for drug-drug interactions.

The second one is the dosing issue. I

think you heard from several members of the Committee that were not confident that we have the best dose for maintenance therapy.

I would at least encourage you to not give up on the population PK/PD issues. The current study that was done was unfortunately just not well done. But there can be a wealth of information that can come out of these. You'll have some, I think, nice opportunities to look at a range of systemic exposures as you look across organ transplant patients, as you look across HIV infected patients.

And I would encourage that and ask you to remember that these types of studies aren't just random things. Population pharmacokinetic studies dynamics really need to be a well designed study just as any other study needs to be. They can use information, you know, SMARTS information, but they still need to be a very well designed study.

CHAIRMAN POMERANTZ: Dr. Bertino.

DR. BERTINO: Well, I'll put in my usual song, which is most of the pharmacokinetic data was done in men, and so sex differences, I think, has to be investigated for this drug.

One of my concerns, I think, kind of extends into what Dr. Fletcher said, which is I'm a

real skeptic myself of population pharmacokinetics just as I'm a skeptic of using age and sex and ethnicity and calculated creatinine clearance to figure out dosing regimens, and I think dose is not a measure of exposure for most people.

And I think that both with this drug and with future drugs that come to this Committee and all of the FDA committees, that we need more individualized dosing information.

Yeah, it's really easy for the practicing physician to only have to remember one dose for everybody, but I think 20 years from now we're all going to say, "Gee, we were pretty naive about how we're using drugs back 20 years ago," and I think we need to start incorporating more of that information, including genetic information, into the equation.

So that would be my comments.

CHAIRMAN POMERANTZ: Other comments? Yes, Dr. Mindel.

DR. MINDEL: I'd like a study looking at frequency of dosing. The IV is given twice a day for induction and cut down to once a day because of ease of giving the drug and matters of quality of life.

The oral drug gives an opportunity to continue the twice a day dosing, possibly at a lower

dose and getting a good response and maybe with less toxicity, maybe with more.

CHAIRMAN POMERANTZ: Thanks.

Chris.

DR. MATHEWS: One area that I think needs further investigation is this issue of how long to continue therapy in the maintenance phase and what are the consequences of discontinuing therapy, and maybe the ophthalmologists here could comment on this entity of immunity recovery, the tridis (phonetic), which my impression has been from the cases we've seen in San Diego that they're nearly always in people who have been taken off antiviral therapy after they've had immune recovery, and that entity is very frequently vision threatening, with poor outcomes unless managed aggressively.

So I think one relevant clinical question is to propose a study that would randomize people either to continued therapy with valganciclovir or stopping maintenance therapy once they've met the threshold of immune recovery to see if both rates of progression, as well as this immune recovery syndrome differ in those two arms.

CHAIRMAN POMERANTZ: Comments from any of our ophthalmological colleagues?

DR. BRESSLER: No, but I just would like to ask the people who are treating many people with CMV retinitis right now as ophthalmologists what their current approach is to maintenance because -- and, Dan, maybe you could address this -- it's my feeling that there's a gamisch of ideas being done out there, and it may be worthwhile using the limited data you have on valganciclovir to expand on it and figure out is this needed for maintenance. Is there a better maintenance?

You showed a curve that said, you know, there was progression in 40 or 60 percent. I think it was 60 percent by the time it got out to almost a year's time.

Well, what if oral ganciclovir does it to 40 percent or something. Is that what people should be on or whatever?

DR. MARTIN: I think you've articulated that very nicely. The bottom line is that we still don't know, although we certainly know more now than we did two years ago.

The idea of withdrawing therapy really began in about two years ago, two and a half years ago, and at that point, at the threshold that many people were using, was 200.

It has become clear over time that this is like all clinical scenarios. It's not as simple as just a single lab value cutoff. The decisions whether or not to withdraw therapy is multi-factorial based on the -- it's all risk-benefit -- location of retinitis, you know. If you have Zone 1 disease splitting the fovea, you tend to err on keeping those patients on a longer period of time.

The extent of retinitis, the degree of immune recovery, the HIV viral load, which would impact the duration of the CD4 count; it's not so simple as just one laboratory cutoff.

But I agree there are certainly more studies that would be indicated. I personally tend to follow patients on maintenance therapy, and at least for me what works quite well is to follow them, following their CD4 count, and not using an individual threshold, but waiting until they're main standard deviations beyond what we had ever seen in a pre-HAART era, and then considering withdrawal of therapy.

I also do want to make one more point on the impact of HAART on maintenance therapy. In the curve that we've shown now several times, some people look at that and have the mistaken idea that somehow CMV disease is easier to treat because of HAART.

That's not necessarily so. That's a very heterogeneous population you're looking at. You're looking at a population, you know; you're looking at a median over the whole population, but when you try to apply that to the individual, it's much more problematic.

You have some patients in there who have failed anti-retroviral therapy, and despite multiple manipulations of HAART, they don't develop immune recovery, and for those individuals, they're going to need long-term maintenance therapy versus those who have a quick response and they never progress.

DR. BRESSLER: So what are you using for maintenance therapy now is my question.

DR. MARTIN: I typically --

DR. BRESSLER: Typically?

DR. MARTIN: Typically will use -- well, first of all, a lot of my patients who are in the valganciclovir trial are continuing on 900 milligrams of valganciclovir once daily. For those patients who had multiple progressions, I added an implant on top of that, and so that's typically what I have used.

DR. BRESSLER: But for the patients who are not on valganciclovir, who walk in tomorrow and finish their induction, they do on what?

DR. MARTIN: We tend to stratify patients -- I do -- depending on what I think their options for immune recovery are. For example, if someone is HAART naive and this is their first OI and it's their wake-up call, and now they're going to start their HAART regimen, that's someone who I'd probably put on oral ganciclovir, one gram t.i.d., hoping for immune recovery.

If it's someone who has exhausted all therapy options that have disease that's splitting the fovea, I'm probably not going to give them an opportunity for pure maintenance. I'll probably put an implant in and then continue them on oral ganciclovir.

DR. BRESSLER: So that's what I would compare to maintenance valganciclovir, and that's the study I would recommend because I'd like to know which is the best regimen to maintain them on. Should they have the implant put in? Should they just take a pill?

Previously when you didn't have the pill option, it wasn't as good or when the pill was so onerous for some of them to take, it wasn't as good. Now, you do have to watch the side effects that they're pointing out, but that's to me what I want to

know in managing them.

CHAIRMAN POMERANTZ: But what I would point out, Neil, I agree, and I like what you're saying about how you manage them down at Emory, but I can tell you you can put three retinal specialists in a room, and you're going to get three different answers to that question.

DR. BRESSLER: Okay.

CHAIRMAN POMERANTZ: That standard of care is very different. That makes sense to me, and I think you look at the nuance as well, but I think it's going to be a difficult study to do because I would imagine that not everyone does that, and you would have to really come up with a standard of care to do it, and we're not quite there yet.

DR. BRESSLER: You're right.

CHAIRMAN POMERANTZ: Because the disease is evolving so quickly. You know, not o behavior the point, but as we talked about, all CD4 cells are not alike. That's an immunological broad brush stroke. In the first few weeks, it's redistribution. In the second few months, it's repopulation of memory, and naive goes out to two year unless you're over 40, where it may never come back. I'm over 40.

So I think you're right to look at it, but

look at it as an evolving entity, and I think Neil also has a good point, but I think it's going to be a difficult study to do now because the ground will change under you as soon as you start getting that study together.

DR. BRESSLER: True.

CHAIRMAN POMERANTZ: Other comments? Dr. Hannush.

DR. HANNUSH: You're waiting for me to drop a bomb again or something.

CHAIRMAN POMERANTZ: No, the votes are already in. Go on.

DR. HANNUSH: This is a follow-up to what Drs. Bressler and Martin just said, and I'm curious because, and it may speak to the issue of labeling. There was a question in the previous version of the questions to the Committee as to how valganciclovir should be used in relationship to other available therapies for CMV retinitis, especially when the fovea is threatened.

Should there be something in the labeling of this product that speaks to this issue, that perhaps this is not a drug to be used if we have sight threatening?

There are four retina people in the room.

DR. BRESSLER: See, that's right. When you have no data, you have to then, I believe, use your judgment. Unless you had a study specifically looking at that, I'd like the physicians to read as much as you end up publishing on this. I'd like them to look at as much as there is on the implant, as much as they know about that patient, and then have to make a decision from the choices you have.

I think it's very hard to put into a label when the fovea is threatened, you must put an implant in and not take a chance with this or vice versa. You must give them this drug.

CHAIRMAN POMERANTZ: Dr. Martin?

DR. MARTIN: I agree. I appreciate your concern, but even most patients who have severe sight threatening disease, most of us don't just do one thing. It's very common just to give an intravitreal ganciclovir injection right there in the office. That way I have no question about whether or not their therapy has been started, and then I'll start them on intravenous ganciclovir or valganciclovir.

I mean, I think most clinicians, if it's really severely sight threatening are not going to rely purely on this. They'll augment as they see necessary.

DR. HANNUSH: Did you say intravitreal ganciclovir?

DR. MARTIN: Yes, yes.

CHAIRMAN POMERANTZ: This is what I mean. I'm sure you can have a debate among the -- I know I've had that at Will's a few times.

Other comments or questions about this interesting but still difficult issue?

(No response.)

CHAIRMAN POMERANTZ: Well, I want to thank the Committee and the FDA and Roche, in particular, because it's not only an important drug for us and probably for other groups of patients, other than what we've discussed today, but it's a real, as I said at the beginning, a real paradigm change in the year of HAART.

And I'm going to suspect that we'll always have to wrestle at least for the next foreseeable future with how you approve drugs such as this, knowing that the studies are bound and the companies are bound by the good part of what is the HAART revolution.

I think that what the FDA heard today is that even though you're comfortable more with these things, these changes, even though they make sense

teleologically, which is what the PK data shows, we still like to see patients get better on it and with nonconfounding variables, and I think that was the major problem with at least Question 2.

But I will imagine that we'll hear this done again at this Committee.

If there aren't any other final comments, I'll adjourn it at this point and thank everyone for their participation, guests, consultants. See you all.

(Whereupon, at 2:53 p.m., the meeting was concluded.)

CERTIFICATE

This is to certify that the foregoing transcript in the matter of: Meeting of the Antiviral Drugs Advisory Committee

Before: DHHS/PHS/FDA/CDER

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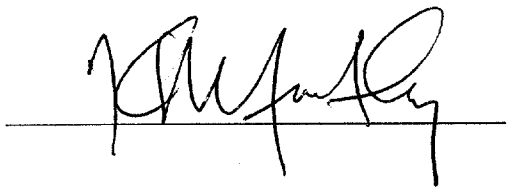

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