DR. SANTANA: I will take the pediatrician's prerogative.

I just have a point of clarification. As I listened to this, I am wondering about something and maybe my logic isn't correct here, but help me.

Thrombocytopenia and platelet refractoriness are hallmarks of VOD. So, these patients that are CRp's, which are having a problem with platelets, are these patients that are also having other liver toxicities that don't quite meet the criteria for VOD, quote, unquote, are there subclinical VOD's that are getting us into this issue of not attaining a complete remission?

DR. SHERMAN: If I can repeat the question, this question relates to the CRp patients and whether or not their delayed platelet recovery is a marker of VOD.

We looked extensively at the safety profile, including hepatic function tests in the CR and CRp patients, and could find no differences in their safety profile.

DR. SCHILSKY: We will take a 15-minute break and reconvene about 10:30.

[Recess.]

DR. SCHILSKY: Before we begin the FDA presentation, the sponsor has requested an additional minute to clarify two issues that the committee inquired about in the previous session.

Dr. Sherman.

[Portion not recorded because of electrical interference.]

DR. SHERMAN: The second point I would like to clarify is information about the exploratory analysis.

[Slide.]

On Slide B-88, this was an exploratory analysis of 26 prognostic factors, including di-efflux.

[Slide.]

On B-90 we can see the results for landmark survival. As I mentioned, di-efflux was not associated with landmark survival, however on an analysis for overall survival, di-efflux was weakly associated.

[Slide.]

On Slide B-89, with an odds ratio of 0.97. FAB categorization was not associated with predicting either remission or overall survival.

Thank you.

DR. SCHILSKY: Thank you.

We will go on to the FDA presentation. Dr. Bross.

FDA Presentation

DR. BROSS: Good morning. My name is Peter Bross. I will be giving the FDA review of gemtuzumab ozogamicin in relapsed CD-positive acute myeloid leukemia.

There are three minor changes between my slides

and the handout that you have. I will be happy to discuss them at the end.

[Slide.]

Gemtuzumab ozogamicin is an immunotoxin, a novel class of anti-neoplastic drug in which a toxin is attached to an antibody and against an antigen found on the surface of cancer cells. In this case, the toxin is calicheamicin, which attaches to DNA, and the antibody is the humanized monoclonal antibody against CD33.

[Slide.]

The proposed indication is the treatment of CD33 positive acute myeloid leukemia in relapse.

Gemtuzumab ozogamicin targets the CD33 antigen, which is found on the surface of these leukemia blast cells in the majority of acute myeloid leukemia patients.

[Slide.]

I would like to attempt to guide you through the regulatory issues involved in this application. The sponsor is seeking accelerated approval for the indication of relapsed CD33-positive acute myeloid leukemia.

To achieve approval, the drug needs to be shown to possess a meaningful therapeutic benefit over existing therapeutic options. Although there is currently no drug specifically approved for use in relapsed acute myeloid leukemia, the sponsor needs to demonstrate that their drug

is better than existing treatments to achieve accelerated approval.

Normally, this is done by demonstrating an improvement in efficacy. In this application, the sponsor is attempting to demonstrate improved safety, but efficacy still needs to be comparable to available treatments.

Complete response is considered a surrogate endpoint in this case because of the difficulty of determining the duration of response.

[Slide.]

For hematologic malignancies, durable complete remissions have been considered as adequate evidence of clinical benefit. In this case, however, the duration of responses are difficult to measure because of subsequent therapies, especially transplantation. Since duration of response is difficult to measure, in this case complete response would be viewed only as a surrogate for clinical benefit.

Since approval is based on a surrogate, the accelerated approval regulations require the sponsor to initiate studies following approval in order to confirm clinical benefit.

[Slide.]

There are several review issues of primary concern in this application. In terms of efficacy, we believe that

some questions still remain concerning clinical equivalence of the response categories of complete remission and CRp.

Is this drug equally as efficacious as conventional salvage chemotherapy regimens? The sponsor needs to demonstrate this.

Which patient groups would benefit most? How do we interpret survival data in the absence of any consistent post-remission therapy?

In terms of safety, how significant is the hepatotoxicity reported in this drug, and more importantly, is there really a safety advantage with this drug over conventional leukemia salvage treatments?

[Slide.]

These were the studies originally submitted for review in October. They include Phase I study of 41 patients, and three, Phase II studies, totalling 104 patients. You will notice that the Phase II studies are still ongoing and accruing patients.

[Slide.]

Originally, we received data on 41 patients in the Phase I study and 104 patients in the Phase II studies. In January, we received efficacy and safety updates on the original study patients plus an additional 38 patients, for a total of 142 patients.

[Slide.]

Differences between the studies are highlighted here in yellow. I might just point out Study 203 allowed older patients with shorter duration of remission, somewhat looser hepatic and renal entry criteria, and this group would be expected to have a worse prognosis.

[Slide.]

The study drug was given as a single, two-hour intravenous infusion, which was repeated once on day 14. I might say that our pharmacokinetic review is not completed, and we found some variability in the half-life, which we are not sure whether it is associated with receptor saturation or problems with the assay. So, we requested further data on this, but this is an innovative form of therapy, and we can't necessarily expect it to behave as a normal chemotherapy drug.

This brief infusion, of course, is in contrast to the standard 7 and 3 classic induction chemotherapy regimen for the induction of myeloid leukemia which has been used for years.

Eligibility was determined on site, but responses were determined by the independent pathologist, and growth factors were not allowed on the study.

[Slide.]

Primary endpoints were safety and efficacy as defined by complete response. Complete response was defined

by the conventions commonly used in leukemia trials including absence of circulating blasts, no increased blasts in bone marrow, and untransfused hematology values as noted. Patients had to be red cell transfusion independent for 14 days and platelet transfusion independent for 7 days.

[Slide.]

Morphologic remission was the term originally coined to describe the group of patients later termed CRp's. These remissions were defined in the same way as complete remissions except that the platelets never achieved 100,000. Remember that CRp was not a primary endpoint in the study and that the patients still were required to achieve red cell and platelet transfusion independence.

[Slide.]

In most leukemia trials that we reviewed, patients who failed to achieve the prespecified hematologic values were grouped with those patients who failed to achieve complete clearance of blasts, and these were called partial remissions.

These usually comprised less than 5 percent of all the patients in the trial. In Phase I trials with gemtuzumab, a substantial number of patients were identified who had durable clearance of blasts with incomplete platelet recovery.

It was postulated that for some reason this group

of patients was particularly susceptible to the toxic effects of the drug on the stem cells, megakaryocyte precursors, although persistent leukemia might also have explained the failure of these patients to achieve normal platelet counts.

The sponsor initiated some studies to confirm in vitro suppression of megakaryocyte colony-forming cells in the marrows obtained from normal donors, however, the long-term toxicities of this drug on the stem cells have yet to be completely delineated.

We believe there are still some questions remaining concerning the pathophysiology of this phenomenon. It would be reassuring to have cytogenetic clearance of the leukemia clone in every case of the patients who achieved a CRp. Unfortunately, we don't have that data yet.

[Slide.]

What does all this have to do with the treatment of leukemia? Combined efficacy results from the original 104 patients are highlighted in yellow. You will notice that there is only a 17 percent complete remission rate, but if you add the CRp's overall response rate was 31 percent.

Overall response rate, therefore, was largely influenced by this group of CRp's. The results were fairly uniform between the different trials with patients in Study 203 demonstrating somewhat decreased response rates, which

would be expected in an older population.

[Slide.]

Updated efficacy results with an additional 38 patients showed a similar overall response rate of about 30 percent, which did not change significantly. The additional data did not alter the overall response rates, but confirmed the contribution of the CRp's to the overall efficacy results.

[Slide.]

The sponsor has presented some data on relapse-free survival in support of the concept that the CRp's are behaving clinically like the CR's. If you look at the median relapse-free survival, here, it appears that the CRp's might be relapsing sooner than the CR's.

[Slide.]

Our review looked at the relapse-free survival curve of the two groups. It still looks more or less similar in our graph of the CR groups.

If you look closely at the curves where we calculated our 50 percent median, it looks like CR's are doing better, later it looks like the CRp's are doing better, and because of the small numbers, a few events can cause the medians to appear markedly different.

I present this information to illustrate the point that there are really insufficient numbers yet to be able to

demonstrate equivalence between the two groups.

[Slide.]

In addition to the small sample size, a problem with the interpretation of survival data in this study was the lack of any consistent post-remission therapy. Patients who were eligible went on to transplant and successful allogeneic transplant is correlated with long-term survival in relapsed acute myeloid leukemia.

About 40 percent of the responders were transplanted and given the small numbers involved, if even a few more CRp patients received allo transplant, that might have affected the survival curves.

[Slide.]

As Dr. Appelbaum previously pointed out, most significant predictors of response in relapsed acute myeloid leukemia are thought to be age and duration of first remission. The response rates varied widely depending on the population.

[Slide.]

Keeping in mind the inherent hazards of drawing conclusions from historical comparisons, non-prespecified subset analysis, in single arm trials with small numbers of patients, as Dr. Simon pointed out, it is not satisfactory, but it's the best we can do, keep in mind the desire to provide some measures for a comparison.

We looked at response rates versus age reported in several studies of salvage regimens for relapsed AML. The references are in the questions. We thought it might be helpful to look at specific regimens rather than just recording a range of values.

[Slide.]

Looking first at the younger patients, you will notice several things. First of all, the complete response rate--if you can see that number, 17, in gemtuzumab, it is much lower than that in the other studies. Even if you add the CRp's to get overall response rate, it looks as if the efficacy is not really comparable in the younger patient groups.

If you look at the older patient group, and remember that these are the people who get leukemia with greater frequency and are less likely to be able to tolerate chemotherapy, it looks like response rates reported in the literature are at least closer to that reported in gemtuzumab trials.

[Slide.]

We compare response rates in the literature versus duration of first remission, looking for patients with shorter duration of first remission. They are treated with a variety of regimens. These presumably had a worse prognosis and are highlighted here in yellow. It looks as

if the results of these five trials are a little closer to that reported in the gemtuzumab trial.

If you look at response rates reported in relapsed patients who have enjoyed relatively long durations of first remission, and these would be expected to have better prognosis, here highlighted in green, we find that response rates reported in gemtuzumab trial are really not as high as the results reported generally in the literature of this group of patients.

Of course, since it wasn't a randomized trial, it is not appropriate to make direct comparisons between these two groups. It is interesting that the same prognostic features that appear to be at work in conventional chemotherapy may not be as important in gemtuzumab trial.

These observations are exploratory and are not intended to suggest any definitive conclusions regarding the relative efficacy of this drug in different patient subgroups. This would need to be established by controlled clinical trials.

[Slide.]

Efficacy conclusions. In the absence of randomized trials, comparable efficacy may be difficult to prove. This drug may be equal to available therapy in certain patient subgroups, but any claim of equivalence of efficacy depends heavily upon the inclusion of the CRp group

in the calculation of the response rates.

The claim of equivalent relapse-free survival between the CR's and CRp's is not yet statistically established. Efficacy in different prognostic subgroups requires further study.

Duration of responses are difficult to compare because of the wide variety of post-remission treatments.

Does it matter that the patient's platelets are 90 or 110? Probably not, but there still are some questions remaining between the different subgroups of response.

[Slide.]

Moving on to safety issues, the safety issues I plan to cover include infusion-related symptoms, development of antibodies, risk of bleeding, risk of infections, and GI toxicity particularly hepatic toxicity.

[Slide.]

Acute infusion-related symptoms were common, but appeared to be generally mild and reversible. Outpatient of this drug appears feasible in an infusion clinic equipped to manage the occasional hypotensive or hypoxic episode. Tumor lysis was rarely observed.

[Slide.]

No antibodies to the humanized murine monoclonal antibody were detected in any of the patients. However, two patients developed antibodies to the linker complex in a

Phase I trial. One patient was transiently symptomatic, but recovered with a few hours of observation.

[Slide.]

Minor bleeding appeared possibly increased comparing the CRp group with the CR group. However, because of the heterogenous nature of these minor bleeding events, I do not feel it was appropriate to analyze them statistically. Major bleeding was sufficiently uncommon to make it impossible to make a statistical analysis. It did not appear that major bleeding was increased in the CRp group, however.

More platelets were transfused in the CRp group compared to the CR's, but in every case bleeding and transfusions were more common in the non-responders as would be expected.

A trend to more red cell transfusion is observed in the CRp group as compared to the CR group.

[Slide.]

Once again, keeping in mind the inherent hazards of historical controls, we looked at several safety events reported in recently published studies of salvage regimens for relapsed acute myeloid leukemia. References are contained in the questions to the committee.

It appears that patients treated with gemtuzumab, here highlighted in yellow, appeared to have more or less a

similar risk of Grade 3/4 bleeding and time to platelet recovery, which was at least equivalent to that reported in other regimens, possibly increased compared to some.

In conclusion, it looks as if the bleeding risk of gemtuzumab appeared to be comparable to that reported with conventional salvage regimens, but again it would be nice to have direct randomized trial data.

[Slide.]

Compared again with literature reports of other salvage regimens, recovery from neutropenia appeared to be comparable, and in some cases more rapid, however, the incidence of severe infections really did appear to be reduced compared to those incidents recorded in the literature with these other salvage regimens.

[Slide.]

GI toxicity, nausea, vomiting, and particularly mucositis appeared reduced in those patients compared to reports of the events in other regimens, however, there did appear to be an increased incidence of liver function abnormalities in patients treated with gemtuzumab compared to those treated with other regimens.

[Slide.]

Unconjugated calicheamicin was noted to be hepatotoxic in preclinical testing. In the trials, about a sixth of the patients experienced elevations of

transaminase, and about a quarter of the patients experienced elevations in bilirubin, and 13 patients exhibited elevations of both AST and bilirubin, which is thought to be a marker of significant possible hepatotoxicity, but most of these elevations were transient and reversible.

[Slide.]

However, hepatic veno-occlusive disease is a well known and potentially fatal complication of myeloablative chemotherapy. Diagnosis is clinical and sometimes difficult from a reviewer's perspective, however, four patients developed transient VOD during the study. Two of these had had prior stem cell transplantation, and another patient developed veno-occlusive disease and died later of a pulmonary embolus.

[Slide.]

One, 74-year-old-male became jaundiced following treatment and eventually died of liver failure about five months following treatment. Three patients who were transplanted following treatment with gemtuzumab ozogamicin died of veno-occlusive disease as a complication of the transplant.

However, two of these patients were non-responders and maybe expected not to do as well with the transplant. However, I am not aware of an increased risk of veno-

occlusive disease in patients who are transplanted not in remission.

One patient who relapsed following transplant was given gemtuzumab on a compassionate single patient IND and developed fatal veno-occlusive disease. Again, it is not clear if the incidence of veno-occlusive disease is significantly increased compared to that, that might be seen in patients treated with the conventional salvage chemotherapy regimens, but we were concerned with these cases.

[Slide.]

In summary, gemtuzumab ozogamicin may have some safety advantages compared with literature reports of conventional salvage regimens. Outpatient administration appears feasible and more convenient than the seven days of continuous chemotherapy using standard induction.

Mucositis and severe infection do appear to be reduced. Bleeding risk appeared similar to those reported in the literature. Hospitalization data are difficult to compare in this age of cost containment because hospitalization rates reported at the same regimen are changing, so it is difficult to compare that.

[Slide.]

Disadvantages. In comparison with literature reports of conventional salvage regimens, gemtuzumab

ozogamicin appeared to have an increased risk of elevated so-called liver function tests, and these are a potential marker for significant hepatotoxicity.

Most of these abnormalities were reversible, but veno-occlusive disease was reported in several patients, particularly those who went on to receive transplant and also in those patients who had previously received a transplant. One patient on a compassionate IND had had a previous history of veno-occlusive disease during transplant.

[Slide.]

Some issues to consider. Is efficacy really equivalent to conventional salvage regimens? The results of this trial are difficult to compare with those of conventional salvage chemotherapy in the absence of randomized trials, but in any case, comparable efficacy would rely on the inclusion of the CRp's.

Is there adequate demonstration of improved safety to warrant accelerated approval? Is there an increased risk of veno-occlusive disease especially in those patients who will go on to transplant or who have already received transplant?

Which patient populations might benefit, the elderly who as we know are the most likely to suffer from acute myeloid leukemia and less likely to tolerate the

chemotherapy? Certain poor prognosis groups, can this be used as palliation in certain cases? Is this drug safe for use in a preparative regimen for transplant or as a temporizing measure for patients awaiting allogeneic match?

This drug may have a place in the treatment of leukemia, but we are not comfortable that we know the answers to many of these questions concerning efficacy, safety, and dosing.

[Slide.]

Remember that any conclusions to be derived from these trials are hampered by relatively small numbers of patients enrolled in single arm trials and subjected to historical comparisons.

There are several regulatory options for the committee to consider. The committee could decide to recommend accelerated approval now based on current interim data with Phase IV commitments to finish ongoing studies.

The committee could also recommend approval with restricted indications for this drug.

Alternatively, the committee could require completion of ongoing Phase II studies and resubmission of the IND application when the studies are finished.

A third option would be to require the completion of randomized clinical trials and resubmission of the NDA at the time of the completion of randomized studies.

[Slide.]

I would like to thank the members of my review team, particularly my statistician Alvis Dunson who is working the slides, and particularly Julie Beitz without whom I would not have been able to complete this review.

Thank you very much.

I would like to point out there are a few minor changes between my slides and the handouts, and I would be happy to answer questions regarding these changes.

DR. SCHILSKY: Thank you, Dr. Bross.

Are there questions from the committee for FDA? Dr. Blayney.

Questions from the Committee

DR. BLAYNEY: Yes. The protocol specified that no colony-stimulating factors were to be used after infusion of the experimental agent. Did you find that there was use of these factors, and does this impact on the time course of counting when a remission was obtained?

DR. BROSS: I looked at that, and I can't remember. The use was very low, and I believe a few of the investigators broke the protocol, but I think it was in less than two cases.

Is the sponsor aware of the incidents of growth factor use? I believe that this use was very, very seldom.

DR. SCHILSKY: Any clarification from the sponsor

on that?

DR. SHERMAN: Growth factor was prohibited, but it was allowed for life-threatening infections, and it was a very low rate of the patients who did ultimately receive a colony-stimulating factor.

DR. SCHILSKY: Thank you.

DR. BLAYNEY: The other thing is that this to my knowledge, if it is approved, would be the first monoclonal that is linked to an intracellular poison, and while we are told that the covalent bond, there is a covalent bond there, sometimes those break, and I guess if calicheamicin is a real hepatotoxin, I would hope that the sponsor and the approving agency would be very careful that the dating or whatever measures you have to take would be important, so that we might not see these liver function things.

Finally, I will just make a comment that comparisons with studies that look at salvage therapy in the leukemic adult and trying to compare that with what we are seeing now are quite difficult because many patients, particularly the patients that I see who are often elderly and have comorbidities would not even enter one of these trials that you showed for comparison, and there is a substantial selection bias for participation in one of these trials, and they are probably not representative of the population as a whole, and even trials I suspect for such a

relatively nontoxic agent as that we are presented with today would not have as much selection bias.

So, I think, you know, Dr. Simon always makes the point about how difficult it is to compare. I think there is actually a biologic selection bias, as well, here.

DR. BROSS: The percentage of free calicheamicin was very low. Certainly, you can, as everybody knows, you can certainly adjust the response rates in your trial by your patient selection, and it certainly is a very imperfect technique to look at historic comparisons.

We decided we would look at specific regimens rather than just reporting a range of results, so you would at least have something to compare it to, but we agree that this is a very imperfect technique.

We allowed these studies to proceed, the application to proceed on the basis of these two studies because the sponsor assured us that they had excellent safety advantages and comparable efficacy, so we said all right, show us.

DR. SCHILSKY: Dr. Sledge.

DR. SLEDGE: I have another question that is partly related to efficacy, but also partly regulatory.

If I was hearing you correctly, you are most comfortable with, by comparison with the historical literature, with evidence of efficacy in the older

population as opposed to the younger population realizing that those comparisons are fraught with hazard, and from what I heard when Dr. Appelbaum was asked about which patients he would treat, there were very distinct groups of patients that he would consider treating or not consider treating with this agent.

If we give this agent blanket approval, is this the equivalent of, for instance, Zoloda approval in breast cancer that we did a year and a half or so ago? I mean if we give this blanket approval, does this sort of become from a regulatory standpoint a new standard against which other drugs have to be measured?

DR. TEMPLE: These questions are a particular problem in oncology where the standard therapy is often completely unrelated to anything that is in labeling.

We have a lot of rules that relate to when you can approve a drug based on a lesser standard because it represents an advantage over available therapy. We are in the process of trying to define what available therapy is.

In almost every other area, we are pretty comfortable saying available therapy means something we have reviewed and labeled, but people are, on the whole, unhappy when you say that about oncology because in the case here, none of these drugs which are sort of what everybody does are labeled.

It certainly is possible that when something finally does become labeled, and we think we know the data, and we have reviewed it and we have looked at the criteria, it does have some tendency to become a standard.

So, one of the things you need to tell us is if you think that it is should be approved for somebody, but that it should be hedged and narrowed and qualified, we would listen to those kinds of advice.

DR. SLEDGE: I guess more specifically, if we approve this and the next six monoclonal antibodies that come along for this indication, which I imagine will in the next few years, are they going to have to have head-to-head comparisons with this agent to get approved?

DR. TEMPLE: It depends a little bit on the basis for what you tell us. Five people have now pointed out the treachery of these historical comparisons, and I personally think it is going to be extremely hard to say based on those comparisons we know this is just like those.

You may very well give us advice based on your feeling that the response rate here stands on its own and is good enough, in which case another product could conceivably be approved because it has a response rate you consider adequate and stands on its own.

We always tell people to do comparisons. We usually tell them to do comparisons where they add to the

available therapy, so that you actually get somewhere, and we will undoubtedly continue to do that.

So, adding one antibody, one monoclonal antibody to another might or might not make sense. It depends on what the mechanism is. But we would almost surely be advising people to start doing comparisons early. We probably wish we had said that here.

DR. SCHILSKY: Dr. Lippman.

DR. LIPPMAN: Again, I would just like to follow up on Dr. Blayney's comment, which I tried to allude to earlier, is that these not only entail the treachery of historical controls, but they are not even comparing patients that were on protocols before, so there is a number of comorbidities which are perhaps even greater in the older age group confounding factors.

Just a point of clarification. When you looked at the historical controls in your response rates versus age, I mean is it reasonable to assume that again these response rates that are compared would be substantially higher if this new definition of CRp were included in the historical group?

DR. BROSS: I am sorry?

DR. LIPPMAN: Did you get a sense of platelet and platelet recovery, what these response rates would have been in your table of response rates versus age, comparing the

other series?

DR. BROSS: You mean if you had included the--

DR. LIPPMAN: CRp.

DR. BROSS: Some CRp's in the other trials?

DR. LIPPMAN: Response rates, did they give data on platelets that would have allowed you to get a sense of--

DR. BROSS: Well, as Dr. Appelbaum stated, that usually in most trials, when patients do not achieve their hematologic values, these are considered partial responders, and this was less than 5 percent of trials. Many trials did not even report partial responders.

So, I suspect it is going to be less than 5 percent in any of the trials.

Does that answer your question?

DR. LIPPMAN: So, in other words, the CRp's would have been included in the partial response criteria category of other trials?

DR. BROSS: Dr. Appelbaum?

DR. APPELBAUM: The MRC data there do not use platelet recovery as a criteria for CR, so it would not change their CR's at all since they don't require platelet recovery, so it would have no effect on those two trials.

In the retrospective review that the group did from Wyeth-Ayerst, they could find fewer than 5 percent of patients would have felt, treated with conventional

chemotherapy, would have fit the criteria of a CR without the platelet recovery when treated with conventional chemotherapy.

DR. LIPPMAN: So, in this case where the CRp has contributed substantially to the overall CR rate, are you saying that the CRp rate appears to be higher in this than a partial response in other--

DR. APPELBAUM: No. What I am saying is in the Rees study and the St. Bart's study, those do include CRp's by this definition, because you don't need platelet recovery in those studies.

DR. LIPPMAN: One final point of clarification. We have heard that 100,000 was the cut-off that was used here, but 90,000 or 110,000 wouldn't be a big difference, and I agree.

Do you have the raw data on those CRp's, I mean were they all 90,000, or where do they peak?

DR. BROSS: As I recall, they were variable, anywhere between 30,000 and 85,000. There was one that came up to 99, but the sponsor was honest not to include that. I don't recall the exact spread of the standardization.

DR. LIPPMAN: But the mean or median of that group of platelets, do you have a sense of that?

DR. BROSS: I am not sure if you guys have that, but, in general, it was kind of all over the place, as I

recall, anywhere between 30 and 99. If the sponsor has that data, I would invite them to present it.

DR. BERGER: Just one second. If you will turn the projector on, we will show the precise data. Basically, the only patient who didn't achieve a maximum platelet count greater than 25,000, achieved a platelet count of 15,000, and actually stayed there for a number of months without platelet transfusions.

All the other patients achieved more than 25,000.

[Slide.]

You can see that 18 of the 19 achieved at least 25,000, 13 of the 19 achieved at least 50,000, and 8 of the 19 achieved at least 75,000. These are the maximum platelet counts. Obviously, they became a CRp patient when they become platelet transfusion independent, and these were the counts that they rose to, again prior to receiving any other therapy.

DR. SCHILSKY: Peter, I wonder if I could ask you, just as a follow-on to Scott's question, it seems to me that a lot of our discussion is going to hinge to a great extent on the comparability of the CR and the CRp patients.

Since you have looked at all the data in much greater detail than anyone around the table here, I wonder if you could give us just your overall opinion as to whether, in your view, having reviewed the information,

whether you would feel that the CRp patients are comparable to the CR patients.

DR. BROSS: Well, that, of course, is the crux of the--

DR. SCHILSKY: I know you are going to ask us for our opinion about that, but I thought I would ask you for your opinion first.

[Laughter.]

DR. BROSS: Well, I guess my short answer is I don't know yet. I mean when you look at it, as I mentioned, I would be more comfortable if I had cytogenetic clearance of the leukemic clone in all of these patients. I would be more comfortable if I knew exactly what was going on.

There is a number of different phenomenon, the post-transplant thrombocytopenia, which is presumably from stem cell toxicity. Looking at a few of the pathology reports, in some cases megakaryocytes were present, in some absent.

Anyway, I am not really sure what is going on here in terms of the clinical behavior of these patients. If you look at the patients who were not treated with further treatment--can you show the very last slide?

[Slide.]

If you look at the relapse-free survival, it is possible that these patients with the high CRp's may be

doing a little bit worse, but again this is not statistically significant.

I think that the question is up in the air, and we really have to operate now on the basis of incomplete information, but the thing I feel uncomfortable about is really seeing this drug and having a young healthy person in relapse be treated with this drug, but I do have, in answer to your question are these two groups comparable or equivalent, and I don't really know if they are.

If I had to guess, I would say they probably will be proven to be equivalent, but that would be I would feel a little uncomfortable with that.

Does that answer your question?

DR. SCHILSKY: No, well, I think that is helpful. I mean I think one of the concerns that the committee will have is if the drug is generally available, might there be patients treated with it who, in fact, would be disadvantaged by it, who would be better treated with more conventional therapy, and yet because this appears to have somewhat fewer side effects, you know, physicians might opt to use this in place of what might ultimately be more effective treatment.

So, I think, you know, your comments are helpful.

Any other questions for Peter?

[No response.]

DR. SCHILSKY: Okay. Peter, thank you very much.

Committee Discussion and Vote

We have a number of issues to discuss. We have quite a few questions that have been specifically posed to us by the agency. It seems to me before we get into the questions per se, it would be worthwhile to have some discussion.

It seems that the issues really hinge on something that was shown on one of Peter's first slides, which relate to what is required for accelerated approval in this case, and that would be some level of confidence that this agent actually has equal efficacy to other available therapies and an improved safety profile.

Certainly, I think it doesn't appear to be superior to available therapies, so the real question is, is it comparable to existing therapies with the presumption that it has an improved safety profile, and the ability to determine, at least in my mind, whether it is comparable hinges a lot on this issue of whether CRp's and CR's are equivalent, because if we put the two together, you start to get into overall response rates that start to look a little bit comparable to existing therapies. If you don't include the CRp's, then, the CR rate seems to be substantially below what one might see with existing therapies.

So, I think we need to have some discussion.

Perhaps I can ask either Dr. Berman or Dr. Przepiorka, our resident leukemia experts, to help us discuss some of these issues.

DR. BERMAN: My opinion is that the CRp's are equivalent, and while the numbers are small, there didn't appear to be any trend toward a worse outcome whether these patients went on to no further therapy or went on to transplant.

I think that we have to keep an open mind when we are dealing with a new agent like a monoclonal antibody because it is not chemotherapy as we know it. So, these appear to be clinically meaningful responses, and whether the platelet count is 75,000 or 100,000 does not have an impact either on survival or post-transplant survival.

So, I would say that they are equivalent.

DR. SCHILSKY: Dr. Przepiorka.

DR. PRZEPIORKA: I think the survival curve for CR versus CRp really does look distinctly different, and I am concerned that those early survivors that haven't made it very far and appear to be doing as well as the other people in the curve may end up actually keeping that curve up, and so I don't think we have enough information to say that they are the same when they are already starting to look different, but if you go to median relapse-free survival, it is 2.1 months in both groups, it is the same.

Unfortunately, it is also much worse than what the sponsor has indicated as the median relapse-free survival of 6.8 months and much lower than what you see in the literature for median relapse-free survival for patients not going on to a transplant.

So, I am also concerned that maybe there is no difference between the two groups because the two groups are actually doing equally poorly rather than equally well.

DR. SCHILSKY: Comments from other committee members? Dr. Simon.

DR. SIMON: My basic view is that we shouldn't really have to struggle with this, that we shouldn't be dealing with a single arm study and with literature comparisons that are probably distorted in all kinds of ways.

But beyond that, given that we are in this situation, it is not so much I don't think whether we think the CRp's do the same as the CR's, it's a matter of what do we compare them to in the literature.

If the literature's CR rate has required platelet recovery to 100,000, then, if we want to compare this series to the literature, we have to look only at the CR rate regardless of whether we think that the outcomes of the two groups are the same or not.

DR. SCHILSKY: Dr. Nerenstone.

DR. NERENSTONE: Speaking as a non-leukemia doctor, I think I am persuaded by the fact that at least in the references that we were given, that two of the larger studies already include those patients in their response rate and that platelet recovery is not required for documentation of CR.

It's a pathologic diagnosis in terms of clearance of blasts, and therefore, I think this is sort of a non-issue because the larger series already don't count these patients. So, again, as a non-leukemia doctor, just looking at the data it seems to me that that is a persuasive argument, that these patients really should be counted as CR.

DR. SCHILSKY: Other comments? Dr. Lippman.

DR. LIPPMAN: Again, based on the actual data we have, I still have a concern about CRp's with substantial differences in median relapse-free survival whether they had further therapy or didn't.

I would like to look at those larger series that we don't have the data, we just have sort of post-communications from these ongoing studies, and really sort that out. But fundamentally, even if these were complete CR's and that we weren't talking about CRp's, I am very, very concerned about the historical, non-protocol comparisons even if they were equivalent.

DR. SCHILSKY: Do you want to elaborate on that in terms of specifically what your concerns are?

DR. LIPPMAN: I think I stated them before, and state them again. I mean there are many, many problems well understood with historical comparisons in general, but I am even concerned more about the fact that these historical comparisons are in clinic persons that weren't even treated on protocols, didn't qualify for protocols because of comorbidities and other problems that we have no way of knowing now.

So, I think, and certainly because of poor prognostic factors, and so on, so I am very concerned about those as being the standard on which to compare.

DR. SCHILSKY: Any other general discussion before we address the questions?

DR. BERMAN: Just to add one thing, and that is that I think the survival, whether you look at the CR's, with the CR/CRp's together, it is equivalent to many of the studies looking at patients with relapsed disease. The survival is usually measured in months once patients relapse.

In the small numbers of patients who went on to transplant, it looked like there was excellent post-transplant survival, certainly at 100 days, so I would say that this falls within the realm of the studies.

Now, what are you asking the drug, that other drugs in development haven't had, and that is that there is no role for a randomized trial in patients with relapsed disease. I mean, first of all, it's not very common. You saw that many of the centers just entered one or two patients all together.

So, in the setting of drug development for this disease, these have always been just straight Phase II that have been compared to the literature.

DR. SCHILSKY: Ellin, could I ask you for your comment--you have made the comment on several occasions now about the good post-transplant survival in the patients who got transplant--I guess my question is might you not have expected similarly good survival post-transplant if patients just got additional chemotherapy and then went on to a transplant?

DR. BERMAN: Well, following high-dose chemotherapy like a traditional high-dose ara-C-containing regimen, some of the patients are bound to develop an infection or some problem that won't allow them to go on to transplant. So, actually, these look like very reasonable transplant survival data.

DR. SCHILSKY: Well, it may be that perhaps more patients got the transplant, but once they got there, I am not sure how you can say anything about whether their

survival post-transplant is sort of influenced by what the pre-transplant therapy was.

DR. BERMAN: It would certainly be no worse than standard therapy.

DR. PRZEPIORKA: Well, actually, that was another question that Dr. Appelbaum pointed out, that he would probably not utilize this drug for the young healthy individual as opposed to what is currently considered standard, but might consider it for a pre-transplant cytoreduction.

There are only 27 patients, if I counted correctly, who went on to transplant, a number of whom developed VOD, and, yes, we don't know if it was transplant related or not. The survival day 100 is probably pretty good using current transplant regimens and standard care.

I would be more interested to see the survival later post-transplant, though, one year or so if you really want to know whether or not the survival is impacted negatively. But I would also be interested in knowing some of the toxicities during the transplant period and whether or not the hepatotoxicity seen pre-transplant actually added to the transplant preparative regimen hepatotoxicity, and that is just data that we don't have.

DR. BERMAN: Well, I think the incidence of VOD seemed to me relatively high following the transplant, and I

would agree with that.

DR. SCHILSKY: Mr. Flatau.

MR. FLATAU: I just wanted to point out that maybe the patients that did have transplants probably didn't need any additional therapy before the transplant, and could have just gone straight to transplant and avoided both the commencing chemotherapy toxicity and any toxicity from this drug.

DR. SCHILSKY: I don't know that we can know that for sure from the data although it is certainly not clear to me at least that the antibody was the preferred pre-transplant therapy compared to just additional chemotherapy.

MR. FLATAU: I mean you could have no therapy at all and just go to transplant. I had that treatment.

DR. SCHILSKY: There is no question some patients will go directly to transplant, but that is not the group of patients that was actually included in this study.

MR. FLATAU: It seems that most of the long-term survivors had transplants, and it is hard for me to think that they actually benefitted from the drug when they may have just gone straight to transplant and done just as well.

DR. SCHILSKY: Other comments? Dr. Temple.

DR. TEMPLE: For someone who doesn't know anything, can you explain that last conversation? I assume that people who were put into remission by a therapy, then

went on to transplant, which consisted entirely of marrow or stem cells or something, but if a person wasn't in remission yet, he would have to have aggressive chemotherapy to put him into remission before the transplant, right? Am I missing something?

DR. SCHILSKY: I think what Mr. Flatau was saying is that some people who obtain a remission with their induction chemotherapy go directly to transplant.

MR. FLATAU: I relapsed and did not have any additional chemotherapy to get me into remission before the transplant. I did, of course, have chemotherapy and radiation as part of the conditioning regimen before.

DR. TEMPLE: But even though you were not in remission, you want to a transplant.

MR. FLATAU: Right.

DR. TEMPLE: There, you have it.

DR. SCHILSKY: Dr. Lippman.

DR. LIPPMAN: Just the issue of whether you could never do a randomized trial in this setting, I guess I need a statistician, but it looks like over the past two years on this trial alone, there have been over 100 patients accrued.

We certainly have seen randomized trials in less common diseases that are less than that and have gone to approval. I think a trial like this with early stopping for toxicity with an equivalency design could be done.

I don't know if Dr. Simon has comments on that, but the idea that we can never have randomized data and we have to use data on the 20 historical controls seems to be--

DR. BERMAN: I am saying in the phase where this drug is now, I mean once you have established the dose and you have the rough efficacy, yes, I would absolutely recommend comparative trials in the future, but I think at least to establish its efficacy, I think you would just want a cohort of patients just to define the toxicity first before moving on to a randomized trial.

DR. SIMON: I agree with Dr. Lippman. I think we would be much better off today if we had a randomized comparison even if it wasn't of the size that we might definitively use to establish efficacy, to establish therapeutic equivalence.

We would be much better off in knowing what its effects were both for toxicity and for efficacy if they had taken the same number of patients and done a randomized trial.

DR. SCHILSKY: Dr. Albain.

DR. ALBAIN: I would like to go back to what we did, though, with kepcytobine [ph], because it's really analogous. There were other options for these women with metastatic breast cancer. There are other drugs out there that could have been tried.

Yet, in Phase II data, there was intriguing results, and we therefore gave it this whatever we called that type of approval, such that the sponsor was required to then go on and do randomized comparisons.

I feel that that is where we are with this particular agent. It is intriguing. There are some subsets of patients that could not get more aggressive chemotherapy, and I think it needs to be out there with a very narrow label as we did with kepcytobine.

DR. BERMAN: I would also just remind you that the rituximab was labeled in a very similar way, that the response rate for rituximab in heavily treated patients with follicular lymphoma also was no better than 30 percent, and following its labeling, it has now proved to be very interesting in combination with other agents.

So, there was no randomized trial when rituximab was up, and this was just two or three years ago.

DR. SCHILSKY: Mr. Flatau.

MR. FLATAU: I just wanted to add for Dr. Temple's benefit or others that Dr. Appelbaum did have some comparison of patients in relapse and second remission in his presentation.

DR. SCHILSKY: Dr. Sledge.

DR. SLEDGE: I have my suspicions that those of use who are non-leukonologists on the committee are

wrestling with the problem of what is the clinical benefit here in not treating these patients.

I would like some real sense from our leukemia people on the committee, who would you treat with this drug. I heard what Dr. Appelbaum said, but what would you guys do if this drug was available?

DR. PRZEPIORKA: I am impressed with the fact that there is less mucositis, there is also less overall response rate in the elderly group, and if I had to, that would be the group that I would target it for.

DR. BERMAN: And I would agree. I think for patients for whom another round of chemotherapy is not an option, I think this would be a good one.

DR. SCHILSKY: We are going to come to this again in the questions, but we do have some options to recommend more restrictive labeling.

DR. SLEDGE: Let me ask about that. Let me follow up on that if I could, because originally, I was certainly confused by the no further therapy category, but what I heard was that it sounded like the majority of the patients in the no further therapy category did receive further therapy.

I mean if you are telling me that you would use it for the population of patients who couldn't get further therapy, but it sounds like in the study, you know,

certainly the majority of these people did get further therapy.

DR. PRZEPIORKA: I was speaking for first-line therapy for first relapse rather than after failing other therapy. I mean if it really does have a response rate similar to more intensive ara-C doses, which are clearly going to be more toxic in the elderly individual, this would be a much better way to do it.

Yes, it would be for palliative benefit. Is it any better than using hydrea? Yes, if you can get the platelet count up and the patient doesn't need transfusion, even it is a small percentage, it is something we need to weigh the option for.

DR. SCHILSKY: Dr. Blayney.

DR. BLAYNEY: I think this would have a place in the elderly people whom I see that aren't a candidate for mucositis-inducing therapy or for patients who are getting geared up to go to the transplant center either for an unrelated donor transplantation or something like that, or for perhaps for somebody who can be repetitively treated.

We saw an example, and I suspect that is what is going to happen - an older patient with a lot of comorbidity and isn't going to have much of a toxicity with this treatment and can be repetitively palliatively induced.

DR. SCHILSKY: Dr. Lippman.

DR. LIPPMAN: Maybe Dr. Temple can clarify, because we are talking about drugs that were approved in the past, and I am not familiar with those issues, Kathy, but were there drugs approved that there were issues about response criteria, and comparing studies that used different response criteria, historical comparisons with non-protocol patients? Has this been done here before?

DR. TEMPLE: I think the reference was to situations where people had exhausted well-documented therapies, and we were looking at people who were refractory to available therapies.

Studies were then carried out in them that showed a response rate, and there have been a number of drugs approved on that basis alone for refractory disease. That is not quite the situation here.

DR. LIPPMAN: It's very different than what is here.

DR. SCHILSKY: We have a number of questions to consider, and I suggest that we get on with the questions to help focus the discussion a little bit further.

There is some fairly long preambles here, and I am not going to read everything. I think I would like to just read again one statement in the introduction here, which says, "Under subpart H, approval can be based on a surrogate endpoint that is reasonably likely to predict clinical

benefit. For hematologic malignancies, durable complete remissions have been considered as adequate evidence of clinical benefit.

"In this case, however, the duration of responses is difficult to measure because of subsequent antileukemic therapies, including hematopoietic stem cell transplantation. Therefore, complete responses in this application are viewed as surrogate endpoints."

We are then presented with a summary of the response rates that have been presented today, indicating an overall CR plus CRp of about 30 percent in these studies.

Then, on the next page we are presented with the table we have already seen, showing the differences in the Kaplan-Meier estimates of relapse-free survival for the CR's, CRp's, and the overall group, and suggesting that the median relapse-free survival for the CRp's might be slightly less than for the CR's although the numbers of patients are quite small and the differences clearly are not statistically significant at this point.

So, the first question: Is there sufficient evidence to conclude that CRp's are comparable to complete responses and should be considered CR's in terms of efficacy outcomes?

Is there any further discussion on that point before we vote on it? Mr. Flatau.

MR. FLATAU: I think we need more data.

DR. SCHILSKY: We are not going to get any more data right now, so you are going to have to vote based on the information we have at the moment.

So, all who would agree that there is sufficient evidence to conclude that CRp's are comparable to CR's, please raise your hand.

[Show of hands.]

DR. SCHILSKY: Seven yes.

All who would vote no?

[Show of hands.]

DR. SCHILSKY: Four no. And I am actually going to abstain on this because I frankly can't tell.

DR. TEMPLE: I don't think that is the right count. Do that again.

DR. SCHILSKY: I apologize. I think there must have been 5 no.

If you were voting no on this, please raise your hand.

[Show of hands.]

DR. SCHILSKY: Five no. Okay. Seven yes, five no, one abstention.

So, we have a majority that voted yes on that question, I guess.

DR. PAZDUR: Richard, your reason for abstaining?

DR. SCHILSKY: My reason for abstaining, I said is because frankly, I can't tell.

DR. SLEDGE: Doesn't that mean that there is insufficient evidence? I mean I wasn't saying when I voted no that I didn't think they are not comparable. I mean the question, as phrased, was is there sufficient evidence.

MR. FLATAU: That is my position, as well.

DR. SCHILSKY: I can't even tell if there is sufficient evidence.

[Laughter.]

DR. PAZDUR: We will take that into consideration.

DR. SCHILSKY: Question 2. We have a table here again showing response rates and relapsed AML by regimen, comparing gemtuzumab to some other regimens that have been reported in the literature.

So the second question is: Does the committee agree that the efficacy of this product can be satisfactorily judged on the basis of the overall response rate and compared with CR's reported in the literature?

Again, we are being asked if we agree that the efficacy can be judged based on the overall response rate.

Discuss.

DR. ALBAIN: I was just impressed on this issue as I read the slides and heard the discussion, that from the two highest accruers to these trials, that they were seeing

cytogenetic normality, is that correct, from Drs. Appelbaum and Larson, in their subsets, because that to me is what tipped me into accepting these as the best surrogate right now. I just wanted to make sure I heard that right.

DR. LARSON: I could address that for the University of Chicago where we have had a long-standing interest in cytogenetics, all of our complete responders and morphologic responders, that is, the CRp group, had normal cytogenetics.

DR. SCHILSKY: Dr. Simon.

DR. SIMON: I am intending to vote no here because, one, I don't trust these literature comparisons on here. I don't think we should be setting a precedent, if we are, for accepting this kind of data. Thirdly, I think the best evidence we have is that these CR's are not durable and in past cases, the standard has been durable CR's for accelerated approval, and the 23 patients who did not get treated in remission had a median CR duration of two months.

I think we have actually evidence. We don't have to go just by CR rate. We have evidence that these are not durable CR's.

DR. SCHILSKY: Dr. Lippman.

DR. LIPPMAN: Again, this is one of the questions I was trying to clarify before, that the highest accruer centers had about 10 patients, so what I was trying to get

at is how many patients of those went into PCR, and of those how many had cytologic remission. So, you can see that we are talking I think about a very small number that we have data on, that we can say that these PCR's are, in fact, cytologically free of disease.

DR. ALBAIN: Scott, I thought that is what I was trying to clarify with the two highest accruing centers, that they had cytogenetic normality.

DR. APPELBAUM: Nobody uses PCR.

DR. LIPPMAN: CRp. The platelet ones, the ones we are talking about. Of those, how many patients did you have that went into CRp?

DR. APPELBAUM: Oh, CRp, I just know of our total CR's both in the Phase I and in the Phase II data. We did not have a single case where there was cytogenetic evidence of formal disease, when they were morphologically in remission, cytogenetically, they were in remission.

DR. LIPPMAN: I am just trying to get a sense of the number of those patients that went into CRp.

DR. APPELBAUM: I am not sure. I think we probably had three or four.

DR. LIPPMAN: Well, I just heard three, so three patients is what we are talking about.

DR. SCHILSKY: Getting back to this question - Does the committee agree that the efficacy of this product

can be satisfactorily judged on the basis of the overall response rate and compared with CR's reported in the literature?

All who would vote yes on that?

[Show of hands.]

DR. SCHILSKY: Two yes.

All who would vote no?

[Show of hands.]

DR. SCHILSKY: Nine no.

Abstain?

DR. SCHILSKY: One abstention. Something doesn't add up. Either I can't count or you guys don't raise your hands very high.

We have two yes. If you are voting no, please raise your hand again high.

[Show of hands.]

DR. SCHILSKY: All right. Ten no, two yes, one abstention.

Question 3. Does the committee agree that the efficacy of this product in relapsed AML has been shown to be comparable to that of conventional salvage regimens?

Any discussion on that?

All who vote yes?

[Show of hands.]

DR. SCHILSKY: Three yes.

All who would vote no?

[Show of hands.]

DR. SCHILSKY: Ten no. Three yes, ten no. No abstentions. A decisive vote.

On to some questions regarding safety. Again, we are shown a table here, Table 4 of adverse events by regimen, comparing gemtuzumab to three different chemotherapy regimens, and pointing out some differences in toxicity profile. I don't think we need to review those again.

The question is: Does the committee agree that there is sufficient evidence to support a claim of improved safety over conventional salvage chemotherapy regimens?

Discussion on that?

DR. SANTANA: I don't think it is improved safety. I think it is a different safety profile just for point of clarification.

DR. SCHILSKY: Any other discussion?

Again, the question is: is there sufficient evidence to support a claim of improved safety over conventional salvage chemotherapy regimens?

All who would vote yes?

[Show of hands.]

DR. SCHILSKY: Eight yes.

All who would vote no?

[Show of hands.]

DR. SCHILSKY: Three no.

Abstentions?

[Show of hands.]

DR. SCHILSKY: Two abstentions.

DR. BERMAN: Can you clarify, though, that it is a different safety profile? I mean can we modify the question to take into account that it is a different profile?

DR. SCHILSKY: Question 5 now deals with approvability. Does the committee believe that there is sufficient evidence of improved safety and comparable efficacy in patients with relapsed acute myeloid leukemia to support approval of gemtuzumab ozogamicin under the Accelerated Approval regulations? Do you recommend accelerated approval?

Discussion?

DR. NERENSTONE: A question to the FDA. Are we allowed to make recommendations as to which category of patients we think this would be appropriate for, in which case I would propose that we reword that to say in elderly patients or patients who are otherwise not candidates for high-dose aggressive chemotherapy?

DR. SCHILSKY: That is actually Question 7.

DR. PAZDUR: The subsequent question.

DR. NERENSTONE: Except I think maybe Question 5,

how we vote depends on if we are going to limit it.

DR. SCHILSKY: Do you want to discuss limitation at this point or do you want to vote on approvability?

DR. TEMPLE: But you also have to come to grips with your response to Question 3, which said that you can't evaluate it. So, you will have to make all those make sense together.

DR. NERENSTONE: We didn't say we had to be consistent.

[Laughter.]

DR. TEMPLE: We didn't ask that question, you are right.

DR. SCHILSKY: I would suggest that we vote on Question 5 as written, and depending upon that vote, we may or may not need to discuss Question 7.

Mr. Flatau?

MR. FLATAU: I just would like to know what happens if we don't approve it for accelerated approval, what happens in the future.

DR. TEMPLE: Remember advisory committees are advisory committees, so let's presume that we agree. You tell us that, and we agree. We would surely work with the sponsor to think what kind of data they would need to make a more persuasive case. I mean that is a generic answer. Many drugs have not made it the first time through an

advisory committee, and subsequently become available.

DR. BERMAN: Can I just summarize something which I think is important, and that is, for patients with relapsed disease, especially for people over the age of 60, there are not a lot of options out there, and we have been shown data in over 110 patients, 140 patients I think, that this has some efficacy, and while it is on a low end of the scale of efficacy compared to high-dose studies, there is a defined efficacy there.

I think that the toxicity is perhaps less well defined with an eye toward liver toxicity, but I think that adding further studies, which is I think the thrust are more data needed, I doubt that the results are going to change significantly.

DR. SIMON: I guess I would think that if we are thinking about a subset of the patients, the older patients for whom there aren't many other options, you could do a whole lot better job of accumulating evidence, of doing a study of either evaluating or comparing this drug to whatever options would be available, and looking at the results for that targeted group of patients.

Here, we have sort of a real scatter of kinds of patients, and it is very difficult with the historical controls and varied treatments that the patients are going onto, to determine whether this drug contributes anything in

the context of an older group of patients.

DR. BERMAN: Actually, I would disagree. I think the data are there, and I think there was between a 25 and 30 percent overall response rate in patients over the age of 60. Now, as a practicing leukemia doctor, I am not sure I would be enthusiastic about randomizing a patient over the age of 60 to something like high-dose ara-C versus this agent.

DR. SIMON: Well, I mean one would have to say for that targeted group of patients, what would be the appropriate comparison. I think given that you have a response rate that is depending upon how you define it, may range it between 15 and 30 percent, and that the median duration are maintained at two months, I would question whether there really is an ethical issue.

DR. BERMAN: Well, I would argue that this is what all of the other single agent and combination studies have shown, and that this fits well within what is published.

DR. SIMON: Well, I think if we set our standards very low for the kind of data that we are going to use to approve agents, then, that is the kind of data we are going to get.

DR. BERMAN: Well, I don't think it is a matter of setting our standards low. I think this is what the results are. We are not going to be held if the FDA tells us that

we are not going to be held that this will be necessarily the standard therapy for all future trials.

DR. SCHILSKY: Dr. Lippman.

DR. LIPPMAN: I think if I felt confident that this agent, which again the reason I abstained earlier is because of different toxicity profile, not to say better or worse, but different, but even with this toxicity profile, if I felt confident that the rates were comparable, even at the low end of active agents, I might feel differently, but I am not even confident in that based on the kind of comparisons we are using, comparing patients that were treated non-protocol, many other issues, historical. That's my concern.

If your statement is true, and I don't think we can tell based on this data, that it's on the low end of an active drug and the toxicity, then, I think it may have a role.

DR. SCHILSKY: Dr. Temple.

DR. TEMPLE: What I hear the committee having told us in Question 3, was not that they didn't think the drug was adequate or knew that it wouldn't be useful, but that the available data didn't characterize its usefulness adequately. Obviously, there could be disagreement about that.

DR. SCHILSKY: I think that is a fair statement.

Any other discussion?

Question 5 then again: Does the committee believe that there is sufficient evidence of improved safety and comparable efficacy in patients with relapsed AML to support approval under the Accelerated Approval regulations? Do you recommend accelerated approval?

All who would vote yes?

[Show of hands.]

DR. SCHILSKY: Four yes.

All who would vote no?

[Show of hands.]

DR. SCHILSKY: Seven no.

Abstain?

[Show of hands.]

DR. SCHILSKY: Two abstentions.

Four yes, seven no, two abstentions.

Question 6, I think we don't have to discuss because it starts with, "If accelerated approval is recommended."

Question 7. If the answer to Question 5 is no, does the committee agree that sufficient evidence of improved safety and comparable efficacy has been demonstrated in a subgroup of patients with relapsed acute leukemia to support approval?

Then, we are referred to two tables on the

following page that give us some breakdown of remission rates versus duration of first CR in Table 5, and remission rates versus age in Table 6.

I want to point out to the committee that there is a typographical error in Table 6, which if you look at the bottom row of Table 6 for the gemtuzumab outline, what it should say is that the CR rate is 18 percent with confidence intervals of 9 to 31 percent, and the CR plus CRp is 34 percent with confidence intervals of 21 to 49 percent.

In the next box over for patients 60 and older, the CR rate is 17 percent with confidence intervals of 8 to 29 percent, and the CR plus CRp is 28 percent with confidence intervals of 16 to 42 percent. Just to be sure that we are looking at the complete information.

It would not appear that there are great differences here based on duration of first response, although there may be differences based on age group.

Since we have heard a lot of discussion from people on the committee, as well as the sponsor and others, about maybe this is the drug to give to older patients with AML, now is the opportunity to discuss that a little bit further.

Is this the drug to give for an older group of patients? Dr. Kelsen.

DR. KELSEN: Does that mean that we would then

have the opportunity to approve it for a specific indication or for accelerated approval for a specific subgroup?

DR. PAZDUR: Yes, and that would be reflected in the labeling.

DR. KELSEN: I think the discussion--I am not a leukemia doctor either--but what I have heard today is that for that targeted subgroup, the options for further therapy are very limited, and they are not the kind of people you give very high-dose intense therapy to, and there isn't a good comparator arm that could leap to your mind, Ellin, as I was listening, and if that is correct, I would think that this is a very reasonable thing to do.

DR. SCHILSKY: So, presumably the indication would be for patients 60 years and older with relapsed AML.

DR. TEMPLE: Just to be sure, you have to explain how whatever answer you give here is consistent with the answer to No. 3, and I guess I would take note of the fact that there are response rates from the literature using something. So, apparently, old people were given something, and those are the response rates there.

So, while you are thinking about this, you need to explain, so we will understand.

DR. SCHILSKY: Dr. Lippman.

DR. LIPPMAN: Unless we are all comfortable potentially telling patients that yes, we have maybe a less

toxic or different toxicity program, elderly patients, but less effective, less active, if that is what we are doing, then, I feel more comfortable, but if we are really comparing again to the literature, I would like to see in this older group, as Dr. Simon mentioned, even the comparisons that we have, what the other criteria, what the other characteristics were of the older groups in these studies.

I am just very concerned about the comparisons and somehow writing off the older patients as not being able to be treated more aggressively, because they have been, and we have seen the results.

DR. BERMAN: Well, they have been, but those are very selected patients who are felt that they can tolerate high-dose therapy, and actually there is no denominator to know how many patients over the age of 60 are offered supportive care in any group of 1,000 patients and how many patients are actually offered therapy.

So, I am not sure why you are quite so dismissive of the literature.

DR. LIPPMAN: I guess I would like to see those data and get some sense of that. I mean if the focus is on this group of elderly patients, then, I would like to see more data from the literature, more discussion of that point in the presentation.

DR. SCHILSKY: Well, you are not going to see any more data today.

DR. LIPPMAN: Right, and that is to answer the question of why I am dismissive of that. That is the reason is I am just not comfortable I have seen enough data to feel confident about it.

DR. SCHILSKY: Dr. Przepiorka?

DR. PRZEPIORKA: I am questioning whether or not those are actually patients put on studies, as well. I am wondering if these are not retrospective reviews rather than prospective studies, and were not quite as selected as we are thinking they are, and I am not certain that we should assume that those were selective patients rather than unselective patients.

I am concerned that the safety data presented was safety data for all patients, not safety data for patients over the age of 60, and so although overall the safety profile looks to be improved, I am not certain that I heard that it was actually also improved in the elderly individuals.

However, I think overall it would look great if it really were that true.

DR. SCHILSKY: Would you feel comfortable using this treatment for a 65-year-old patient with relapsed AML?

DR. PRZEPIORKA: I think that will come up in my

vote.

[Laughter.]

DR. SCHILSKY: Dr. Nerenstone.

DR. NERENSTONE: As a practicing oncologist, we make the decision all the time with the patient whether to trade a drug with less toxicity or different toxicity profile with response rate, and I see this as giving the hematologist another weapon in their armamentarium to present to a patient.

I am very struck by the mucositis data. I mean these patients, Grade 3 and 4 mucositis in a leukemic, their whole GI tract sloughs, and it is very distressing to the patient, they are often in the hospital, they are getting TPN, they get infected, they get febrile, they get septic, they are very sick, and the fact that that toxicity may be traded for other toxicities is still I think an important tradeoff that the physician and the patient will have the opportunity to decide.

DR. BERMAN: I would agree with that. I think that it is wrong to probably discriminate by age, because I think if this, in fact, with larger numbers, proves to be a more successful agent, that is going to get out there, and I think the market, so to speak, will bring this to bear.

I don't think that if in the end it proves not to be effective, then it not going to be used, but I don't

think it should be denied the patients who are 59 years old, the opportunity to have this as an option.

DR. SCHILSKY: I think we have already voted about that.

DR. LIPPMAN: I guess if we could put in the approval, just not to confuse the doctors in the community who are treating, that the toxicity profile we think may be better, less mucositis, and so on, but we are not sure if the activity is equivalent to what is out there, so they could decide, as you mentioned, so that doctors could decide if they want to trade that off, then, I think that is another issue, but if we label this as feeling confident that it's equivalent based on the data we have, I have concerns with that.

DR. SCHILSKY: I think, generally speaking, the agency hears these discussions, and if we were to come up with a category of patients for whom we thought approval was appropriate, then, they would probably be able to work with the sponsor to develop appropriate language.

DR. PAZDUR: Could you also help us, maybe the leukemia doctors, help us characterize what is it about the age group here that makes it at higher risk, is it because we are comparing it to comorbid illnesses in this patient population?

Specifically, if we are going to label something

on an age basis, is there any better handle we could have about this? If they got less toxic therapy, but the same drugs that we are using, would that be another situation that we could be looking at, a conventional agent?

Can you give us a better handle of the problem with age here?

DR. BERMAN: I think there are two. First of all, older people just don't survive the regimen because of the high risk of infection or other comorbid problems, but the second is their leukemia tends to be more resistant because they have a higher incidence of unfavorable cytogenetics.

DR. PAZDUR: So, it is inherent in the disease.

DR. SCHILSKY: Let me suggest that we vote on the following question: Does the committee agree that sufficient evidence of improved safety and comparable efficacy has been demonstrated in patients 60 years of age or older with relapsed AML?

That is a paraphrase of adding Question 5 to adding Question 7. So, I would read it again.

Does the committee agree that sufficient evidence of improved safety and comparable efficacy has been demonstrated in patients 60 years of age or older with relapsed AML?

DR. SANTANA: I must point out that we have not been presented any safety data using this apparent

dichotomy, so just a point of comment.

DR. SCHILSKY: Are you saying that you don't want to vote on this particular question or are you indicating how you would vote on it?

DR. SANTANA: We are making up a question, but part of the data has been presented, but the other part we haven't been presented that same way, the age criteria.

DR. PAZDUR: Sufficient data for the question, so if there is not sufficient data--

DR. SCHILSKY: The question says, "Does the committee agree that sufficient evidence of improved safety and comparable efficacy has been demonstrated?"

Dr. Albain.

DR. ALBAIN: I am just concerned with making this 60 dichotomy here. I think that we are all sensing that there is a group of patients with comorbidities for whom a well-intentioned practicing physician is going to look at and say I am not going to give high-dose ara-C, too, I am not going to do all the things that will result in what Dr. Nerenstone just described.

I think we need to leave some room here for the judgment of the primary caregiver, and there is going to be a 55-year-old with bad diabetes and hypertension and other things that you also might want to consider.

Also, that group about bridging into transplant

was another one we haven't brought up here that I think is worth discussing.

DR. SCHILSKY: Let me remind you that, first, we have already voted against approvability in general.

DR. ALBAIN: For a subgroup of patients, as worded. I am proposing another subgroup of patients.

DR. SCHILSKY: What subgroup would you be proposing, whatever group the doctor feels like he wants to treat with this? Is that your subgroup?

DR. ALBAIN: No, patients with comorbidities for whom more aggressive reinduction therapies are not indicated, and that subgroup that may need a bridging agent into high-dose therapy. Those are the two subgroups that I have heard as being potentially attractive for this agent.

DR. SCHILSKY: Dr. Nerenstone.

DR. NERENSTONE: Just a point of clarification. In the briefing documents that the sponsor gave to us, page 73 discusses the fact that effective age was looked at on side effects, and that there were no differences age less than 60 or age greater than or equal to 60.

Remember that their third study looked exclusively at the older patient population. So, the data is gone into in quite some detail over those next few pages. So, I do think we do have the data to look at age, and it does not look to be more toxic in the older patients.

DR. BLAYNEY: And their Slide 15 showed there is no difference in early deaths greater than 60 and less than 60.

DR. BERMAN: The other is that, as Dr. Albain said, if we begin to pick out subgroups less than 60 for whom it may be appropriate, then, why not just leave it as approvable regardless of specific age groups.

DR. SCHILSKY: Dr. Temple.

DR. TEMPLE: We need to understand the logic of this. If it is necessary to know that efficacy is comparable, you have told us in vote on 5 that you didn't think you could know from the available literature.

An alternative theory for approval is that it doesn't make any difference how it compares with other therapy as long as in some sense it works at least a little, but you need to be explicit in telling us what you think about that. Otherwise, the answers won't look like they make sense together.

DR. SCHILSKY: My own sense from hearing the discussion at least is that many of the leukemia doctors would feel--and I won't speak for my colleagues around the table, but I will--that many patients with relapsed AML who are in the over age 60 group are not good candidates for aggressive chemotherapy, don't tolerate it well, do tend to have poor outcomes from it, and that this is an agent that,

as best as we can tell from the available information, seems to have a different, perhaps more favorable toxicity profile and appears to produce outcomes that are no worse than what one might expect with giving those people chemotherapy.

DR. TEMPLE: You just voted on that, and what you said was you can't tell on the outcomes.

DR. SCHILSKY: For the population overall.

DR. TEMPLE: I guess I would submit that what you are really saying is it obviously gives you some responses, there is no doubt about that, you can see them, and that it doesn't matter whether it is comparable to aggressive chemotherapy because you don't want to give that therapy to these people.

DR. SCHILSKY: Well, I think that is another valid way of looking at it, and I will ask Dr. Berman and Dr. Przepiorka if you would accept that, Dr. Temple's notion.

DR. PRZEPIORKA: I would feel comfortable answering a question that was worded is there sufficient evidence of improved safety and acceptable efficacy as opposed to a comparable efficacy.

DR. BERMAN: I would agree with that.

DR. SCHILSKY: In the group of 60 years and older with relapsed AML. Would that help reconcile the vote for you?

DR. TEMPLE: Yes. I mean that is logically

consistent. I mean you could say both of things together, I think.

DR. SCHILSKY: Dr. Albain.

DR. ALBAIN: Rich, why are you focusing on 60? I am still troubled by that. Why couldn't the question leave the age out, because you have got the patients with great comorbidities who are younger than 60?

DR. SCHILSKY: If you leave the age out, then, it is the same question as Question 5, and there are no other particular groups of individuals that we have heard any data on at all.

Personally, I don't know what you mean by comorbidities. We all could conjure up what comorbidities might be, but which comorbidities are important? Would you want to give this to a 55-year-old with osteoarthritis?

DR. ALBAIN: I think leukemia experts frequently answer this in their practice every day, and I don't know that we could resolve this around the table at this minute, but I think there is enough of the literature that this type of a grouping could be described in more detail, you know whether there is drug efflux in the leukemic cells, too. There is a growing literature from South West Oncology Group that documents, not age per se, as it is the drug efflux system that seems to be more out of whack in this older group.

DR. BERMAN: I don't think it is up to the FDA to kind of say, well, it should be used for this comorbidity and not that comorbidity. I think it should be available, so the practicing physician can make that decision under the rubric of clinical judgment.

DR. PAZDUR: With the existing data that we have, we would be unable to label around existing comorbidities, et cetera. We have seen an analysis on age here, which does make some sense to us to consider.

DR. BERMAN: And it showed no difference.

DR. SCHILSKY: Dr. Temple.

DR. TEMPLE: There is a general injunction that drugs that appear are supposed to have adequate directions for use, which generally means you are supposed to be able to characterize their value, and things like that.

We do not just, as a rule, put something out because it has activity, because, you know, you know that within the first few patients. So, this may be well characterized, sufficiently characterized, I am not trying to make that judgment, but the mere existence of activity is not usually considered sufficient.

You want to be able to tell somebody something about how it is going to work, how it compares with other therapies, if that is relevant, and things like that.

DR. SIMON: But here, all you do have is an

evidence of activity. You have a response rate and you either have no duration of response or the duration you view as very short.

DR. TEMPLE: I am not trying to make a judgment about that. You have responses, they have a duration, and it is up to people who know about these things to tell us whether they think that is worth anything.

DR. SCHILSKY: Dr. Lippman.

DR. LIPPMAN: To vote on changing it again to acceptable activity confuses me, because what we are really saying, and what I said before, was that it has activity, but we are not confident that it's equivalent to what's out there, and I think if we just use the term "acceptable," I am not sure that that helps accomplish what we want.

Some people could interpret acceptable as being comparable.

DR. SIMON: We are not really even sure that that activity is clinically meaningful to the patient. The patient may be better off without treatment if we are talking about patients who are really not candidates for cytotoxic chemotherapy.

Those patients may be better off getting nothing than getting this drug given what we know about the limited durability of these responses.

DR. BERMAN: I don't think that is so. I just

don't think that is a fact.

DR. SIMON: Well, I think we have to distinguish wanting to have something to treat patients with from being able to get evidence as to whether the drugs really benefit the patients.

DR. BERMAN: And that is a Phase III question. That is a randomized trial to look at this versus no further therapy.

DR. SIMON: And this is for approval.

DR. BERMAN: But that doesn't mean that it shouldn't be approved at this stage.

DR. SIMON: We usually require evidence of clinical benefit or something that we really believe looks like it.

DR. BERMAN: Well, and we have seen that when you compare it, when the company has shown on the graph that this falls on the low end of the scale of response, but there is a defined response.

DR. SIMON: It seems to me like where we are basically is we have activity, we have nothing more, the responses aren't durable, and we are trying to come up with some rationale for just making the drug available without any real evidence of benefit.

DR. BERMAN: Well, not to just get in the last word, but--[laughter]--the survival with any kind of

chemotherapy, once you relapse with this disease, there is no more than four months with any form of high-dose therapy with the exception of transplant.

DR. SCHILSKY: I think we have had adequate discussion on a variety of issues here, and if it is agreeable to the agency, I might propose that we take a vote on the following question: Does the committee agree that sufficient evidence of improved safety and acceptable efficacy has been demonstrated in patients 60 years of age and older with relapsed AML?

Would that be useful for you if we voted on that question?

DR. TEMPLE: We listened, we heard the rest of the discussion, too.

DR. SCHILSKY: So, that is the question.

If there is sufficient evidence of improved safety and acceptable efficacy in patients 60 and older with relapsed AML, all who would vote yes, please raise your hand.

[Show of hands.]

DR. SCHILSKY: Twelve, I think.

All who would vote no?

[Show of hands.]

DR. SCHILSKY: I must have miscounted again. We have two no.

All who would vote yes, please raise your hands again.

[Show of hands.]

DR. SCHILSKY: Eleven yes.

So, it is eleven yes and two no.

Okay. That concludes our proceedings. Thank you very much.

[Whereupon, at 12:20 p.m., the proceedings were concluded.]

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CERTIFICATE

I, **ALICE TOIGO,** the Official Court Reporter for Miller Reporting Company, Inc., hereby certify that I recorded the foregoing proceedings; that the proceedings have been reduced to typewriting by me, or under my direction and that the foregoing transcript is a correct and accurate record of the proceedings to the best of my knowledge, ability and belief.

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