From: Jim Welsh
Sent: Wednesday, December 17, 2008 10:47 PM
To: Ashley Tull; Cindy Flannery; Christian Einberg; Robert Lewis; Eggli, Douglas; Fisher, Darrell Gilley, Debbie; Lieto, Ralph; Malmud, Leon; Mattmuller, Steve; Nag, Subir; Suleiman, Orhan Bruce Thomadsen; Van Decker, William; Vetter, Richard
Subject: RE: INFO: NRC ACMUI teleconference participant list

Dear ACMUI and NRC Staff

Due to a change in flight schedule I will not be able to participate in tomorrow's teleconference. This is unfortunate and I apologize. It is unfortunate because I understand that the Neovista vote went in a direction that I would not have personally endorsed and once again I am unable to voice my opinions and concerns. I trust that my radiation oncologist colleague Dr Nag will be able to voice some concerns that I believe many in the field share.

I remain unconvinced by the presentations at our last ACMUI meeting by the Neovista rep and the retinal specialist that it would not benefit patients by having a radiation medicine specialist somehow involved. (Although we are now frequently called "radiation oncologists" rather than the older term "therapeutic radiologists" because the vast majority of what we now do is cancer-related, the term "radiation medicine specialist" may be more appropriate since a good deal of what many of us do relates to non-malignant conditions). I have heard the argument that to get the radiation medicine physician involved would be too cumbersome and would significantly slow down the process. Not true if the radiation specialist is not directly involved in the actual procedure. Assuming the AU does not have to be physically present (as is now the case in Y-90 microsphere therapy), why not take advantage of that individual's years of training and experience in radiation medicine? It may be true that "one size fits all" with this treatment for now but what if the data suggests that some patients might benefit from doses that differ from others? Not unreasonable since this is the case with just about *everything* else in medicine. If or when this happens, there will be judgments made about patient-specific dosing – just what a radiation oncologist does every day. What will happen if we learn that a different dosimetric margin than the current standard is needed in certain situations? How will the one-size-fits-all policy work then? Will we be right back here debating this? Or will we have opened the door already for retinal surgeons to be deciding patient specific doses and margins? Although there are some analogies between this new therapy and Sr-90 eye applicators for pterygium, there are significant differences. I agree with Dr Nag that this is more akin to eye plaque therapy for melanoma than it is to superficial Sr-90 therapy.

Again, if the AU does not have to be directly involved in the actual treatment delivery, there would be no reason to believe there will be any slowdown that would adversely affect patients in need, as has been claimed by Neovista. I personally am not in favor of insiting that a radiation oncologist AU has to be physically present and directly involoved in these cases. No radiation oncologist would want to be playing the role of the retinal specialist and manipulating the applicator over the diseased area on the retina. This requires a great deal of experience and skill, skill that comes from years of retinal surgery training. But why would the retinal surgeon wish to assume the role of the radiation specialist? This may not be extremely complicated or high-risk treatment from a radiation safety perspective but again, why not take advantage of the fact that there are ample physicians already trained and well versed in radiation safety matters who could serve as consultants and authorized users of record, instead of trying to train retinal surgeons in the nuances of radiation medicine? Conversely, patients will likely benefit from the fact that a specialist with years of training and experience in radiation medicine has consulted on the case and will serve as authorized user.

Finally the fact that Neovista has already launched this trial before consulting with ACMUI and NRC is concerning as this is after all, an application of byproduct material and probably should have been discussed with NRC and ACMUI before rather than after initiation. This does bother me if it has happened this way although it has no bearing on my above discussion.

Jim Welsh