



International Rare Cancers Initiative (IRCI) Metastatic Anal Cancer group – ASCO meeting MINUTES

Friday 29th May 2015 at 3:30 – 5:30 pm (local Chicago time time)

Location – Hyatt Chicago Hotel, 151 East Wacker Dr, Chicago, IL

Chair: Al Benson

Attendees: Al Benson, Randy Ernst, Lakshmi Rajdev, Paulo Hoff, Lisa Kachnic, Richard Adams, Rob Glynne-Jones, Matt Seymour, Amitesh Roy, Eva Segelov, Vera Gorbunova, Carlo Aschele, Andrea Mc Connell, Elisabeth Dupont

Al Benson (AB) welcomed everyone to the meeting. All participants briefly introduced themselves.

The minutes of the meeting held alongside GI ASCO 2015 were approved unanimously.

Update on the InterAACT trial: A Phase II International Multicentre Randomised Advanced Anal Cancer Trial Comparing Cisplatin plus 5FU vs. Carboplatin plus Weekly Paclitaxel in Patients with Relapsed or Metastatic disease

20 patients on the study – 20 sites open (19 in the UK and 1 in Norway) – 1st patient from Norway has been accrued. List of open sites and patient recruitment numbers in the attached presentation (Appendix 1).
15 out of the 20 patients have signed up for translational work

Sites near to opening: 3 additional sites in the UK, 1 site in Denmark and 6 sites in Australia with AGITG sponsorship

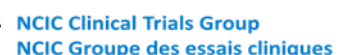
Sites currently in set up: 9 more sites in the UK, US sites with ECOG-ACRIN sponsorship, 12 sites in Europe with EORTC coordination (4 in France, 5 in Germany and 2 in Portugal).

Al Benson advised that in the US the response to the NCI has just been completed and they hope that this response will be the final step.

Carlo Aschele advised that the study was presented to the group at the last STAR meeting in November and 30 out of the 51 members were interested in joining the study but that there were some financial issues as funding would be needed to cover some initial costs such as translation and submission to the ethical committee. Actual costs of running the trial would not be an issue.

This financial problem was echoed by Paolo Hoff. With some initial funding to cover these administrative costs, centers in Brazil would have been able to join the study.

In Australia, the study is still under review by the ethical committee. It is hoped that ethical approval will be obtained soon. The next step would be to activate the lead site. Contracts are being worked out and it is anticipated that the first site will be activated in the next 2/3 months. 5 sites have agreed to join. The 6th one





is under negotiation.

Additional discussion were held about:

- 1- Ways to avoid issues faced with CTEP for the next trial to be proposed:
 - Early buy-in from NCI with the concept
 - Joint CTAAC & NCI Steering Committee review pilot
 - Guidance document on how to approach new concepts in each participating region – “Tool kit” for IRCI trials

- 2- Funding needs for some countries to activate the centers (admin work, translation and ethical review)

These two issues will be brought to the Cross Leads Meeting for consideration.

International Coordination of localized anal trials

- Update on the US locally advanced vaccine trial (see attached slides – Appendix 2)
- Update on ACT3, ACT4 and ACT5 (PLATO) (see attached slides – Appendix 3)

International engagement for ACT 4 and ACT 5 has been very helpful. ACT3 is not looking for an international component but there would be room for international component in ACT4 and ACT5.

The issue of data sharing was briefly discussed.

Eva Segolov mentioned that there is a need for consumer representation on the group. Lakshmi Radjev advised that AMC has experienced patient advocates who are very much involved in their group and will discuss whether one of them would be willing to become a member of the IRCI metastatic anal cancer group. Questions were raised about funding for travel of patient advocates to participate in the meetings. Al Benson mentioned that NCI might be asked whether they would be willing to provide that support.

Subgroups activities

Anal Staging Consensus Subgroup (RA)

Making some progress

Template for reporting has been created in the UK

Web-based platform to be created to report on images & feedback centrally

AB asked whether an outline/some conclusions could be submitted to AJCC so that they could consider including a statement on anal staging consensus produced by the IRCI metastatic anal cancer group.

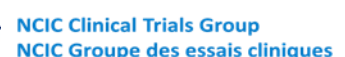
Database/Endpoint (RA)

Little progress made since the last meeting.

Surveillance (RA)

A survey has been circulated and 78 results have already been received, mainly from the US and Australia.

Richard Adams will circulate the survey more widely in the UK, Carlos Aschele in Italy and Paulo Hoff in Brazil and in other Latin American countries.





Agreement of time and place of next group

The next meeting will be held alongside GI ASCO 2016 in San Francisco.

Action items

Matt Seymour:	to report at the cross leads meeting on the funding needs for some countries to activate the survey & on the need for some guidance document on how to approach new concepts [Actioned]
Lakshmi Rajdev:	to discuss with AMC patient advocates for possible participation in the IRCI anal metastatic cancer group
Al Benson/E. Dupont:	to ask NCI whether some funding would be available to support participation of a patient advocate in meetings of the IRCI anal metastatic cancer group
E. Dupont, Carlo Aschele & Paulo Hoff	To send the link of the Surveillance Survey to Carlo Aschele for distribution in Italy and to Paulo Hoff for distribution in Brazil and other LA countries
Richard Adams	to provide an outline (anal staging consensus) to Al Benson for AJCC as soon as possible
Al Benson	to present the anal staging consensus outline to the AJCC editorial board

