

Please read on for an update on the key highlights and achievements for each of the IRCI rare cancer groups over the last 6 months. A big thank you to all those involved for their continued hard work and enthusiasm in driving forward the progress of this initiative.

## IRCI Relapsed/metastatic anal cancer group



*InterAACT:* This study has now opened in the UK and the first patient has been recruited. The protocol has been submitted to the EORTC PRC for approval, the outcome of which is due imminently. The US cooperative group ECOG are currently in the process of preparing a submission to the NCI-CTEP. The AGITG GI Working group and Scientific Advisory Committee has agreed to participate in the study with an application for funding planned later this year.

## IRCI Ocular melanoma group



*A randomised two-arm phase II study of Trametinib alone and in combination with GSK214795 in patients with advanced uveal melanoma:* This trial has recruited 8 patients in the US. Submissions to Regulatory Authorities in mainland Europe and the UK will commence imminently. The investigators, along with GSK, are continuing to work on an exciting translational research plan to compliment the trial.

## IRCI Small bowel adenocarcinoma group



*The BALLAD study:* Glasgow CTU is close to finalisation of the protocol, which will then be shared with the collaborators. The French Ministry of Health has approved funding for this study and there is continued interest from the US, Japan, Australia, Canada and other individual European sites to join the trial. *Metastatic study:* A proposal for an international trial in patients with metastatic small bowel adenocarcinoma is currently in development.

## IRCI Desmoplastic Small Round Cell Tumour (DSRCT) group



Following a small DSRCT Working Group meeting held alongside the ECCO 2013 Annual Meeting, a study outline is in the process of being drafted with the intention to present this to the wider DSRCT alongside an international conference such as ESMO or CTOS later this year.

## IRCI Gynaecological sarcoma group



*uLMS:* This study has recruited 10 patients in the US. Local Regulatory Authority and local Research and Development departments approvals are currently underway in mainland Europe and the UK respectively, with France and Glasgow due to open imminently. *HGUS:* The EORTC PRC has now approved the protocol, and submissions to Regulatory Authorities are due to commence in mainland Europe and the UK. The GOG are currently addressing operational aspects of opening the trial in the US ahead of submission to CTEP. *ESS:* Following further discussion between the chief investigators regarding the study design, an amended outline was submitted to the EORTC PRC and approved. The EORTC is currently working on the protocol in collaboration with the international investigators.

## IRCI Salivary cancer group



*A randomised phase II study to evaluate the efficacy and safety of chemotherapy vs. androgen deprivation therapy in patients with recurrent and/or metastatic, androgen receptor expressing, salivary gland cancer:* The EORTC PRC has now approved the protocol, and submissions to Regulatory Authorities have commenced in mainland Europe. The study is also currently in set up in the UK. The Alliance co-operative group has submitted a Letter of Intent to NCI-CTEP for review, the outcome of which is due imminently.

## IRCI Penile cancer group



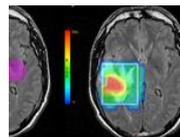
*InPACT:* The protocol for this study is currently in development with the aim of submitting for Regulatory Authority approvals in quarter four 2014. The aim is to work towards opening to recruitment in November 2014. The proposal is due to be reviewed by the ECOG GU Steering Committee ahead of submission to NCI-CTEP. The EORTC Headquarters has kindly agreed to assist the ICR with European site selection and set-up.

## IRCI Thymoma group



*Randomised phase 3 study of resected stage III Invasive thymoma with or without postoperative radiation therapy:* Following feedback from NCI-CTEP, the ECOG co-operative group is planning to resubmit a Letter of Intent to CTEP for review. The EORTC Board will also review the updated Letter of Intent, and an application to PRC and CTAAAC will proceed. The trial has also been approved for participation by the French Intergroup.

## IRCI Rare brain tumour group



This group is currently discussing international collaboration for patients with Anaplastic meningioma (potentially a randomised trial of trabectedin, and/or a trial using smoothed and AKT1 inhibitors) and Adult medulloblastoma (a proposal is currently in development by Martin McCabe and Gillian Whitfield). The group plan to meet alongside ASCO to further discuss.

### IRCI Cross Lead meeting alongside ASCO 2014:

This year we are bringing together the leads of each of the IRCI groups/trials for a meeting alongside ASCO to discuss the progress of the initiative to date, and to share common challenges and solutions. We look forward to sharing some of the key outputs from this meeting with you late this year in the IRCI 3-year report.

## IRCI Small bowel adenocarcinoma group

*The BALLAD study: A global study to evaluate the potential benefit of adjuvant chemotherapy for small bowel adenocarcinoma (IRCI 002)*

Chief Investigator: Dr Richard Wilson - Belfast/ Dr Jeff Evans- Beatson

Lead co-ordinating centre: Glasgow CTU

US Lead: Dr Rob McWilliams - Mayo Clinic

Australian Lead: Professor David Goldstein - Prince of Wales Clinical Centre

Japan Lead: Kenichi Nakamura - National Cancer Centre

*Metastatic study- name tbc*

Chief Investigator: Dr Rob McWilliams - Mayo Clinic

Lead co-ordinating centre: Mayo Clinic

UK Lead: Dr Richard Wilson - Belfast

EU Lead: Dr Arnaud Roth - Hopitaux Universitaires de Geneve

## IRCI Relapsed/metastatic anal cancer group

*InterAACT: 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 (IRCI 003)*

Chief Investigator: Dr Sheela Rao - Royal Marsden

Lead co-ordinating centre: Royal Marsden CTU

US Lead: Dr Cathy Eng - MD Anderson

EU Lead: Professor Dirk Arnold - Arcor

## IRCI Salivary cancer group

*A randomised phase II study to evaluate the efficacy and safety of chemotherapy vs. androgen deprivation therapy in patients with recurrent and/or metastatic, androgen receptor expressing, salivary gland cancer (IRCI 007)*

Chief Investigator: Dr Lisa Licitra - Istituto Nazionale dei Tumori Milan

Lead co-ordinating centre: EORTC

UK Lead: Dr Kevin Harrington - ICR

US Lead: Dr Alan Ho - MSKCC

## IRCI Penile cancer group

*InPACT – International Penile Advanced Cancer Trial (IRCI 004)*

Chief investigator: Dr Steve Nicholson - Charing Cross

Lead co-ordinating centre: ICR CTU

US Lead: Dr Curtis Pettaway - MD Anderson

## IRCI Rare brain tumour group

UK Lead: Dr Colin Watts - Cambridge

US Lead: Dr Eva Galanis- Mayo Clinic

EU Lead: Dr Wolfgang Wick - Heidelberg

## IRCI Ocular melanoma group

*A randomised phase two-arm phase II study of Trametinib alone and in combination with GSK214795 in patients with advanced uveal melanoma (IRCI 005)*

Chief Investigator: Dr Rich Carvajal - MSKCC

Lead co-ordinating centre: MSKCC

UK Lead: Dr Ernie Marshall - Clatterbridge

EU mainland lead: Dr Serge Leyvraz - CHUV

## IRCI Gynaecological sarcoma group

*HGUS: A randomised phase II study evaluating the role of maintenance therapy with Cabozantinib in High Grade Uterine Sarcoma (HGUS) after stabilisation or response to chemotherapy following surgery or in metastatic first line treatment (IRCI 006)*

Chief Investigator: Dr Isabelle Ray-Coquard - Léon Bérard Cancer Center

Lead co-ordinating centre: EORTC

UK Lead: Dr Helena Earl - Cambridge

US Lead: Dr Martee Hensley - MSKCC

*uLMS: A phase III randomised trial of gemcitabine plus docetaxel followed by doxorubicin versus observation for uterus-limited, high grade uterine leiomyosarcoma (IRCI 001)*

Chief Investigator: Dr Martee Hensley - MSKCC

Lead co-ordinating centre: GOG

UK Lead: Dr Helen Hatcher - Cambridge

EU Lead: Professor Jean Yves Blay - Léon Bérard Cancer Center/Petronella Ottevanger (EU, Radboud University Medical Center Nijmegen)

*ESS: Efficacy of aromatase inhibitors in stage III-IV or recurrent endometrial stromal sarcoma: a phase II trial*

Chief Investigator: Dr Frederic Amant - U.Z. Leuven,

Lead co-ordinating centre: EORTC

UK Lead: Dr Helena Earl - Cambridge

US Lead: Dr Martee Hensley - MSKCC

## IRCI Thymoma group

*PORT: Randomised phase 3 study of resected stage III Invasive thymoma with or without postoperative radiation therapy*

Chief Investigator: Dr Heather Wakelee - Stanford University

Lead co-ordinating centre: ECOG

UK lead: Professor Mike Lind - Hull

EU Lead: Dr Sanjay Popat - Imperial

## IRCI Desmoplastic Small Round Cell Tumour (DSRCT) group

UK Lead: Dr Jeremy Whelan- University College London

US Lead: Dr Paul Meyers/ Richard Gorlick- MSKCC/Einstein

EU Lead: Dr Wynette Van der Graaf – UMC St Radboud