

## Welcome to the first issue of the IRCI Update!

We hope that all IRCI investigators have had an enjoyable summer break! The IRCI Board thought that it may be of interest to you all to receive a brief update on the progress of each of the IRCI rare cancer groups. This is not intended to be an exhaustive list of all of the activities of each of the groups, but a highlight of key achievements to date. Additionally, the IRCI Board would like to inform you that the IRCI website has recently gone live – [www.irci.info](http://www.irci.info). It is in early stages of development and will be amended and improved over the coming months. We would like to thank you all for your hard work and enthusiasm to date and to encourage you all to continue efforts in the hope of seeing progress in the development of IRCI trials during the latter part of 2012.

## IRCI Gynaecological sarcoma group - 1<sup>st</sup> IRCI study open to recruitment!!!



*A phase III randomised trial of gemcitabine plus docetaxel followed by doxorubicin versus observation for uterus-limited, high grade uterine leiomyosarcoma (IRCI 001)* - This IRCI study is led by Dr Martee Hensley (MSKCC) and co-ordinated by GOG. It opened to recruitment at the MSKCC early in September. 42 sites in the US have submitted IRB approvals. Dr Hensley has already given out a patient consent form so it is hoped that the first patient will be recruited to this study imminently. The study is currently being processed by the EORTC and Glasgow Clinical Trials Unit.

*A randomized phase II study evaluating the role of maintenance therapy with pazopanib in High Grade Uterine Sarcoma (HGUS) after stabilization or response to chemotherapy following surgery or in metastatic first line treatment* - This IRCI study is led by Dr Isabelle Ray- Coquard (Léon Bérard Cancer Center) and co-ordinated by the EORTC. The study has received approval from the EORTC and the EORTC are currently developing a study protocol and are in negotiations with Pharma about this study. Once a study drug has been secured the study will progress in the UK and the US.

*Efficacy of aromatase inhibitors in stage III-IV or recurrent endometrial stromal sarcoma: a phase II trial* - This IRCI study is led by Dr Frederic Amant (U.Z. Leuven, Belgium) and coordinated by EORTC. The study outline has been endorsed by EORTC PRC, and EORTC is currently developing the protocol and negotiating with Pharma on drug support.

## IRCI Small bowel adenocarcinoma group



*The BALLAD study: A global study to evaluate the potential benefit of adjuvant chemotherapy for small bowel adenocarcinoma* – This IRCI study is led by Dr Richard Wilson (Queen’s University Belfast) and co-ordinated by Glasgow Clinical Trials Unit. It has received preliminary approval in the UK and will be considered for final approval in November 2012.

## IRCI Salivary gland cancer group



*A randomised phase II study to evaluate the efficacy and safety of Chemotherapy (CT) versus androgen deprivation therapy (ADT) in patients with recurrent and/or metastatic, androgen receptor (AR) expressing, salivary gland cancer (SGCs)* – This study is led by Dr Lisa Licitra (Istituto Nazionale dei Tumori Milan) and co-ordinated by the EORTC. The study has received approval by the EORTC and the EORTC are in the process of securing a drug supply and developing a study protocol.

## IRCI Relapsed/metastatic anal cancer group



*InterAAct: A Phase II International Multicentre Randomized Advanced Anal Cancer Trial Comparing Cisplatin plus 5FU vs. Carboplatin plus Weekly Paclitaxel in Patients with Relapsed or Metastatic Disease* – This IRCI study is led by Dr Sheela Rao (Royal Marsden Hospital) and co-ordinated by the Royal Marsden Clinical Trials Unit. Dr Rao has submitted the study for review in the UK in November 2012.

## IRCI Penile cancer group



*INPACT – International Penile Advanced Cancer Trial* – This IRCI study is led by Dr Steve Nicholson (University of Leicester) and co-ordinated by the Institute of Cancer Research Clinical Trials and Statistics Unit. It has received preliminary approval in the UK and will be considered for final approval in March 2013. Dr Curtis Pettaway (MD Anderson Cancer Centre) is actively trying to identify a US co-operative group to play a lead role in this study in the US.

## IRCI Thymoma group



*Randomized Study of Resected Stage III Invasive Thymoma or Stage II –III Thymic Carcinoma with or without Postoperative Radiation Therapy* – This IRCI study is led by Dr Heather Wakelee (Stanford University and Stanford Cancer Institute). Dr Wakelee is actively trying to identify a US co-operative group to lead this study internationally.

## IRCI Ocular melanoma group



The ocular melanoma group has been extremely active but has recently received unfortunate news that the study that they had been developing (*A Randomized Multi-Arm Multi-Stage Phase II Study of Molecularly Targeted Agents in Patients with Advanced Uveal Melanoma*) had not received approval from CTEP as a result of the Pharma company not wanting to support an international study, preferring in this case to support a US-based study. The group are now discussing how best to move forwards.

## Possible new IRCI rare cancer group

An initial teleconference has been arranged to discuss the possibility of developing international trials for relapsed Ewing’s sarcoma and Desmoplastic small round cell tumours