NCIC CLINICAL TRIALS GROUP

GASTROINTESTINAL

DISEASE SITE COMMITTEE MEETING

AGENDA

Delta Chelsea Hotel, Toronto, Ontario
Sunday, April 18, 2004 - 8:30 a.m. - 3:30 p.m.
Room: Churchill Ballroom A

Chair: Malcolm Moore

8:30 am Welcome and Introduction M Moore

8:35 am CLOSED TRIALS [Brief comments] Various

CO.11 (SWOG 9304): Postoperative Evaluation of 5FU by Bolus Injection vs 5FU by Prolonged Venous Infusion Prior To and Following Combined Prolonged Venous Infusion Plus Pelvic Radiation Therapy vs Bolus 5FU Plus Leucovorin Plus Levamisole Prior To and Following Combined Pelvic Radiation Therapy Plus Bolus 5FU Plus Leucovorin in Patients with Rectal Cancer

CO.12 (NCCTG 93-46-53): A Prospective Randomized Trial Comparing Laparoscopic-Assisted Colectomy with Open Colectomy for Colon Cancer

CO.13 (NCCTG N9741): A Randomized Phase III Trial of Combinations of Oxaliplatin (OXAL) 5-Fluorouracil (%-FU), and Irinotecan (CPT-11) as Initial Treatment of Patients with Advanced Adenocarcinoma of the Colon and Rectum

CO.14 (CALGB 9581): Phase III Randomized Study of Adjuvant Immunotherapy with Monoclonal Antibody 17-1A versus No Adjuvant Therapy Following Resection for Stage II (Modified Astler-Coller B2) Adenocarcinoma of the Colon

CO.15 (CALGB 89803): A Phase III Intergroup Trial of Irinotecan (CPT-11) Plus Fluorouracil (5-FU)/Leucovorin in Comparison to Fluorouracil/Leucovorin Alone After Surgery in Patients with Stage III Colon Cancer

PA.3: A Randomized Placebo Controlled Study of OSI-774 (Tarceva™) Plus Gemcitabine in Patients with Locally Advanced, Unresectable or Metastatic Pancreatic Cancer

8:50 am ACTIVE TRIALS

CO.16 (MRC CR07): Pathology-guided Treatment in Rectal Cancer - A randomised trial comparing pre-operative radiotherapy and selective post-operative chemoradiotherapy in rectal cancer J Couture

CO.17: A Phase III Randomized Study of Cetuximab (Erbitux™, C225) and Best Supportive Care versus Best Supportive Care in Patients with Pretreated Metastatic Epidermal Growth Factor Receptor (EGFR)-Positive Colorectal Carcinoma D Jonker

ES.2 (TROG 03.01): A Randomised Phase III Study in Advanced Oesophageal Cancer to Compare Quality of Life and Palliation of Dysphagia in Patients Treated with Radiotherapy versus Chemotherapy Rebecca Wong

PA.2 (ESPAC-3): Adjuvant Chemotherapies in Resectable Pancreatic Cancer S Gallinger/ M Moore

BI.1: A Phase III Study of Gemcitabine Plus Capecitabine (GEMCAP) versus Gemcitabine Alone in Advanced Biliary Cancer J Knox

continued . . .
2004 GASTROINTESTINAL DISEASE SITE AGENDA

9:45 am  **IND REPORT**
Closed Trials, Open Trials, Approved but not open trials, Future plans  Ralph Wong

10:00 am  **ENDORSED CTSU TRIALS**
**PAC.1** (SWOG-S0205): A Randomized Placebo Controlled Study of Cetuximab plus Gemcitabine in Patients with Locally Advanced, Unresectable or Metastatic Pancreatic Cancer  Ralph Wong

**PAC.2** (ECOG-E4201): A Randomized Phase III Study of Gemcitabine in Combination with Radiation Therapy versus Gemcitabine Alone in Patients with Localized, Unresectable Pancreatic Cancer  J Biagi

**GAC.1** (CALGB-80101): A Phase III Trial of Adjuvant Chemoradiation After Resection of Gastric Or Gastroesophageal Adenocarcinoma  G Bjarnason

10:30 am  Refreshment Break

10:45 am  **PARTICIPATING IN CTSU TRIALS**  S Riordan

11:00 am  **DISEASE ORIENTED GROUP REPORTS / NEW TRIALS**

**Colon DOG**  D Jonker
CTSU trials for endorsement
Elderly/ less fit phase I/II capecitabine ± oral VEGF  C Cripps
Adjuvant PTK in stage III colorectal cancer  M Moore/ D Lebwohl/ A Kay
Other trials...

**Esophageal DOG**  Rebecca Wong / R Malthaner
CTSU trials for endorsement
Other trials...

12:00 pm  Lunch

1:00 pm  **DISEASE ORIENTED GROUP REPORTS / NEW TRIALS (continued)**

**Rectal DOG**  J Brierley / J Couture
CTSU trials for endorsement
A phase I/II study of the use of FDG as a radiation sensitizer in patients with locally advanced rectal cancer  Raimond Wong
Other trials...

**Pancreas/Stomach/Liver DOG**  M Moore/ S Gallinger
CTSU trials for endorsement
Neoadjuvant pancreas trial  A Wei
Randomized phase II trial of Xelox + Avastin vs ECF in recurrent and/or metastatic gastroesophageal cancer  E Chen
Other trials...

2:00 pm  **GI INTERGROUP UPDATE**
Executive  M Moore
Colon Task Force  D Jonker / M Moore
Esophageal Task Force  Rebecca Wong
Rectal Task Force  J Brierley
Pancreas Task Force  M Moore

2:30 pm  **DISCUSSION SESSION**
Oxaliplatin, Avastin, Cetuximab.  M Moore
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<td>Closing Remarks &amp; Adjournment</td>
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<tr>
<td>3:15 pm</td>
<td>Closed Session: GI Executive Meeting</td>
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