

NCIC CLINICAL TRIALS GROUP

GASTROINTESTINAL

DISEASE SITE COMMITTEE MEETING

AGENDA

OPEN SESSIONS

Venue: Churchill Room A, Delta Chelsea Hotel

Date: Sunday, May 4th, 2008

Time: 8:30 am – 3:30 pm

Chair: Dr. Derek Jonker

7:15 am **CONTINENTAL BREAKFAST AVAILABLE**

8:30 am **WELCOME AND INTRODUCTION**

Dr. D. Jonker

8:45 am **SELECTED APPROVED AND OPEN TRIALS FOR DISCUSSION**

CO.21: A Phase III Study of the Impact of a Physical Activity Program on Disease-Free Survival in Patients with Early Stage Colon Cancer: A Randomized Controlled Trial (CHALLENGE)

Dr. C. Booth

CO.20: A Phase III Randomizes Study of Brivanib Alaninate (BMS-582664) in Combination With Cetuximab (Erbitux[®]) versus Placebo in Combination with Cetuximab (Erbitux[®]) in Patients Previously Treated with Combination Chemotherapy for Metastatic Colorectal Carcinoma

Dr. L. Siu

CRC.2 (NCCTG N0147): A Randomized Phase III Trial of Irinotecan (CPT-11) and/or Oxaliplatin (OXAL) Plus 5-Fluorouracil (5-FU)/Leucovorin (CF) with or without Cetuximab (C225) after Curative Resection for Patients with Stage III Colon Cancer

Dr. S. Gill

CRC.3 (ECOG E5202): A Randomized Phase III Study Comparing 5-FU Leucovorin and Oxaliplatin versus 5-FU, Leucovorin, Oxaliplatin and Bevacizumab in Patients with Stage II Colon Cancer at High Risk for Recurrence to Determine Prospectively the Prognostic Value of Molecular Markers.

Dr. S. Koski

CRC.4 (ECOG E5204): Intergroup Randomized Phase III Study of Postoperative Oxaliplatin, 5-Fluorouracil and Leucovorin vs Oxaliplatin, 5-Fluorouracil, Leucovorin and Bevacizumab for Patients with Stage II or III Rectal Cancer Receiving Pre-operative Chemoradiation.

Dr. J. Brierley

CRC.5 (CALGB 80405): A Phase III Trial of Irinotecan / 5-FU / Leucovorin or Oxaliplatin / 5FU / Leucovorin with Bevacizumab, or Cetuximab, or with the Combination of Bevacizumab and Cetuximab for Patients with Untreated Metastatic Adenocarcinoma of the Colon or Rectum

Dr. S. Berry

9:45 am **BREAK**

10:05 am **PRESENTATION AND PRIORITIZATION OF NEW CONCEPTS**

This is the most critical discussion of the meeting. Concepts here will have been vetted and brought forward by working group chairs as being ready for consideration by the Clinical Trials Committee. These presentations will include survey results (if available) and will be followed by a show-of hands prioritization opportunity. Not all trials presented here would be able to move forward to the CTC. **Maximum participation is critical.**

Trials may include: TheraSphere in liver-dominant refractory CRC, NSABP colorectal resectable liver metastases, Adjuvant stage III colon (3 vs 6 months FOLFOX), Advanced HCC doxorubicin plus sorafenib, RTOG pancreas study, others.

DOG / Study Chairs

12:05 pm **LUNCH**

1:05 pm **OTHER TRIALS (APPROVED, IN PROGRESS, OR COMPLETED)**

NEC.2 (CALGB-80701) Randomized Phase II Study of Bevacizumab Alone, in Combination With Everolimus, or in Combination With Temozolomide in Patients With Locally Advanced or Metastatic Pancreatic Neuroendocrine Tumors.

Dr. H. Kennecke

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 Chemo-Radiotherapy

Dr. Rebecca Wong

GAC.1 (CALGB-80101): A Phase III Trial of Adjuvant Chemoradiation After Resection of GastricOr Gastroesophageal Adenocarcinoma

Dr. G. Bjarnason

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

Dr. J. Knox

PA.2 (ESPAC-3): Adjuvant Chemotherapies in Resectable Pancreatic Cancer

Dr. M. Moore

IND.171: Phase I Open-Label, Dose-Seeking Study of AZD2171 Given Daily Orally in Combination with Standard Chemotherapy in Patients with Advanced Incurable NSCLC or CRC

Dr. D. Jonker

IND.187: A Phase I Study Of AZD2281 In Combination With Irinotecan In Patients With Locally Advanced or Metastatic Incurable Colorectal Cancer

Dr. E. Chen

2:05 pm **DISEASE ORIENTED WORKING GROUP REPORTS (ONLY AS REQUIRED)**

Colon DOG

Dr. D. Jonker / Dr. S. Gill

Rectal DOG

Dr. N. Baxter/ Dr. T. Vuong

Esophageal / Gastric DOG

Dr. Rebecca Wong / Dr. C. Kollmannsberger

Pancreas DOG

Dr. M. Moore / Dr. S. Gallinger

Hepatobiliary DOG

Dr. O. Bathe / Dr. J. Knox

Neuroendocrine DOG

Dr. L. Siu

IND REPORT

Dr. D. Jonker

GI INTERGROUP UPDATE

Dr. D. Jonker

CLOSING REMARKS & ADJOURNMENT

Dr. D. Jonker

CLOSED SESSION: GI EXECUTIVE MEETING

Dr. D. Jonker