



Adult CIRB – Late Phase Emphasis Meeting Agenda

Thursday, June 15, 2017
9:00 am – 12:45 pm (Eastern)

I Initial Review

EA8153, Cabazitaxel with Abiraterone versus Abiraterone alone Randomized Trial for Extensive Disease following Docetaxel: the CHARTED2 Trial (Protocol Version Date 05/10/17)

II Initial Review:

NRG-GU003, A Randomized Phase III Trial of Hypofractionated Post-Prostatectomy Radiation Therapy (HYPORT) versus Conventional Post-Prostatectomy Radiation Therapy (COPORT) (Protocol Version Date 05/22/17)

III Initial Review Study Chair Response

S1613, A Randomized Phase II Study of Trastuzumab and Pertuzumab (TP) Compared to Cetuximab and Irinotecan (CETIRI) in Advanced/Metastatic Colorectal Cancer (MCRC) with HER-2 Amplification (Protocol Version Date 05/31/17)

IV Amendment Review Revision 2

S1609, DART: Dual Anti-CTLA-4 and Anti-PD-1 Blockade in Rare Tumors (Protocol Version Date 04/26/17)

V Continuing Review

A041202, A Randomized Phase III Study of Bendamustine Plus Rituximab Versus Ibrutinib Plus Rituximab Versus Ibrutinib Alone in Untreated Older Patients (≥ 65 Years of Age) with Chronic Lymphocytic Leukemia (CLL) (Protocol Version Date 11/18/16)

VI Continuing Review

GOG-0263, Randomized Phase III Clinical Trial of Adjuvant Radiation Versus Chemoradiation in Intermediate Risk, Stage I/IIA Cervical Cancer Treated with Initial Radical Hysterectomy and Pelvic Lymphadenectomy (Protocol Version Date 04/08/14)

VII Continuing Review

S1207, Phase III Randomized, Placebo-Controlled Clinical Trial Evaluating the Use of Adjuvant Endocrine Therapy +/- One Year of Everolimus in Patients with High-Risk Hormone Receptor-Positive and HER2/neu Negative Breast Cancer. e3 Breast Cancer Study - evaluating everolimus with endocrine therapy (Protocol Version Date 11/09/16)

VIII **Continuing Review**

N1048, A Phase II/III Trial of Neoadjuvant FOLFOX, with Selective Use of Combined Modality Chemoradiation versus Preoperative Combined Modality Chemoradiation for Locally Advanced Rectal Cancer Patients Undergoing Low Anterior Resection with Total Mesorectal Excision (Protocol Version Date 02/03/16)

IX **Continuing Review**

NSABP-B-55, A Randomised, Double-blind, Parallel group, Placebo-controlled Multi-centre Phase III Study to Assess the Efficacy and Safety of Olaparib Versus Placebo as Adjuvant Treatment in Patients with Germline BRCA1/2 mutations and High Risk HER2 Negative Primary Breast Cancer Who Have Completed Definitive Local Treatment and Neoadjuvant or Adjuvant Chemotherapy (Protocol Version Date 04/05/17)

X **Continuing Review**

NRG-BR002, A Phase IIR/III Trial of Standard of Care Therapy with or without Stereotactic Body Radiotherapy (SBRT) and/or Surgical Ablation for Newly Oligometastatic Breast Cancer (Protocol Version Date 09/16/16)

XI **Reports of Expedited Reviews May 2017**

- Late Phase Emphasis CIRB Local Context Subcommittee Report
 - Expedited Reviews and Study Acknowledgements
 - Study Activation Acknowledgements
 - Amendment Activation Acknowledgements
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