

Adult CIRB – Late Phase Emphasis Meeting Agenda

Thursday, July 20, 2017
9:00 am – 11:45 pm (Eastern)

I Initial Review

A091603, A Randomized Phase II Trial of Adjuvant Nivolumab or Expectant Observation Following Neoadjuvant Ipilimumab Plus Nivolumab and Surgical Resection of High-Risk Localized, Locoregionally Advanced, or Recurrent Mucosal Melanoma (Protocol Version Date 05/26/17)

II Amendment Review – Pre-Activation Amendment 1

NRG-GI004, Colorectal Cancer Metastatic MSI-High Immuno-Therapy (COMMIT) Study: A Randomized Phase III Study of mFOLFOX6/Bevacizumab Combination Chemotherapy with or without Atezolizumab or Atezolizumab Monotherapy in the First-Line Treatment of Patients with Microsatellite Instability-High (MSI-H) Metastatic Colorectal Cancer (Protocol Version Date 05/23/17)

III Continuing Review

S1403, A Randomized Phase II/III Trial of Afatinib Plus Cetuximab Versus Afatinib Alone in Treatment-Naive Patients with Advanced, EGFR Mutation Positive Non-Small Cell Lung Cancer (NSCLC) (BI 1200.124) (Protocol Version Date 02/27/17)

IV Continuing Review

A151216, Adjuvant Lung Cancer Enrichment Marker Identification and Sequencing Trial (ALCHEMIST) (Protocol Version Date 06/08/17)

V Continuing Review

A011106, ALTERNATE approaches for clinical stage II or III Estrogen Receptor positive breast cancer NeoAdjuvant TrEatment (ALTERNATE) in postmenopausal women: A Phase III Study (Protocol Version Date 03/10/17)

VI Continuing Review

GOG-0281, A Randomized Phase II/III Study To Assess The Efficacy of Trametinib (GSK 1120212) In Patients With Recurrent Or Progressive Low-Grade Serous Ovarian Cancer Or Peritoneal Cancer. NCT # NCT02101788 (Protocol Version Date 05/15/17)

VII Continuing Review

S1512, A Phase II and Pilot Trial of PD-1 Blockade with MK-3475 (Pembrolizumab) in Patients with Resectable or Unresectable Desmoplastic Melanoma (DM) (Protocol Version Date 05/08/17)

VIII Continuing Review

EA8141, A Prospective Phase II Trial of Neoadjuvant Systemic Chemotherapy followed by Extirpative Surgery for Patients with High Grade Upper Tract Urothelial Carcinoma (Protocol Version Date 05/06/16)

IX Continuing Review

NRG-GY005, A Randomized Phase II/III study of the combination of Cediranib and Olaparib compared to Cediranib or Olaparib alone, or Standard of care chemotherapy in women with recurrent platinum-resistant or -refractory ovarian, fallopian tube, or primary peritoneal cancer (COCOS) (Protocol Version Date 03/28/17)

X Reports of Expedited Reviews June 2017

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