



Adult CIRB – Late Phase Emphasis Meeting Agenda

Thursday, April 6, 2017
9:00 am – 1:00 pm (Eastern)

I Initial Review

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 02/15/17)

II Initial Review

NRG-GY009, A Randomized, Phase II/III Study of Pegylated Liposomal Doxorubicin and CTEP-Supplied Atezolizumab (IND #) versus Pegylated Liposomal Doxorubicin/Bevacizumab and CTEP-Supplied Atezolizumab versus Pegylated Liposomal Doxorubicin/Bevacizumab in Platinum Resistant Ovarian Cancer (Protocol Version Date 02/06/17)

III Initial Review

S1616, A Phase II Randomized Study of Nivolumab (NSC-748726) with Ipilimumab (NSC-732442) or Ipilimumab Alone in Advanced Melanoma Patients Refractory to an Anti-PD1 or Anti-PD-L1 Agent (Protocol Version Date 02/16/17)

IV Amendment Review – Amendment 2

NRG-BN001, Randomized Phase II Trial of Hypofractionated Dose-Escalated Photon IMRT or Proton Beam Therapy Versus Conventional Photon Irradiation With Concomitant and Adjuvant Temozolomide in Patients With Newly Diagnosed Glioblastoma (Protocol Version Date 02/16/17)

V Amendment Review – Revision 3

S1314, A Randomized Phase II Study of Co-Expression Extrapolation (COXEN) With Neoadjuvant Chemotherapy for Localized, Muscle-Invasive Bladder Cancer (Protocol Version Date 02/08/17)

VI Continuing Review

A011502, A Randomized Phase III Double-Blinded Placebo Controlled Trial of Aspirin as Adjuvant Therapy for Node Positive HER2 Negative Breast Cancer: The ABC Trial (Protocol Version Date 08/15/16)

VII **Continuing Review**

CALGB-10701, A Phase II Study of Dasatinib (Sprycel®) (IND #73969, NSC #732517) as Primary Therapy Followed by Transplantation for Adults \geq 18 Years with Newly Diagnosed Ph+ Acute Lymphoblastic Leukemia by CALGB, ECOG and SWOG (Protocol Version Date 02/21/17)

VIII **Continuing Review**

NRG-GI002, A Phase II Clinical Trial Platform of Sensitization Utilizing Total Neoadjuvant Therapy (TNT) in Rectal Cancer (Protocol Version Date 08/22/16 Update Date 01/09/17)
