



Adult CIRB – Late Phase Emphasis Meeting Agenda

Thursday, May 4, 2017
9:00 am – 11:25 am (Eastern)

I Initial Review

S1607, A Phase II Study of Combining Talimogene Laherparepvec (T-VEC) (NSC-785349) and MK-3475 (Pembrolizumab) (NSC-776864) in Patients with Advanced Melanoma who have Progressed on ANTI-PD1/L1 Based Therapy (Protocol Version Date 03/28/17)

II Amendment Review (Update 6)

A091401, Randomized Phase II Study Of Nivolumab With Or Without Ipilimumab In Patients With Metastatic Or Unresectable Sarcoma (Protocol Version Date 03/31/17)

III Amendment Review (Addendum 9)

E1910, A Phase III Randomized Trial of Blinatumomab for Newly Diagnosed BCR-ABL-negative B lineage Acute Lymphoblastic Leukemia in Adults (Protocol Version Date 03/13/17)

IV Continuing Review

CALGB-80702, A Phase III Trial of 6 Versus 12 Treatments of Adjuvant FOLFOX Plus Celecoxib or Placebo for Patients with Resected Stage III Colon Cancer (Protocol Version Date 08/22/16)

V Continuing Review

E2906, Phase III Randomized Trial of Clofarabine as Induction and Post-Remission Therapy vs. Standard Daunorubicin & Cytarabine Induction and Intermediate Dose Cytarabine Post-Remission Therapy, Followed by Decitabine Maintenance vs. Observation in Newly-Diagnosed Acute Myeloid Leukemia in Older Adults (Age \geq 60 Years) (Protocol Version Date 04/25/14)

VI Continuing Review

E4A03, A Randomized Phase III Study of CC-5013 Plus Dexamethasone Versus CC-5013 Plus Low Dose Dexamethasone in Multiple Myeloma with Thalidomide Plus Dexamethasone Salvage Therapy for Non-Responders (Protocol Version Date 06/15/16)

NRG-GY008, A Phase II Evaluation of Copanlisib (BAY 80-6946), (IND #130822), A Selective Inhibitor of PI3KCA, in Patients with Persistent or Recurrent Endometrial Carcinoma Harboring PIK3CA Hotspot Mutations (Protocol Version Date 03/21/17)
