

Adult CIRB - Late Phase Emphasis Meeting Agenda

Thursday, December 21, 2017 9:00 am – 11:25 am (Eastern)

I. Initial Review

\$1702, A Phase II Study of Isatuximab (SAR650984) for Patients with Previously Treated AL Amyloidosis (Protocol Version Date 11/03/17)

II. Amendment Review - Addendum 12

E1910, A Phase III Randomized Trial of Blinatumomab for Newly Diagnosed BCR-ABL-negative B lineage Acute Lymphoblastic Leukemia in Adults (Protocol Version Date 10/27/17)

III. Amendment Review - Addendum 2

EA8143, A Phase 3 RandOmized Study Comparing PERioperative Nivolumab vs. Observation in Patients with Localized Renal Cell Carcinoma Undergoing Nephrectomy (PROSPER RCC) (Protocol Version Date 12/11/17)

IV. Amendment Review - Revision 12

\$1400, A Biomarker-Driven Master Protocol for Previously Treated Squamous Cell Lung Cancer (Lung-Map) (Protocol Version Date 11/20/17)

V. Continuing Review

GOG-0262, A Phase III Trial of Every-3-Weeks Paclitaxel Versus Dose Dense Weekly Paclitaxel In Combination With Carboplatin With Or Without Concurrent and Consolidation Bevacizumab (NSC #704865, IND #113912) in the Treatment of Primary Stage II, III OR IV Epithelial Ovarian, Peritoneal or Fallopian Tube Cancer and ACRIN 6695: Perfusion CT Imaging To Evaluate Treatment Response in Patients Participating in GOG-0262 (Protocol Version Date 08/31/16)

VI. Continuing Review

E2112, A Randomized Phase III Trial of Endocrine Therapy plus Entinostat/Placebo in Patients with Hormone Receptor-Positive Advanced Breast Cancer ((Protocol Version Date 07/15/16 Update Date 10/04/17)