

**Adult CIRB – Early Phase Emphasis
Meeting Agenda**

Tuesday, November 21, 2017

I Initial Review

10107, Phase 1 Safety Run-In and Phase 2 Randomized Clinical Trial of Anetumab Ravnansine and MK-3475 (Pembrolizumab) Compared to MK-3475 (Pembrolizumab) Alone for Mesothelin-Positive Malignant Pleural Mesothelioma (Protocol Version Date 10/10/17)

II Initial Review

10100, A Randomized, Phase 2 Trial to Evaluate the Safety and Efficacy of Eribulin Mesylate in Combination with Atezolizumab Compared to Atezolizumab Alone in Subjects with Locally Advanced or Metastatic Transitional Cell Urothelial Cancer Where Platinum-Based Treatment is Not an Option (Protocol Version Date 10/06/17)

III Initial Review

10104, A Randomized Phase 2 Study of Cabozantinib in Combination with Nivolumab in Advanced, Recurrent Metastatic Endometrial Cancer (Protocol Version Date 10/15/17)

IV Continuing Review

9742, Multicenter Phase II Study of Nivolumab in Previously Treated Patients with Recurrent and Metastatic Nasopharyngeal Carcinoma (Protocol Version Date 01/06/17)

V Continuing Review

NRG-GY003, Phase II Randomized Trial of Nivolumab with or without Ipilimumab in Patients with Persistent or Recurrent Epithelial Ovarian, Primary Peritoneal or Fallopian Tube Cancer (Protocol Version Date 07/14/17)

VI Reports of Expedited Reviews between 10/01/17 – 10/31/17

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