

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

Tuesday, December 19, 2017

I Initial Review

10136, A Phase 2 Study Of AZD1775, A WEE1 Inhibitor, In Patients With CCNE1 Amplification (Protocol Version Date 11/20/17)

II Initial Review

10147, A Phase II randomized study of topotecan/carboplatin with or without veliparib or placebo in advanced myeloproliferative disorders and chronic myelomonocytic leukemia (CMML) (Protocol Version Date 11/20/17)

III Continuing Review

9837, Phase I Study of TRC102 in Combination with Cisplatin and Pemetrexed in Patients with Advanced Solid Tumors, with Expansion Cohort in Mesothelioma / Phase II Study of TRC102 with Pemetrexed in Patients Refractory to Pemetrexed and Cisplatin or Carboplatin (Protocol Version Date 09/28/17)

IV Reports of Expedited Reviews between 11/01/17 – 11/30/17

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