

Pediatric Central IRB Meeting Agenda

Thursday, January 11, 2018

I Reports for 12/01/17 – 12/31/17

- Pediatric CIRB Local Context Subcommittee Report
- Expedited Reviews and Study Acknowledgements
- Study Activation Acknowledgements
- Amendment Activation Acknowledgements

II Continuing Review

AOST1321, Phase II Study of Denosumab (IND #127430, NSC# 744010), a RANK Ligand Antibody, for Recurrent or Refractory Osteosarcoma (Protocol Version Date 07/06/16)

III Continuing Review

ADVL1416, A Phase I Study of Ramucirumab, A Human Monoclonal Antibody Against the Vascular Endothelial Growth Factor-2 (VEGFR-2) Receptor in Children with Refractory Solid Tumors, Including CNS Tumors (Protocol Version Date 07/19/17)

IV Continuing Review

ACCL1633, The Effectiveness of Lactobacillus plantarum (LBP, IND #17339) in Preventing Acute Graft-versus-Host Disease (GVHD) in Children undergoing Alternative Hematopoietic Progenitor Cell Transplantation (HCT) (Protocol Version Date 08/08/17)

V Amendment Review

ADVL1622, Phase 2 Trial of XL184 (Cabozantinib) an Oral Small-Molecule Inhibitor of Multiple Kinases, in Children and Young Adults with Refractory Sarcomas, Wilms Tumor, and Other Rare Tumors (Amendment # 1, Protocol Version Date 12/15/17)

VI Amendment Review

ANHL12P1, A Randomized Phase II Trial of Brentuximab Vedotin (SGN35, NSC# 749710) or Crizotinib (NSC#749005, commercially labeled) in Combination with Chemotherapy for Newly Diagnosed Patients with Anaplastic Large Cell Lymphoma (ALCL) IND # 117117 (Amendment #6A, Protocol Version Date 12/05/17)
