



Pediatric Central IRB Meeting Agenda
Thursday, April 13, 2017
11:00am – 2:45 pm Eastern Time

Agenda

I. General Business

- **Next Meeting Dates:** Friday, April 21, 2017 and Thursday, May 11, 2017
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II. Reports for 03/01/17 – 03/31/17

- Pediatric CIRB Local Context Subcommittee Report
 - Expedited Reviews and Study Acknowledgements
 - Study Activation Acknowledgements
 - Amendment Activation Acknowledgements
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III. Review/Approval of Minutes

- March 9, 2017
 - March 23, 2017
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IV. Continuing Review

ACNS0332, Efficacy of Carboplatin Administered Concomitantly With Radiation and Isotretinoin as a Pro-Apoptotic Agent in Other Than Average Risk Medulloblastoma/PNET Patients: A Groupwide Phase III Study (Protocol Version Date 07/11/16)

V. Continuing Review

AALL08B1, Classification of Newly Diagnosed Acute Lymphoblastic Leukemia (ALL) (Protocol Version Date 11/08/16)

VI. Continuing Review

AOST1421, A Phase II Study of Human-Mouse Chimeric Anti-Disialoganglioside Monoclonal Antibody ch14.18 (Dinutuximab, NSC# 764038, IND# 4308) in Combination with Sargramostim (GM-CSF) in Patients with Recurrent Osteosarcoma (Protocol Version Date 05/19/16)

VII. Unanticipated Problem Review

AOST1421, A Phase II Study of Human-Mouse Chimeric Anti-Disialoganglioside Monoclonal Antibody ch14.18 (Dinutuximab, NSC# 764038, IND# 4308) in Combination with Sargramostim (GM-CSF) in Patients with Recurrent Osteosarcoma (Protocol Version Date 05/19/16)

VIII. Study Chair Response to Review for Single Patient Treatment Continuation

AOST1421, A Phase II Study of Human-Mouse Chimeric Anti-Disialoganglioside Monoclonal Antibody ch14.18 (Dinutuximab, NSC# 764038, IND# 4308) in Combination with Sargramostim (GM-CSF) in Patients with Recurrent Osteosarcoma (Protocol Version Date

IX. Unanticipated Problem Review

ADVL1414, A Phase 1 Study of Selinexor (KPT-330, IND #125052), A Selective XPO1 Inhibitor, In Recurrent and Refractory Pediatric Solid Tumors, Including CNS Tumors (Protocol Version Date 01/17/17)

X. Amendment Review

ADVL1412, A Phase 1/2 Study of Nivolumab in Children, Adolescents, and Young Adults with Recurrent or Refractory Solid Tumors as a Single Agent and in Combination with Ipilimumab (Amendment #6, Protocol Version Date 02/24/17)

XI. Amendment Review

ACNS1022, A Phase II Randomized Trial of Lenalidomide (NSC # 703813, IND # 70116) in Pediatric Patients with Recurrent, Refractory or Progressive Juvenile Pilocytic Astrocytomas and Optic Pathway Gliomas (Amendment #5, Protocol Version Date 02/28/17)

XII. Amendment Review

AAML1421, A Phase 1/2 Study of CPX-351 (NSC# 775341; IND #129443) Alone Followed by Fludarabine, Cytarabine, and G-CSF (FLAG) for Children with Relapsed Acute Myeloid Leukemia (AML) (Amendment #1, Protocol Version Date 02/23/17)

XIII. Amendment Review

APEC14B1, The Project: Everychild Protocol: A Registry, Eligibility Screening, Biology and Outcome Study (Amendment #1B, Protocol Version Date 11/18/16)

XIV. Initial Review

ACNS1422, A Phase 2 Study of Reduce Therapy for Newly Diagnosed Average-Risk WNT-Driven Medulloblastoma Patients (Protocol Version Date 07/26/16)
