



Pediatric Central IRB Meeting Agenda

February 22, 2010
12:00 p.m. – 3:35 p.m.

Agenda

I. General Business

- Thank you all for working with us to reschedule this month's meeting.
- Next Meeting: March 11, 2010

II. Review/Approval of Minutes

- January 14, 2010

III. Adverse Event Review

IV. Continuing Review

AAML0523, A Phase I/II Study of CLOLAR® (Clofarabine, IND# 73,789) in Combination with Cytarabine in Pediatric Patients with Refractory/Relapsed Leukemia (Protocol Version Date 09/17/09)

V. Continuing Review

AAML07P1, A Phase II Pilot Study of Bortezomib (PS-341, Velcade, IND# 58,443) Combined with Reinduction Chemotherapy in Children and Young Adults with Recurrent, Refractory or Secondary Acute Myeloid Leukemia (Protocol Version Date 01/22/09)

VI. Continuing Review

AHEP0731, Treatment of Children with All Stages of Hepatoblastoma: A Groupwide Phase III Study (Protocol Version Date 06/19/09)

VII. Continuing Review

AREN0532, Treatment for Very Low and Standard Risk Favorable Histology Wilms Tumor: A Groupwide Phase III Study (Protocol Version Date 12/18/09)

VIII. Amendment Review

ARAR0332, Treatment of Adrenocortical Tumors with Surgery plus Lymph Node Dissection and Multiagent Chemotherapy: A Groupwide Phase III Study (Amendment #1A, Protocol Version Date 12/22/09)

IX. Amendment Review

ASCT0631, A Phase III Randomized Trial of G-CSF Stimulated Bone Marrow vs. Conventional Bone Marrow as a Stem Cell Source in Matched Sibling Donor Transplantation (Amendment #1A, Protocol Version Date 01/19/10)

X. Initial Review

ASCT0631D, A Comparison of Acute and Long-term Toxicities in Bone Marrow Donors with and without G-CSF Treatment Prior to Harvest: A Companion Study to ASCT0631: Phase III Study (Protocol Version Date 01/19/10)

XI. Initial Review

ADVL0921, A Phase II Study of MLN8237 (IND# 102984), a Selective Aurora A Kinase Inhibitor in Children with Recurrent/Refractory Solid Tumors and Leukemias (Protocol Version Date 01/07/10)

XII. Expedited Reviews and Acknowledgements

Includes studies and letters reviewed and acknowledged from January 12, 2010 – February 17, 2010. Please contact the Operations Office if you would like to review any of the following submissions that were expedited.

Amendment Reviews

ADVL06B1, A Pharmacokinetic-Pharmacodynamic-Pharmacogenetic Study of Actinomycin-D and Vincristine in Children with Cancer: A Groupwide Non-Therapeutic Study (Amendment #1, Protocol Version Date 01/12/10)

AEPI05N1, Carcinogen Metabolism, DNA Repair, Parental Exposures and Retinoblastoma: A Groupwide Non-Therapeutic Study (Amendment #4, Protocol Version Date 01/13/10)

ANHL04B1, Rare and Cutaneous Non-Hodgkin Lymphoma Registry (Amendment #4, Protocol Version Date 01/25/10)

AREN0321, Treatment of High Risk Renal Tumors: A Groupwide Phase II Study (Amendment #4, Protocol Version Date 01/19/10)

Group Responses to Amendment Reviews

ADVL0221, A Phase II Study of Trabectedin (ET-743, Yondelis®) in Children with Recurrent Rhabdomyosarcoma, Ewing Sarcoma, or

Nonrhabdomyosarcomatous Soft Tissue Sarcomas (Amendment #2, Protocol Version Date 01/29/10)

AREN03B2, Renal Tumors Classification, Biology, and Banking Study: A Groupwide Study (Amendment #4, Protocol Version Date 01/22/10)

Continuing Reviews

ANBL0322, A Phase II Study of hu14.18-IL2*(BB-IND-9798) In Children with Recurrent or Refractory Neuroblastoma: A Groupwide Phase II Study (Protocol Version Date 03/28/07)

ALTE07C1, Neuropsychological, Social, Emotional, and Behavioral Outcomes in Children with Cancer: A Groupwide Non-Therapeutic Study (Protocol Version Date 07/28/08)

ADVL0524, Phase II Trial of Ixabepilone (BMS-247550), an Epothilone B Analog, in Children and Young Adults with Refractory Solid Tumors (Protocol Version Date 10/01/07)

AOST06B1, A Children's Oncology Group Protocol for Collecting and Banking Osteosarcoma Specimens (Protocol Version Date 11/26/07)

Group Responses to Continuing Reviews

AGCT0521, Treatment of Recurrent or Resistant Pediatric Malignant Germ Cell Tumors with Paclitaxel, Ifosfamide and Carboplatin: A Groupwide Phase II Study (Protocol Version Date 07/10/09)

Study Closures

ACCL0521, A Group-Wide Double-Blind Randomized Placebo-Controlled Trial of Palifermin to Prevent Chemotherapy and/or Radiotherapy Induced Oral Mucositis in Children Undergoing Autologous or Allogeneic Hematopoietic Stem Cell Transplantation

Acknowledgements

AALL0622 Activation of Amendment #3, Intensified Tyrosine Kinase Inhibitor Therapy (Dasatinib: IND# 73969, NSC# 732517) in Philadelphia Chromosome Positive Acute Lymphoblastic Leukemia (ALL): A Groupwide Phase III Study

AAML07P1 Dose Escalation for Arm B from Dose Level 1 to Dose Level 2, A Phase II Pilot Study of Bortezomib (PS-341, Velcade, IND# 58,443) Combined with Reinduction Chemotherapy in Children and Young Adults with Recurrent, Refractory or Secondary Acute Myeloid Leukemia

AEWS07P1 Closure to Accrual – Effective January 15, 2010, A Pilot Study of Chemotherapy Intensification by Adding Vincristine, Topotecan, and Cyclophosphamide to Standard Chemotherapy Agents with an Interval Compression Schedule in Newly Diagnosed Patients with Localized Ewing Sarcoma Family of Tumors

ANBL0931 Aldesleukin Compounding Instructions Training Module

Revisions, A Comprehensive Safety Trial of Chimeric Antibody 14.18 (Ch14.18) with GMCSF, IL-2 and Isotretinoin in High-Risk Neuroblastoma Patients Following Myeloablative Therapy: A Limited Institution Study

AREN0321 Temporary Suspension of Accrual onto the Window Therapy

Arm, Treatment of High Risk Renal Tumors: A Groupwide Phase II Study

ARST08P1 Study Activation, A Pilot Study to Evaluate Novel Agents

(Temozolomide and Cixutumumab [IMC-A12, Anti-IGF-IR Monoclonal Antibody, IND #100947, NSC # 742460]) in Combination with Intensive Multi-Agent Interval Compressed Therapy for Patients with High-Risk Rhabdomyosarcoma: A Groupwide Pilot Study
