



Pediatric Central IRB Meeting Agenda

January 14, 2010
11:00 a.m. – 2:25 p.m.

Agenda - Revised

I. General Business

- Next Meeting: February 11, 2010
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II. Review/Approval of Minutes

- December 10, 2009
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III. Adverse Event Review

IV. Group Response to Continuing Review

AALL0434, Intensified Methotrexate, Nelarabine (Compound 506U78; IND # 52611) and Augmented BFM Therapy for Children and Young Adults with Newly Diagnosed T-cell Acute Lymphoblastic Leukemia (ALL): A Groupwide Phase III Study (Protocol Version Date 10/31/08)

V. Group Response to Amendment Review

AREN03B2, Renal Tumors Classification, Biology, and Banking Study: A Groupwide Study (Amendment #4, Protocol Version Date 12/16/09)

VI. Continuing Review

AALL0433, Intensive Treatment for Intermediate-Risk Relapse of Childhood B-Precursor Acute Lymphoblastic Leukemia (ALL): A Randomized Trial of Vincristine Strategies. A Groupwide Phase III Study (Protocol Version Date 05/07/09)

VII. Continuing Review

ACNS0221, A Phase II Study of Conformal Radiotherapy In Patients with Low-Grade Gliomas (Protocol Version Date 11/15/05)

VIII. Continuing Review

AHOD03P1, Treatment of Children with Newly-Diagnosed Low Stage Lymphocyte Predominant Hodgkin Disease (LPHD): A Groupwide Pilot Study (Protocol Version Date 09/30/09)

IX. Continuing Review

AHOD0431, A Phase III Study for the Treatment of Children and Adolescents With Newly Diagnosed Low Risk Hodgkin Disease (Protocol Version Date 05/11/07)

X. Continuing Review

ARAR0331, Treatment of Childhood Nasopharyngeal Carcinoma with Neoadjuvant Chemotherapy and Concomitant Chemoradiotherapy: A Groupwide Phase III Study (Protocol Version Date 04/14/09)

XI. Amendment Review

AAML0431, The Treatment of Down Syndrome Children with Acute Myeloid Leukemia (AML) and Myelodysplastic Syndrome (MDS) Under the Age of 4 Years: A Groupwide Phase III Stud (Amendment #1, Protocol Version Date 12/16/09)

XII. Amendment Review

ANBL0532, Phase III Randomized Trial of Single vs. Tandem Myeloablative Consolidation Therapy for High-Risk Neuroblastoma: A Groupwide Phase III Study (Amendment #2, Protocol Version Date 12/01/09)

XIII. Amendment Review

AREN0532, Treatment for Very Low and Standard Risk Favorable Histology Wilms Tumor: A Groupwide Phase III Study (Amendment #4, Protocol Version Date 12/18/09)

XIV. Amendment Review

AREN0533, Treatment of Newly Diagnosed Higher Risk Favorable Histology Wilms Tumors: A Groupwide Phase III Study (Amendment #2, Protocol Version Date 12/04/09)

XV. Continuing Review

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)

XVI. Continuing Review

ANBL00P3, A Phase III Randomized Trial of Intravenous Gammaglobulin Therapy for Patients with Neuroblastoma Associated Opsoclonus-Myoclonus-Ataxia Syndrome Treated with Chemotherapy and Prednisone (Protocol Version Date 09/25/09)

XVII. Continuing Review

ARST0332, Risk-Based Treatment for Non-Rhabdomyosarcoma Soft Tissue Sarcomas (NRSTS) in Patients Under 30 Years of Age (Protocol Version Date 04/07/09)

XVIII. Continuing Review

ACNS0334, A Phase III Randomized Trial for the Treatment of Newly Diagnosed Supratentorial PNET and High Risk Medulloblastoma in Children < 36 months Old with Intensive Induction Chemotherapy with Methotrexate Followed by Consolidation with Stem Cell Rescue vs. the Same Therapy Without Methotrexate: A Phase III Group-Wide Study (Protocol Version Date 06/15/07)

XIX. Expedited Reviews and Acknowledgements

Includes studies and letters reviewed and acknowledged from December 1, 2009 – January 11, 2010. Please contact the Operations Office if you would like to review any of the following submissions that were expedited.

Amendment Reviews

AALL03N1, Understanding the Ethnic and Racial Differences in Survival in Children with Acute Lymphoblastic Leukemia (Amendment #5, Protocol Version Date 12/10/09)

AALL0622, Intensified Tyrosine Kinase Inhibitor Therapy (Dasatinib: IND# 73969, NSC# 732517) in Philadelphia Chromosome Positive Acute Lymphoblastic Leukemia (ALL): A Groupwide Phase III Study (Amendment #3, Protocol Version Date 12/04/09)

AEPI07N1, Genetic Susceptibility Factors in the Etiology of Neuroblastoma: A Groupwide Non-Therapeutic Study (Amendment #4, Protocol Version Date 12/18/09)

ANBL0931, A Comprehensive Safety Trial of Chimeric Antibody 14.18 (ch14.18) with GM-CSF, IL-2 and Isotretinoin in High-Risk Neuroblastoma Patients Following Myeloablative Therapy: A Limited Institution Study (Activation Amendment #1, Protocol Version Date 12/17/09)

Continuing Reviews

AALL03N1, Understanding the Ethnic and Racial Differences in Survival in Children with Acute Lymphoblastic Leukemia (Protocol Version Date 08/14/09)

ABTR04B1, Establishing Continuous Cell Lines and Xenografts from Pediatric Cancers for Biological and Pre-Clinical Therapeutic Studies (Protocol Version Date 10/12/09)

ACCRN07, Protocol for the Enrollment on the Official COG Registry, The Childhood Cancer Research Network (CCRN) (Protocol Version Date 08/06/08)

ANBL0421, A Phase II Study of Irinotecan + Temozolomide in Children with Recurrent Neuroblastoma: A Groupwide Phase II Study (Protocol Version Date 06/21/07)

AEWS0521, A Randomized Phase II Study of Bevacizumab (NSC 704865, BB-IND# 7921) Combined with Vincristine, Topotecan and Cyclophosphamide in Patients with First Recurrent Ewing Sarcoma (Protocol Version Date 10/13/08)

ARET0331, Trial of Systemic Neoadjuvant Chemotherapy for Group B Intraocular Retinoblastoma: A Phase III Limited Institution Study (Protocol Version Date 09/14/07)

Group Response to Continuing Reviews

AALL0331, Standard Risk B-precursor Acute Lymphoblastic Leukemia (ALL): A Phase III Group-Wide Study (Protocol Version Date 03/25/09)

ACNS0333, Treatment of Atypical Teratoid/Rhabdoid Tumors (AT/RT) of the Central Nervous System with Surgery, Intensive Chemotherapy, and 3-D Conformal Radiation: A Phase III Group-Wide Study (Protocol Version Date 11/07/08)

AOST0331, A Randomized Trial of the European and American Osteosarcoma Study Group to Optimize Treatment Strategies for Resectable Osteosarcoma Based on Histological Response to Pre-Operative Chemotherapy (IND# 12697): A Phase III Intergroup Study (Protocol Version Date 08/03/09)

Study Closures

ACCL04C2, Randomized Study of Electroacupuncture Treatment for Delayed Chemotherapy-induced Nausea and Vomiting in Patients with Pediatric Solid Tumors 02-AT-0172

ACCL0631, Impact of Obesity on the Pharmacokinetics of Anticancer Therapy in Children with High Risk Acute Lymphoblastic Leukemia (ALL): A Group-wide Non-Therapeutic Study

ADVL0524, Phase II Trial of Ixabepilone (BMS-247550), an Etoposide B Analog, in Children and Young Adults with Refractory Solid Tumors

Acknowledgements

AAML0523 Study Reactivation – Effective January 4, 2010, A Phase I/II Study of CLOLAR[®] (Clofarabine, IND# 73,789) in Combination with Cytarabine in Pediatric Patients with Refractory/Relapsed Leukemia

ADVL0221 Temporary Closure of Rhabdomyosarcoma Stratum – Effective December 2, 2009, A Phase II Study of Trabectedin (ET-743, Yondelis[®]) in Children with Recurrent Rhabdomyosarcoma, Ewing Sarcoma, or Nonrhabdomyosarcomatous Soft Tissue Sarcomas

ADVL06B1 Stratum Closures – Effective December 4, 2009, A Pharmacokinetic-Pharmacodynamic-Pharmacogenetic Study of Actinomycin-D and Vincristine in Children with Cancer

AHOD0831 Study Activation – Effective December 7, 2009, A Non-Randomized Phase III Study of Response Adapted Therapy for the Treatment of Children with Newly Diagnosed High Risk Hodgkin Lymphoma: A Groupwide Phase III Study
