Alliance Administrative and Protocol Office Update

Trini Ajazi, MM

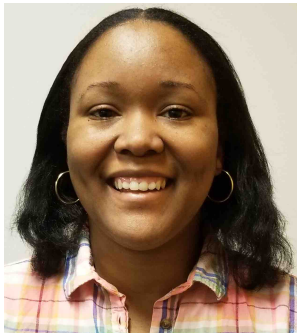
Clinical Research Professional Information Session

May 11, 2017

New Staff | Chicago Office

Linda Sluman, MD
Executive Officer

- Breast
- Genitourinary (GU)
- Respiratory



Velvet Woods
Executive Assistant

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Alliance Chicago Office Departures

- Scott Smith, MD, Executive Officer (effective 6/1/17)
- Olwen Hahn, MD, Executive Officer
- Seun Oyewo, Audit Coordinator

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Registration Trials

- New Drug Application (NDA) for marketing of an investigational new drug
- Retrospective
  - Pharmaceutical company decides to file NDA after Alliance study results are released; e.g., supplemental NDA for label extension of drug approved for another indication
- Prospective
  - Pharmaceutical company requests development of trial with registration intent
- NDA filed by pharmaceutical company for approval by US Food and Drug Administration (FDA)

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FDA Approved!!

CALGB (Alliance) 100104 Study Results Lead to FDA Approval of Lenalidomide (Revlimid) as Maintenance Therapy for Multiple Myeloma

February 2017:
US FDA and European Commission approved lenalidomide (REVLIMID®) as maintenance therapy for multiple myeloma following autologous hematopoietic stem cell transplant based on two studies including CALGB 100104

CALGB 100104: A phase III randomized, double-blind study of maintenance therapy with CC-5013 (NSC # 703813, IND # 70116) or placebo following autologous stem cell transplantation for multiple myeloma

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FDA Approved!!

CALGB (Alliance) 10603 RATIFY Study Results Lead to FDA Approval of New Combination Treatment for Acute Myeloid Leukemia

April 2017:

US Food and Drug Administration approved midostaurin (Rydapt©) for the treatment of adult patients with newly diagnosed FLT-3 mutated acute myeloid leukemia (AML) who have specific genetic mutation called FLT3, in combination with chemotherapy

C10603: A phase III randomized, double-blind study of induction (Daunorubicin/Cytarabine) and consolidation (high-dose Cytarabine) chemotherapy + Midostaurin (PKC412) (IND # 101261) or placebo in newly diagnosed patients < 60 years of age with FLT3 mutated acute myeloid leukemia (AML)

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Registration Trial Related Initiatives

CTEP/NCTN and Alliance initiatives aim to improve compliance with FDA requirements and Good Clinical Practice (GCP) guidelines for conduct, sponsor oversight and monitoring of Investigation New Drug (IND) and NDA studies.

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Related Initiatives: Central Monitoring

- Central Data Monitoring
  - Source documents uploaded in Rave
  - Source data review and verification
  - Key eligibility, disease outcomes/primary endpoints, treatment, AE, patient termination
  - Conducted by central monitor at data center
  - Applies to investigational new drug (IND) studies, even if not planned for NDA/registration

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Related Initiatives for IND/NDA

- Audits with documented targeted source data verification (TSDV) in Rave
- Delegation of Task Log (DTL)
- Registration and Credential Repository (RCR)
  - Training documentation (GCP, protocol-specific)
  - Financial disclosure
  - Investigator registration
- CTEP-AERS/Rave integration

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Registration Trial Considerations

- Trial Master File/Investigator Site File
- Protocol Deviations Reporting
- On-site monitoring plan (optional for registration trial)
- FDA/Regulatory Inspection Readiness
- Alliance to provide guidance and training

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Questions

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