CLINICAL TRIALS

FALL 2023

FOX CHASE CANCER CENTER DEPARTMENT OF HEMATOLOGY/ONCOLOGY & FOX CHASE-TEMPLE UNIVERSITY HOSPITAL DEPARTMENT OF BONE MARROW TRANSPLANT AND CELLULAR THERAPIES

ACUTE MYELOID LEUKEMIA

20-1043: Asya Varshavsky, MD — **NEWLY DIAGNOSED**

TAS1440-01: A Phase 1 Study of Safety, Pharmacokinetics, and Preliminary Activity of TAL1440, as a Single Agent or in Combination with All-Trans Retinoic Acid (ATRA) in Subjects with Relapsed or Refractory (r/r) Acute Myeloid Leukemia (AML)

Drug: TAS1440 as a single agent and in combination with ATRA

Key Eligibility

- Inclusions:
  - Histological confirmation of AML for whom all other available conational therapies have failed
  - Peripheral blood or bone marrow blast count > 5% at time of enrollment
  - Have disease that:
    - Is refractory to standard induction chemo, including but not limited to anthracycline and cytarabine combination therapy, or
    - Has relapsed after anthracycline and cytarabine therapy or stem cell transplant, or
    - Is refractory to or has relapsed after a front-line regimen containing a hypomethylating agent, alone or in combination
    - ECOG 0-1
- Exclusions:
  - Known clinically active central nervous system leukemia
  - BCR-ABL-positive leukemia
  - Diagnosis of acute promyelocytic leukemia (M3 AML or APML or APL)

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LYMPHOMA

20-1066: Rashmi Khanal, MD — **FOR RELAPSED/REFRACTORY**

Multi-Center, Open-Label, Phase 1/2 Clinical Trial to Evaluate the Safety and Anti-Tumor Activity of AB-101 Monotherapy and AB-101 Plus Rituximab in Patients with Relapsed/Refractory Non–Hodgkin Lymphoma of B-Cell Origin Key Eligibility

Drugs: AB-101 (comprised of ex vivo-expanded allogeneic cord blood-derived natural killer (NK) cells cryopreserved in an infusion-ready suspension medium) w/ or w/o Rituximab

Key Eligibility:

- Inclusions:
  - Patients must have progressed beyond, have demonstrated intolerance to, or have declined treatment with available FDA-approved therapies for NHL
  - Permitted, but not required, prior lines:
    - Prior hematopoietic stem cell transplantation
    - Prior treatment(s) with an FDA-approved CAR-T
    - Prior treatment(s) with an investigational
- Exclusions:
  - Excluded sub-types: AIDS-associated lymphoma, Burkitt's lymphoma, CNS lymphoma, Post-transplant lymphoproliferative disorder, Castleman's Disease, and High-grade B-cell lymphomas not otherwise specified
  - No active CNS lymphoma, or involvement of the CNS unless there is a history of at least 3 months of sustained remission among those with treated disease

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Fox Chase Cancer Center
Temple Health

Fox Chase – Temple University Hospital
Bone Marrow Transplant Program

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LYMPHOMA

22-1021: Rashmi Khanal, MD — **LYMPHOMA UNDERGOING HD-AHCT**

A Phase 3 Double-Blind, Randomized, Placebo controlled Study to Evaluate the Efficacy and Safety of AB-205 plus Standard of Care versus Placebo plus Standard of Care in Adults with Lymphoma Undergoing High-Dose Therapy Autologous Hematopoietic Cell Transplantation (HDT-AHCT) (E-CELERATE)

Drugs: AB-205/placebo + SoC

Key Eligibility:

- Inclusions:
  - Diagnosis of Hodgkin lymphoma or non-Hodgkin lymphoma
  - Candidates for HDT-AHCT with one of the following condition regimens: BEAM or BeEAM
  - achieved CR or PR prior to planned HDT
- Exclusions:
  - CNS lymphoma
  - prior HCT

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22-1026: Marcus Messmer, MD — **FOR RELAPSED/REFRACTORY AND NEWLY DIAGNOSED**

Protocol # 22-1026: A Phase 1b/2, Open-Label Study to Evaluate Safety and Tolerability of Epcoritamab in Combination with Anti-Neoplastic Agents in Subjects with Non-Hodgkin Lymphoma

Drugs: Epcoritamab + chemotherapy

Key Eligibility:

- Inclusions:
  - DLBCL with histologically confirmed CD20+ disease- included DLBCL (NOS), High-grade B cell lymphoma with MYC and BCL-2 and/or BCL-6 translocations, FL Grade 3B
  - no prior treatment with Epcoritamab or any other bispecific antibody targeting CD3 and CD20 DLBCL

More Information: Jill.Samaha@fccc.edu or 215-214-3125

22-1046: Shazia Nakhoda, MD

A Phase 3, Randomized, Double-blind, Placebo-Controlled Study of Acalabrutinib in Combination with Rituximab, Cyclophosphamide, Doxorubicin, Vincristine, and Prednisone (R-CHOP) in Subjects ≤ 70 Years with Previously Untreated Non-Germinal Center Diffuse Large B-cell Lymphoma

Drugs: Acalabrutinib

Key Eligibility:

- Inclusions:
  - No prior treatment for DLBCL, except prior steroids and/or vincristine prophase as well as CNS prophylaxis
  - IPI score of 1-5. Subjects with IPI 1 must be Ann Arbor Stage III or IV-FDG-avid measurable disease
- Exclusions:
  - Known CNS lymphoma
  - Prior history of indolent lymphoma or CLL
  - Known high-grade B-cell lymphoma with MYC and BCL2 and/or BCL6 rearrangements (double-hit or triple-hit lymphoma)

More Information: Nicole.Ahrens@fccc.edu or 215-214-3173

KEY ACCOUNT MANAGEMENT TEAM

If you have any questions, our key account management team is here to help you.

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For general questions about clinical trials, call **215-214-1515** or visit **FoxChase.org/ClinicalTrials**.

To refer a patient to a clinical trial listed here, see the "More Information" section within each listing.

New clinical trials are continuously being added.
For updated information, visit **FoxChase.org/HemeTrials**.