DEPARTMENT OF HEMATOLOGY/ONCOLOGY & DEPARTMENT OF BONE MARROW TRANSPLANT AND CELLULAR THERAPIES

CLINICAL TRIALS

MYELOPROLIFERATIVE

23-1048: HM-224: Peter Abdelmessieh, DO MSc — **UNRESPONSIVE TO FRONTLINE**

Phase I study assessing the safety of pacritinib in combination with talazoparib in patients with myeloproliferative neoplasms unresponsive to frontline JAK2 inhibition

Key Eligibility:

- Inclusions:
  - Patients must have histologically or cytologically confirmed primary myelofibrosis (PMF), post-polycythemia vera-myelofibrosis (PPV-MF), post-essential thrombocythemia-myelofibrosis (PET-MF), chronic myelomonocytic leukemia, polycythemia vera, or essential thrombocytosis according to the 2008 World Health Organization criteria
  - Subject has at least 2 symptoms with a score ≥3 or a total score of ≥12, as measured by the MFSAF v4.0
  - Subject classified as intermediate-2 or high-risk MF, as defined by the Dynamic International Prognostic Scoring System Plus (DIPSS+70).
  - Subject must currently be on treatment or have received prior treatment with a single JAK2 inhibitor
- Exclusions:
  - Patients that have transformed to acute myeloid leukemia defined by >20% blasts count on peripheral blood smear or bone marrow biopsy evaluation
  - Subjects must not be experiencing toxicity due to prior therapy that has not resolved to ≤Grade 1 by study registration, with the exception of sensory neuropathy related to previous systemic therapy exposure, alopecia, and fatigue.
  - Patients may not be receiving any other investigational products

More Information: Allandria.Straker-Edwards@fccc.edu or 215-214-3022

LYMPHOMA

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

Multi-Center, Open-Label, Phase I/II 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 product
- 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

More Information: Allandria.Straker-Edwards@fccc.edu or 215-214-3022

IRB 23-1039: Rashmi Khanal, MD **RECURRENT OR REFRACTORY**

A Phase 2, Open-Label, Multicenter Study of Innate Cell Engager Afm13 in Combination with Allogeneic Natural Killer Cells (Ab-101) in Subjects with Recurrent or Refractory Hodgkin Lymphoma and Cd30-Positive Peripheral T-Cell Lymphoma (LuminICE-203)

Key Eligibility:

- Inclusions:
  - Subject has a diagnosis of FDG-avid relapsed or refractory classical HL OR select subtypes of FDG-avid R/R PTCL
    - For subjects with R/R PTCL—a pre-enrollment tumor biopsy positive for CD30 locally assessed by Ber-H2 targeted immunohistochemistry at ≥1% is mandatory
    - PTCL subtypes:
      - PTCL-NOS
      - Angioimmunoblastic T-cell lymphoma
      - ACL, anaplastic lymphoma kinase (ALK)-positive
      - ALCL, ALK-negative
  - Prior treatment for disease under study consistent with the following:
    - Subjects with R/R HL must have received at least 2 lines of therapy including 1 prior line of combination therapy. Prior therapy must also have included brentuximab vedotin and a PD1 checkpoint inhibitor
    - Subjects with R/R PTCL must have received at least 1 prior line of combination chemotherapy. Subjects with ALCL subtype of PTCL must have received or been intolerant to brentuximab vedotin
    - Subjects with R/R classical HL AND R/R PTCL: Prior ASCT is permitted if completed at least 3 months prior to the first dose of study treatment. Prior allogeneic stem cell transplantation will be permitted if completed at least 1 year from study enrollment ad there are no signs or symptoms of GVHD.
      - Prior CAR-T is permitted if last CAR-T dose completed at least 6 months prior to first dose of study treatment
  - ECOG Performance Status (PS) 0 or 1
- Exclusions:
  - Treatment within prior 3 weeks with any anti-cancer agent, investigational or approved
  - Continued toxicity from prior treatment that has not resolved to Grade ≤1, with allowable exceptions (e.g., alopecia)
  - Active CNS involvement (untreated or uncontrolled parenchymal brain metastasis or positive cytology of cerebrospinal fluid)
  - Prior treatment with AFM12 or CBNK cells

More Information: Allandria.Straker-Edwards@fccc.edu or 215-214-3022

23-1042: Marcus Messmer, MD **PREVIOUSLY UNTREATED**

A Phase III, Multicenter, Randomized, Open-label Study Comparing the Efficacy and Safety of Glofitamab (RO7082859) in Combination with Polatuzumab Vedotin plus Rituximab, Cyclophosphamide, Doxorubicin, and Prednisone (POLA-R-CHP) versus POLA-R-CHP in Previously Untreated Patients with Large B-cell Lymphoma

Key Eligibility:

- Inclusions:
  - Previously untreated with CD20-positive LBCL, including one of the following diagnoses:
    - DLBCL, not otherwise specified (NOS) including germinal centre B-cell type activated B-cell type
    - T-cell/histiocyte-rich large B-cell lymphoma
    - Epstein-Barr virus-positive DLBCL, NOS
    - Kaposi's sarcoma associated herpesvirus/human herpesvirus-8 positive DLBCL
    - DLBCL/HGBCL with MYC and BCL2 rearrangements
    - HGBCL, NOS
  - Ability to provide tumor tissue; archival or freshly collected
  - IPI 2-5
  - ECOG: 0, 1, or 2
  - At least one bi-dimensionally measured lesion as measured by CT or MRI
- Exclusions:
  - - History of indoent lymphoma (FL, MZL, Waldenstrom macroglobulinemia)
  - - Primary or secondary CNS lymphoma
  - - Prior treatment with systemic immunotherapeutic agents
  - - Current Grade > 1 peripheral neuropathy

More Information: Madeline.Graziani@fccc.edu or 215-214-3024

24-1003: Shazia Nakhoda, MD **PREVIOUSLY UNTREATED**

A Phase 3, Open-label, Randomized Study of Sonrotoclax (BGB-11417) Plus Zanubritinib (BGB-3111) Compared with Venetoclax plus Obinutuzumab in Patients with Previously Untreated Chronic Lymphocytic Leukemia

Key Eligibility:

- Inclusions:
  - Treatment-naïve adult patient ≥ 18 years with confirmed diagnosis of CLL that meets the iwCLL criteria
  - For those patients with a screening lymphocyte count < 5000 cells/μL, historical data confirming a lymphocyte count ≥ 5000 cells/μL at time of CLL diagnosis is required.
  - CLL requiring treatment as defined by ≥ 1 of the following criteria:
    - Evidence of progressive marrow failure as manifested by the development of, or worsening of, anemia and/or thrombocytopenia. Hemoglobin concentrations < 10 g/dL or platelet counts < 100 x 109 cells/L are generally regarded as indications for treatment.
    - Massive (ie, ≥ 6 cm below the left costal margin), progressive, or symptomatic splenomegaly.
    - Massive (ie, ≥ 10 cm in longest diameter [LDi]), progressive or symptomatic lymphadenopathy.
    - Progressive lymphocytosis with an increase of ≥ 50% over a 2-month period, or lymphocyte doubling time (LDT) <6 months. NOTE: LDT can be obtained by linear regression extrapolation of absolute lymphocyte counts obtained at intervals of 2 weeks over an observation period of 2 to 3 months; patients with initial blood lymphocyte counts < 30 x 109 cells/L may require a longer observation period to determine the LDT. Factors contributing to lymphocytosis other than CLL (eg, infections and steroid administration) should be excluded.
    - Symptomatic or functional extranodal involvement (eg, skin, kidney, lung, and spine).
    - Disease-related symptoms as defined by any of the following: – Unintentional weight loss ≥ 10% within the previous 6 months. – Fevers ≥ 100.5°F or ≥ 38.0°C for 2 or more weeks without evidence of infection. – Night sweats for ≥ 1 month without evidence of infection. – Significant fatigue (ie, ECOG [Eastern Cooperative Oncology Group] performance score of 2 or worse; cannot work or unable to perform usual activities). NOTE: Patients with significant fatigue cannot have an ECOG score of 0
  - Measurable disease by CT or MRI
- Exclusions:
  - Previous systemic treatment for CLL (Note: up to 4 doses of anti-CD-20 antibody specifically for autoimmune cytopenia is allowed; the last dose should be given ≥ 6 months before screening)
  - Known prolymphocytic leukemia or hisoty of, or currently suspected, Richter's transformation
  - Known central nervous system involvement

More Information: Madeline.Graziani@fccc.edu or 215-214-3024

Contact Us

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**.

Key Account Management Team

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

Sharon Klaver
sharon.klaver@fccc.edu | 267-990-1254

Joseph Karensky
joseph.karensky@fccc.edu | 445-206-5228

Laura Higdon
laura.higdon@fccc.edu | 267-605-2020

Diane Brown
diane.brown@fccc.edu | 215-880-9969

Locations

Fox Chase Cancer Center – Main Campus

333 Cottman Avenue,
Philadelphia, PA 19111

Fox Chase Cancer Center – Buckingham

2325 & 2365 Heritage Center Dr.,
Furlong, PA 18925

Fox Chase Cancer Center – Chestnut Hill

8835 Germantown Avenue,
Philadelphia, PA 19118

Fox Chase Cancer Center – East Norriton

2701 Dekalb Pike,
Norristown, PA 19401

Fox Chase Cancer Center – Huntingdon Pike

8 Huntingdon Pike,
Rockledge, PA 19046

Fox Chase Cancer Center – Voorhees

502 Centennial Blvd, Suite 7,
Voorhees, NJ 08043

Fox Chase Cancer Center at Temple University Hospital – Main Campus

3509 N. Broad Street,
Boyer Pavilion, 6th Floor,
Philadelphia, PA 19140

Fox Chase Cancer Center at Temple University Hospital – Northeastern Campus

2301 E. Allegheny Avenue,
Mandel Pavilion, 1st Floor,
Philadelphia, PA 19134

Fox Chase – Temple University Bone Marrow Transplant Program

Temple University Hospital – Jeanes Campus
Patient Care Center, 5th Floor,
7600 Central Avenue,
Philadelphia, PA 19111

Scan the QR code to explore our physician resources, continuing medical education offerings, and other information on the latest at Fox Chase Cancer Center.

To refer a patient, please call **888-FOX-CHASE (888-369-2427)** or visit **FoxChase.org/refer**.

Fox Chase Cancer Center
Temple Health

Fox Chase – Temple University Hospital
Bone Marrow Transplant Program

8/24