Protocol Version Date: 02/28/2024

NCI National Clinical Trials Network

ComboMATCH / EAY191

For Patients with Locally Advanced/Advanced Solid Tumors whose Disease has Progressed Following at least One Line of Standard Systemic Therapy or for whom No Standard Therapy Shown to Prolong Overall Survival Exists

EAY191 is Now Available Through the CTSU

Molecular Analysis for Combination Therapy Choice (ComboMATCH)

Patient Population

See Section 3.0 for Complete Eligibility Details

- Must have measurable disease.
- Must have an ECOG PS between 0-2, OR Lansky PS of ≥ 50% OR, Karnofsky PS of ≥ 50%.
- Must have sequencing results available from an NCI credentialed Designated Laboratory (DL).
- Must have locally advanced or advanced histologically documented solid tumors requiring therapy and meet one of the following criteria:
  - Must have progressed on at least one line of standard systemic therapy OR,
  - Patients whose disease has no standard treatment that has been shown to prolong overall survival.
- Must meet one of the following requirements:
  - Patients 18 years and older who have tumor amenable to minimal risk image-guided or direct vision biopsy and must be willing and able to undergo a tumor biopsy to obtain samples for research if the patient is to enroll in a ComboMATCH treatment trial. OR
  - Patients 18 years and older who do not have disease that is biopsiable at minimal risk to the patient must confirm availability of an archival tumor tissue specimen for submission for research if the patient enrolls to a ComboMATCH Treatment Trial. This tumor tissue must have been collected within 12 months prior to registration to the EAY191 Registration Trial; must not have had a RECIST response (CR or PR) to any intervening therapy after collection of the tissue; FFPE tumor tissue block(s) or slides must be available. OR,
  - Patients under 18 years old must confirm willingness to submit an archival tumor tissue specimen, if available, for research if the patient enrolls to a ComboMATCH Treatment Trial. FFPE tumor tissue block(s) or slides.

Treatment Plan

See Sections 5.0 for Complete Treatment Details

- Patients must first be registered to the ComboMATCH Registration protocol.
- Patients will be assigned to a ComboMATCH Treatment Trial according to MATCHBox algorithms that includes clinical and genomic data provided by the enrolling site and the Designated Labs (DLs) prior to trial entry.
- Following disease progression on a ComboMATCH Treatment Trial, patients who are eligible for a crossover within a ComboMATCH Treatment Trial will be able to do so via OPEN without repeating the registration steps. In addition, patients may also be assigned to a second ComboMATCH Treatment Trial after progression during the first ComboMATCH Treatment Trial if they retain eligibility for it.
- Patients who progress after a second ComboMATCH Treatment Trial enrollment will require a new ComboMATCH Registration Trial enrollment in OPEN (that will be linked to the initial screening registration) and must meet all ComboMATCH Registration Trial eligibility criteria at that time.
- No biospecimens will be collected or submitted until the patient has enrolled to a ComboMATCH Treatment Trial.

Number of Participants: 2900

ECOG-ACRIN Chair:
James M. Ford, M.D.

Co-Chair:
Funda Meric-Bernstam, M.D.
Peter O'Dwyer, M.D.

NCI Study Co-Chairs:
Lyndsay N. Harris, M.D.
Jeffrey Moscow, M.D.

Patient Enrollment

All Sites: Oncology Patient Enrollment Network (OPEN) https://open.ctsu.org/open

Protocol Information

CTSU Help Desk: 1-888-823-5923, CTSUcontact@westat.com, www.ctsu.org

Please Enroll Your Eligible Patients!

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