Cancer Research Consortium of West Michigan
P: 616.391.1230 | 800.336.6299 | www.crcwm.org

Fast Facts

Molecular Analysis for Therapy Choice (MATCH)

MATCH Treatment Subprotocol A: Phase II Trial of Afatinib in Patients with Solid Tumors (Other Than Small Cell and Non-Small Cell Lung Cancer) or Lymphomas, That Have Activating Mutations of EGFR and Have Progressed After Standard Treatment

Treatment: Afatinib 40 mg PO QD, repeat cycles every 28 days until progression of disease, unacceptable toxicities or withdrawal of consent. **Drug is provided.**

ELIGIBILITY CRITERIA

1. Patients must fulfill all eligibility criteria outlined in Section 3.1 of MATCH Master protocol.
2. Patient's tumor must have either:
    a) Activating mutations of EGFR (del 19, L858R) by MATCH NGS assay.
    b) Any malignancy harboring any of the following mutations: EGFR G719A, G719C, G719D, G719S EGFR L861Q, EGFR S768I
    c) Tumors with an exon 20 insertion alone without the above mutations will be excluded. See Appendix III for a list of the EGFR mutations and corresponding Levels of Evidence (LOE).
3. Patients must have an electrocardiogram (ECG) within 8 weeks prior to treatment assignment and must have no clinically important abnormalities in rhythm, conduction or morphology of resting ECG (e.g. complete left bundle branch block, third degree heart block).
4. Patients with known left ventricular dysfunction must have ECHO or a nuclear study (MUGA or First Pass) within 4 weeks prior to registration to treatment and must not have left ventricular ejection fraction (LVEF) < institutional lower limit of normal (LLN). If the LLN is not defined at a site, the LVEF must be > 50% for the patient to be eligible. **NOTE:** Pre-treatment LVEF determination in patients without known left ventricular dysfunction is NOT otherwise required.
5. Patients must not have known hypersensitivity to Afatinib or compounds of similar chemical or biologic composition.
6. Patients must have ≤ Grade 1 renal function as defined below:
    - Creatinine ≤ 1.5 x normal institutional limits **OR** Measured Creatinine clearance ≥ 60 mL/min/1.73 m2 for patients with creatinine levels above institutional normal or as calculated by the Cockcroft-Gault Equation.

The above renal eligibility criteria should be strictly followed and will override the MATCH Master Protocol requirements.

7. Patients must not have had prior treatment with an EGFR TKI (e.g. Afatinib, Erlotinib, Gefitinib, Neratinib, Dacomitinib, AZD9291, Cabertinib, CO-1696).
8. Patients with non-small cell lung cancer and small cell lung cancer will be excluded.
9. Patients with a history of interstitial lung disease will be excluded.
10. Patients must have ≤ Grade 1 diarrhea at baseline.

Study Parameters

4.1 Therapeutic Parameters for Afatinib Treatment

NOTE: In addition to the study parameters listed in the MATCH Master Protocol, the below parameters must also be performed for patients receiving afatinib treatment.

NOTE: All assessments required prior to registration to treatment should be done ≤ 4 weeks prior to registration to Steps 1, 3, 5, 7, excluding the radiologic evaluation and electrocardiogram (ECG).

Test/Assessment	Prior to Registration to Treatment	Treatment			End of Treatment	Follow Up[F]
		Cycle 1, day 8 and day 15[G]	Every Cycle, prior to treatment	Every 2 Cycles		
H&P, Weight, Vital signs[A]	X		X[J]			X
Performance status	X	X	X[J]			X
CBC w/diff, plts[B]	X		X[J]			X
Serum chemistry[B]	X		X[J]			X
Radiologic evaluation[D]	X			X[D]		X[F]
β-HCG[C]	X					
Toxicity Assessment[G]		X	X		X	X[F]
Pill Count/Diary[H]			X		X	
ECG[K]	X		X[I]			
Echocardiogram or Nuclear Study[K]	X[I]		X[I]			X[I]
Tumor biopsy and blood sample for MATCH Master Protocol[E]					X	