Cancer Research Consortium of West Michigan
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Fast Facts

Molecular Analysis for Therapy Choice (MATCH)

MATCH Treatment Subprotocol R: Phase II Study of Trametinib in Patients with BRAF Fusions, or with Non-V600E, Non-V600K BRAF Mutations

Treatment: Trametinib 2 mg oral daily, continuous dosing until progression or unacceptable toxicity. **Drug Provided**

Eligibility Criteria

1. Patient must fulfill all eligibility criteria outlined in Section 3.1 of MATCH Master Protocol (excluding section 3.1.16) at the time of registration to treatment step (step 1, 3, 5, 7).
2. Patients must have a BRAF non-V600 mutation or BRAF fusion as identified via the MATCH Master Protocol. See Appendix II for a list of the targeted BRAF mutations/fusions and the corresponding Levels of Evidence (LOE).
3. Patients must have an electrocardiogram (ECG) within 8 weeks prior to treatment assignment and must have NONE of the following cardiac criteria:
   - Clinically important abnormalities in rhythm, conduction or morphology of resting ECG (e.g. complete left bundle branch block, third degree heart block).
   - Treatment-refractory hypertension defined as a blood pressure of systolic >140 mmHg and/or diastolic >90 mmHg which cannot be controlled by anti-hypertensive therapy.
4. Patients with a history of interstitial lung disease or pneumonitis are excluded.
5. Patients must have an ECHO or a nuclear study (MUGA or First Pass) within 4 weeks prior to registration to treatment and must not have a left ventricular ejection fraction (LVEF) < the 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.
6. Patients must not have known hypersensitivity to trametinib or compounds of similar chemical or biologic composition or to dimethyl sulfoxide (DMSO).
7. Patients must not have a history or current evidence/risk of retinal vein occlusion (RVO). An eye exam is required at baseline. See Appendix III for the Trametinib Ophthalmic Exam Form.
8. Patients who previously received MEK inhibitors (including, but not limited to, trametinib, binimetinib, cobimetinib, selumetinib, RO4987655 (CH4987655), GDC-0623 and pimasertib) will be excluded.
9. Patients who previously received monoclonal antibody therapy (eg. ipilimumab, nivolumab, pembrolizumab and others) must have stopped the prior therapy for 8 or more weeks before starting on trametinib.

Test/Assessment	Prior to Registration to Treatment	Treatment		End of Treatment	Follow Up[F]
		Every Cycle, prior to treatment	Every 2 Cycles		
H&P, Weight, Vital signs[A]	X	X[J]			X
Performance status	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[F]
Pill Count/Diary[H]		X		X	
ECG[K,L]	X	X[L]			
Echocardiogram or Nuclear Study[L]	X	X[L]			
Eye Exam	X	X[I]			
Tumor biopsy and blood sample for MATCH Master Protocol[E]				X	

The procedures listed below are required only for this study and will be provided at no charge:

Echocardiogram (ECHO) or nuclear study (multigated acquisition [MUGA] or similar scan), at week 5, week 13, and every 12 weeks thereafter.

Eye exam by an ophthalmologist before the study and as clinically needed thereafter.