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

FAST FACTS

MATCH Treatment Subprotocol Z1A: Binimetinib in Patients with Tumors (Other Than Melanoma) with NRAS Mutations

Binimetinib 45mg PO BID until progression or toxicity / Cycle = 28 days

1. Patients must fulfill all eligibility criteria outlined in Section 3.1 of MATCH Master Protocol (excluding Section 3.1.6) at the time of registration to treatment step (Step 1, 3, 5, 7).
2. Patients must have NRAS mutation in codon 12, 13, 61 as determined by the MATCH screening assessment. See Appendix II for a list of the specific variants and corresponding Levels of Evidence.
3. Patients must have an electrocardiogram (ECG) within 8 weeks prior to treatment assignment and must have no clinically significant abnormalities in rhythm, conduction or morphology of resting ECG (e.g. complete left bundle branch block, third degree heart block).
4. Patients must have adequate bone marrow, organ function and laboratory parameters
   - Creatinine ≤ 1.5 mg/dL, or calculated creatinine clearance (determined as per Cockcroft-Gault) ≥ 50mL/min;
5. Patients must have adequate cardiac function:
   - left ventricular ejection fraction (LVEF) ≥ 50% as determined by a multigated acquisition (MUGA) scan or echocardiogram,
   - QTc interval ≤ 480 ms
6. Patients must not have known hypersensitivity to binimetinib or compounds of similar chemical or biologic composition.
7. Patients with melanoma are excluded.
8. Patients must not have any active CNS lesion (i.e., those with radiographically unstable, symptomatic lesions) and/or leptomeningeal metastases. NOTE: Patients treated with stereotactic radiotherapy or surgery are eligible if the patient remained without evidence of CNS disease progression ≥ 3 months. Patients must be off corticosteroid therapy for ≥ 3 weeks.
9. Patients must not have a history or current evidence of retinal vein occlusion (RVO) or predisposing factors to RVO (e.g. uncontrolled glaucoma or ocular hypertension, history of hyperviscosity or hypercoagulability syndromes).
10. Patients must not have a history of retinal degenerative disease.
11. Patients must not have a history of Gilbert's syndrome.
12. Patients must not have uncontrolled arterial hypertension despite medical treatment.
13. Patients must not have active hepatitis B, and/or active hepatitis C infection.
14. Patients must not have neuromuscular disorders that are associated with elevated CK (e.g., inflammatory myopathies, muscular dystrophy, amyotrophic lateral sclerosis, spinal muscular atrophy).
15. Patients must not have impairment of gastrointestinal function or gastrointestinal disease (e.g., ulcerative disease, uncontrolled nausea, vomiting, diarrhea, malabsorption syndrome, small bowel resection).
16. Patients who have received prior MEK inhibitors are excluded.