Cancer Research Consortium of West Michigan
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Fast Facts

Molecular Analysis for Therapy Choice (MATCH)

MATCH Treatment Subprotocol X: Phase II Study of Dasatinib in Patients with Tumors with DDR2 Mutations

Treatment Plan

Cycle 1: Dasatinib 140 mg by mouth once a day for 28 days / Restage every 2 cycles / Continue until progression. **Drug is provided.**

Evaluation for progression: restage with CT chest/abdomen/pelvis and bone scan or PET scan (same modalities used at baseline) every 8 weeks for years 1 and 2 and then every 12 weeks thereafter.

Eligibility Criteria

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 one of the following missense mutation in DDR2: S768R, I638F, L239R. See Appendix II for a list of targeted mutations and corresponding LOEs.
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 must not have known hypersensitivity to dasatinib or compounds of similar chemical or biologic composition.
5. Patients with known left ventricular dysfunction must have an 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.
6. Patients with prior use of dasatinib will be excluded.
7. Dasatinib should NOT be given in the presence of STRONG CYP 3A4 inhibitors/inducers. Patients who take these drugs concurrently are ineligible for treatment with dasatinib. These drugs must be discontinued prior to initiation of dasatinib. See the attached link for a list of drugs identified as STRONG CYP 3A4 inhibitors/inducers. http://www.fda.gov/Drugs/DevelopmentApprovalProcess/DevelopmentResources/DrugInteractionsLabeling/ucm093664.htm
8. Dasatinib should NOT be given in the presence of H2-Antagonists or Proton Pump Inhibitors. Patients who take these drugs concurrently are ineligible for treatment with dasatinib. These drugs must be discontinued prior to initiation of dasatinib. Antacids taken 2 hours before or after dasatinib administration can be used in place of H2-antagonists or proton pump inhibitors if some acid-reducing therapy is needed.

Study Parameters

4.1 Therapeutic Parameters for Dasatinib Treatment

NOTE: In addition to the study parameters listed in the MATCH Master Protocol, the below parameters must also be performed for patients receiving dasatinib 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]
		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]	X	X[I]			
Echocardiogram or Nuclear Study	X[I]				
Tumor biopsy and blood sample submission for MATCH Master Protocol[E]				X	

D. Tumor measurements are repeated every 2 cycles for the first 26 cycles, and every 3 cycles thereafter until PD or start of another MATCH treatment step. The baseline evaluation should be performed as closely as possible to the beginning of treatment and never more than 6 weeks before registration to treatment step. Documentation (radiologic) must be provided for patients removed from study for progressive disease.