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Fast Facts

Molecular Analysis for Therapy Choice (MATCH)

MATCH Treatment Subprotocol F: Crizotinib in Patients with Tumors (Other Than Adenocarcinoma of Lung or ALCL) with ALK Translocations

Treatment: Crizotinib 250 mg orally twice daily on a continuous daily dosing schedule. Crizotinib should be taken approximately 12 hours apart and without regard to meals. Cycles are defined in 28-day periods to facilitate scheduling of visits and assessments.

Eligibility Criteria

1. Patients must have an ALK rearrangement as determined by the MATCH screening assessment. See Appendix IV for a list of the ALK mutations and corresponding Levels of Evidence.
2. Patients must not have non-small cell lung cancer or ALCL.
3. Patients with a history of interstitial lung disease or pneumonitis are excluded.
4. Patient must fulfill all eligibility criteria outlined in Section 3.1 of the MATCH Master Protocol (excluding section 3.1.16) at the time of registration to treatment step (step 1, 3, 5, 7).
5. 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).
6. Patients must not have known hypersensitivity to crizotinib or compounds of similar chemical or biologic composition.
7. Patients must not have had prior ALK-targeted inhibitors, including crizotinib, ceritinib, alectinib, AP26113, TSR-011, X-396, RXDX-101, CEP-37440, PF-06463922
8. Patients must not have had brain metastases unless 1) treated and neurologically stable for at least 2 weeks, or 2) untreated, asymptomatic, and treatment is not indicated. Steroids are permitted if doses are stable (or tapering) for 2 weeks prior to study enrollment.
9. Patients using drugs or foods that are known potent CYP3A4 inhibitors or inducers will be excluded. Please see Appendix II.

4.1 Therapeutic Parameters for Crizotinib Treatment

NOTE: In addition to the study parameters listed in the MATCH Master Protocol at Step 0, the below parameters must also be performed for patients on Crizotinib 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]			
Tumor biopsy and blood sample for MATCH Master protocol[E]				X	