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Fast Facts

Molecular Analysis for Therapy Choice (MATCH)

MATCH Treatment Subprotocol G: Phase II Study of Crizotinib in Patients with ROS1 Translocations (Other Than Patients with Non-Small Cell Lung Cancer)

Treatment: Crizotinib 250 mg orally twice daily on a continuous daily dosing schedule. 12 hours apart and without regard to meals. Cycles = 28 day periods.

1. Patients must be positive for translocation or inversion events involving the ROS1 gene as detected on the MATCH NGS assay. List below of the ROS1 translocations and inversions and corresponding LOEs.
2. Patients must not have NSCLC with ROS1 rearrangements.
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 3.1.6) 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 using drugs or foods that are known potent CYP3A4 inhibitors or inducers will be excluded (See Appendix II)
8. Patients must not have had prior therapy with any ROS1 inhibitor including crizotinib, ceritinib, foretinib, cabozantinib, AP26113, ASP3026, WZ-5-126, TAE684, KIST301072, KIST301080, AZD1480, PF-06463922, RXDX-101 and PF-3922

Study Parameters

2/16 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	