Cancer Research Consortium of West Michigan
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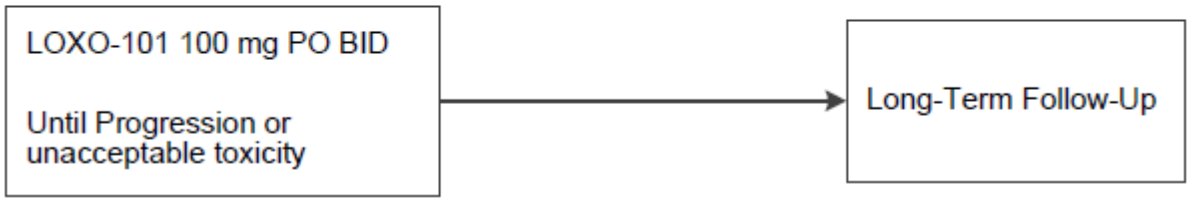
Fast Facts

Molecular Analysis for Therapy Choice (MATCH)

MATCH Treatment Subprotocol Z1E: LOXO-101 in Patients with Tumors with NTRK Fusions

Schema



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 a malignancy harboring an NTRK1, NTRK2 or NTRK3 gene fusion, as determined by the MATCH screening assessment. See Appendix II for a list of the NTRK fusions and corresponding Levels of Evidence.**
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).**
   Date of ECG: _____
4. **Patients must not have known hypersensitivity to LOXO-101 or compounds of similar chemical or biologic composition.**
5. **Patients with inability to discontinue treatment with a strong CYP3A4 inhibitor or inducer prior to start of treatment are excluded.**
6. **Patients who have previously received treatment with a TRKA, TRKB, or TRKC inhibitor are excluded. Such inhibitors include LOXO-101, entrectinib (RXDX-101), TSR-011, DS6051, Altiratinib (DCC-2701), MGCD516, Dovitinib (TKI258, CHIR528), AZD7451, PLX7486, and BIBF1120.**

Study Parameters

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	X	