

Fast Facts

Molecular Analysis for Therapy Choice (MATCH)

MATCH Treatment Subprotocol Z1L: BVD-523FB (Ulixertinib) in Patients with Tumors with BRAF Fusions, or with Non-V600E, Non-V600K BRAF Mutations

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 BRAF non-V600 mutation or BRAF fusion, or another BRAF aberration, as determined via the MATCH Master Protocol and according to Appendix II. See Appendix II for information on the targeted mutations/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).
4. Patients must not have known immediate or delayed hypersensitivity reaction or idiosyncrasy to drugs chemically related to BVD-523FB (ulixertinib), dimethyl sulfoxide (DMSO), or excipients.
5. Patients must not have a left ventricular ejection fraction (LVEF) < the institutional lower limit of normal (LLN) or < 50% (whichever is higher).
6. Patients must not have prior use of MEK or ERK 1/2 inhibitors.
7. Patients must not have a history of RVO or central serous retinopathy. Patients with visible retinal pathology as assessed by ophthalmologic exam that is considered a risk factor for retinal vein thrombosis or central serous retinopathy will be excluded.
8. Intraocular pressure is ≤ 21 mm Hg as measured by tonography. Patients diagnosed with glaucoma within 1 month prior to Step 1 Registration are excluded.
9. Patients must not have leptomeningeal metastases or spinal cord compression due to disease.
10. Patients must not have primary malignancy of the central nervous system.

Schema

