

Fast Facts

Molecular Analysis for Therapy Choice (MATCH)

MATCH Treatment Subprotocol Z1C: Phase II Study of Palbociclib (PD-0332991) in Patients with Tumors with CDK4 or CDK6 Amplification and Rb Protein Expression by IHC

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 CDK4 amplification or CDK6 amplification and tumor Rb protein expression by immunohistochemistry as determined by the MATCH screening assessment. See Appendix II for a list of the targeted mutations 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 breast cancer, mantle cell lymphoma, myeloma, or liposarcoma.
5. Patients must not have known hypersensitivity to palbociclib or compounds of similar chemical or biologic composition.
6. Patients with known or symptoms of left ventricular dysfunction will be excluded.
7. Patients must not have received prior therapy with a CDK4 or CDK6 inhibitor (including but not limited to palbociclib, abemaciclib, or ribociclib).
8. Patients must not be using drugs or foods that are known potent CYP3A4 inhibitors or inducers, or are CYP3A substrates with narrow therapeutic indices (See Appendix III of this subprotocol).

Study Parameters

Test/Assessment	Prior to Registration to Treatment	Treatment			End of Treatment	Follow Up ^F
		Every Cycle, prior to treatment	Cycle 1 & 2, Day 14	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 ^L			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	