# Cancer Research Consortium of West Michigan

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# FAST FACTS

## MATCH Treatment Subprotocol Z1B: Phase II Study of Palbociclib (PD-0332991) in Patients with Tumors with CCND1, 2, 3 Amplification and Rb Protein Expression by IHC

Palbociclib 125mg by mouth once daily for 21 days with 7 days off until progression

Cycle = 28 days

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 amplification of CCND1, 2, or 3 and tumor Rb protein expression by IHC as determined by the MATCH screening assessment. See Appendix II for a list of the targeted mutations and corresponding Levels of Evidence.

   NOTE: As mentioned in Section 1.2, less information is available for CCND2 or 3 amplifications. From TCGA study, it seems that the CCND2/3 amplifications are less frequent than CCND1. CCND2 and CCND3 will be included in the next version of NCI-MATCH assay which is expected to be analytically validated and employed later in the year 2016. When the next version is implemented for patient screening, both CCND2 and CCND3 will be used in addition to CCND1 for treatment arm selection.

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 hypersensitivity to Palbociclib or compounds of similar chemical or biologic composition.
5. Patients must not have breast cancer, mantle cell lymphoma or myeloma.
6. Patients with known or symptoms of left ventricular dysfunction will be excluded.
7. Patients must not have had prior treatment with Palbociclib, Ribociclib, Abemaciclib or any other CDK4/6 inhibitors.
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).