Cancer Research Consortium of West Michigan
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Fast Facts

Molecular Analysis for Therapy Choice (MATCH)
MATCH Treatment Subprotocol I: GDC-0032 (taselisib) in Patients with Tumors (other than breast cancer) with PIK3CA Mutation but without KRAS Mutation or PTEN Loss

Treatment: GDC-0032 (taselisib) 4mg PO daily / cycle = 28 days / Drug is provided

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 PIK3CA mutation detected in their tumor sample as determined by the MATCH screening assessment. See Appendix II for a list of the eligible PIK3CA alterations 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 with known left ventricular dysfunction must have ECHO or MUGA within 4 weeks prior to registration to treatment and must not have left ventricular ejection fraction (LVEF) < institutional lower limit of normal (LLN). If the LLN is not defined at a site, the LVEF must be > 50% for the patient to be eligible.
5. Patients must not have known hypersensitivity to GDC-0032 (taselisib) or compounds of similar chemical or biologic composition.
6. Patients must have a fasting glucose ≤ 125 mg/dL. NOTE: Please provide clear documentation that the glucose test was conducted at a fasting state.
7. Patients must not have breast cancer.
8. Patients with squamous cell carcinoma of the lung who have PIK3CA mutations are not eligible.
9. Patients must not have KRAS mutations, and/or PTEN mutation or loss, detected in the tumor sample as determined by the MATCH screening assessment. PTEN loss will be determined by immunohistochemistry. See Appendix II for a list of the exclusionary KRAS and PTEN alterations and corresponding Levels of Evidence.
10. Patients must not have had prior therapy with a PI3K inhibitor or PI3K/mTOR inhibitor. These include, but are not limited to: BEZ235, XL-765 (SAR245409), GDC-0980, PF-04691502, PF-05212384 (PKI-587), SF-1126, GSK 2126458, P-7170, BGT-226, LY3023414, GDC-0084, DS-7423, BKM-120 (buparlisib), PX-866, XL-147, GDC-0941 (pictilisib), VS-5584, BAY-80-6946, ZSTK-474, WX 037, AZD8835, GSK2636771, GS-9820, BYL719, MLN1117 (INK1117), Idelalisib, TGR1202, RP6530, duvelisib (IPI-145), CUDC-907. Prior GDC-0032 (taselisib) is not allowed.
11. Patients must not have had prior therapy with an Akt inhibitor. These include, but are not limited to: MK-2206, GSK690693, AZD5363, triciribine, perifosine, GSK2141795, GSK2110183, SR13668, BAY1125976, GDC-0068 (ipatasertib), LY2780301, ARQ092.
12. Patients with prior treatment with an mTOR inhibitor are acceptable. These include, but are not limited to: temsirolimus, everolimus, ridaforolimus, sirolimus, CC-223, MLN128 (INK128), DS-3078, CC-115, AZD-2014, AZD8055.

13. Patients must not have type 1 or 2 diabetes requiring anti-hyperglycemic medication (e.g. metformin, glipizide, insulin)
14. Patients must not have current dyspnea at rest or require any daily supplemental oxygen
15. Patients must not have history of inflammatory bowel disease (e.g. Crohn's disease or ulcerative colitis) or active bowel inflammation (e.g. diverticulitis)

Study Parameters

4.1 Therapeutic Parameters for GDC-0032 (taselisib) Treatment

NOTE: In addition to the study parameters listed in the MATCH Master Protocol, the below parameters must also be performed for patients receiving GDC-0032 (taselisib) 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	Cycle 1, Day 15	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
Fasting blood glucose	X	X[J]	X[M]			
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	