Cancer Research Consortium of West Michigan
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# Fast Facts

## Molecular Analysis for Therapy Choice (MATCH)

## MATCH Treatment Subprotocol T: GDC-0449 (vismodegib) in Patients with Tumors (except basal cell skin carcinoma) with Smoothened (SMO) or Patched 1 (PTCH1) Mutations

**Treatment:** GDC-0449 (vismodegib) 150 mg PO daily until progression or unacceptable toxicity / 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 activating mutations of Smoothened (SMO) or deleterious Patched 1 (PTCH1) as determined by the MATCH screening assessment. See Appendix II for a list of the Smoothened (SMO) or Patched 1 (PTCH1) mutations and corresponding Levels of Evidence.
3. Patient must not have basal cell carcinoma.
4. Patients must have an electrocardiogram (ECG) within 8 weeks prior to treatment assignment and must have NONE of the following cardiac criteria:
   - No clinically unstable abnormalities in rhythm, conduction or morphology of resting ECG e.g. complete left bundle branch block, third degree heart block.
   - No factors that increase the risk of QTc prolongation or risk of arrhythmic events such as congenital long QT syndrome, family history of long QT syndrome or unexplained sudden death under 40 years of age
5. Patients with known left ventricular dysfunction must have ECHO or nuclear study (MUGA or First Pass) 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.Patients must not have known hypersensitivity to GDC-0449 (vismodegib) or compounds of similar chemical or biologic composition.
6. Patient must not have had any of the prior therapies: GDC-0449 (vismodegib)
7. Women of childbearing potential and men who are sexually active must agree to use adequate contraception defined as appropriate double barrier method of birth control (such as female use of a diaphragm, intrauterine device (IUD), sponge and spermicide, in addition to the male use of a condom or involve female use of prescribed "birth control pills" or a prescribed birth control implant. Both double barrier contraception and birth control pills or implants must be used for at least one week prior to the start of the study and continue for for 7 months after completion of study for women, and 3 months after completion of study for men.

# Study Parameters

4.1 Therapeutic Parameters for GDC-0449 (vismodegib) 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-0449 (vismodegib) 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] |
|---|---|---|---|---|---|
| | | Cycle 1, 2, 3, and 4, and then every other cycle thereafter | After Cycle 2, 4 and then after every 2 cycles thereafter | | |
| 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 | X | | | |
| Toxicity Assessment[G] | | X[J] | | X | X[F] |
| Pill Count/Diary[H] | | X[J] | | X | |
| ECG[K] | X | | | | |
| Echocardiogram or Nuclear Study | X[I] | | | | |
| Tumor biopsy and blood sample for MATCH Master Protocol[E] | | | | X | |