Cancer Research Consortium of West Michigan
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Fast Facts

Molecular Analysis for Therapy Choice (MATCH)

MATCH Treatment Subprotocol Q: Ado-trastuzumab Emtansine in Patients with Tumors with HER2 Amplification (Except Breast and Gastric/Gastro-Esophageal Junction (GEJ) Adenocarcinomas)

Treatment: Ado-trastuzumab Emtansine administered at 3.6mg/kg intravenously every 3 weeks until toxicity* or progression. **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' tumor sample must have HER2 amplification > 7 based on targeted custom Ampliseq panel on the Ion Torrent PGM. See Appendix I ***(table below)*** for a list of the ERBB2 amplifications and corresponding Levels of Evidence.
3. Adequate hematologic function as defined by:
   - Hemoglobin ≥ 9.0g/dL (which may be reached by transfusion)
4. Patients will be allowed if on anticoagulation (except warfarin and other coumarin derivatives) or on aspirin 81 mg by mouth daily. Additional monitoring while on anticoagulation will be based on institutional guidelines and/or physician discretion. However, patients will not be allowed if on long acting anti-platelet agents such as clopidogrel.
5. Patients must have an electrocardiogram (ECG) within 4 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).
6. Patients must have ECHO or nuclear study (MUGA or First Pass) within 4 weeks prior to registration to treatment and must not have a left ventricular ejection fraction (LVEF) < 50% to be eligible.
7. Patients with a diagnosis of Breast cancer or gastric/GEJ cancer will be excluded.
8. Patients must not have known hypersensitivity to ado-trastuzumab emtansine or compounds of similar chemical or biologic composition.
9. Patients with current peripheral neuropathy of Grade 3 or greater (NCI-CTC, version 4.0) will be excluded. Neuropathy assessment and grade assignment will be based on history (location, duration, balance and gait, effect on activity of daily living (ADLs)) and physical exam.
10. Patient must not have had any of the prior therapies:
    - FDA approved: Trastuzumab; Pertuzumab; Ado-trastuzumab emtansine
    - Investigational: Margetuximab; PF-05280014 (Pfizer, Trastuzumab Biosimilar); CT-P6 (Celltrion, Trastuzumab Biosimilar); ABP-980 (Amgen, Trastuzumab Biosimilar)
11. Women of childbearing potential and men must agree to use adequate contraception (hormonal or barrier method of birth control; abstinence) prior to study entry, for the duration of study participation, and for 7 months after completion of study.

Study Parameters

4.1 Therapeutic Parameters for Ado-trastuzumab emtansine Treatment

NOTE: In addition to the study parameters listed in the MATCH Master Protocol, the below parameters must also be performed for patients receiving ado-trastuzumab emtansine 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.

Test/Assessment	Prior to Registration to Treatment	Treatment		End of Treatment	Follow Up[F]
		Every Cycle, prior to treatment	Every 3 Cycles		
H&P, Weight, Vital signs[A]	X	X[H]			X
Performance status	X	X[H]			X
CBC w/diff, plts[B]	X	X[H]			X
Serum chemistry[B]	X	X[H]			X
Radiologic evaluation[D]	X		X[D]		X[F]
β-HCG[C]	X				
Toxicity Assessment		X		X	X[F]
ECG[G]	X				
Echocardiogram or Nuclear Study[I]	X		X		
Tumor biopsy and blood sample for MATCH Master Protocol[E]				X	