Cancer Research Consortium of West Michigan
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Fast Facts

Molecular Analysis for Therapy Choice (MATCH)
MATCH Treatment Subprotocol E: AZD9291 in Patients with Tumors Having EGFR T790M Mutations (Except Non-Small Cell Lung Cancer) or Rare Activating Mutations of EGFR

Treatment: AZD9291 80mg orally once daily continuously. A cycle is defined as 28 days. **Drug Provided.**

Eligibility Criteria

1. Patient must fulfill all eligibility criteria outlined in Section 3.1 of MATCH Master Protocol (excluding section 3.1.16) at the time of registration to treatment step (Step 1, 3, 5, 7).
2. Patients must have either of the below, or another aberration, as determined via the MATCH Master Protocol and according to Appendix IV::
   a. Any malignancy except NSCLC with EGFR T790M identified in their tumor, with or without an activating mutation **OR**
   b. Any malignancy harboring any of the following mutations: EGFR G719A, G719C, G719D, G719S EGFR L861Q, S786I or an EGFR exon 19 in frame insertion mutation. See Appendix IV for a list of the EGFR 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.
4. Patients must have an ECHO or a nuclear study (MUGA or First Pass) within 4 weeks prior to registration and must not have a 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 osimertinib (AZD9291) or compounds of similar chemical or biologic composition.
6. Patient must not have received osimertinib (AZD9291), WZ4002, CO-1686, HM61713, EGF816 or ASP8273 previously.
7. Patients known to harbor germline EGFR T790M mutations are excluded from the study. Prospective testing for germline mutations is not required.
8. Patients must not have a history of interstitial lung disease, idiopathic pulmonary fibrosis, organizing pneumonia (eg, bronchiolitis obliterans), drug-induced pneumonitis, idiopathic pneumonitis, radiation pneumonitis requiring steroids, or evidence of active pneumonitis on screening chest computerized tomography (CT) scan. History of radiation pneumonitis in the radiation field (fibrosis) is permitted.
9. Patients must not currently be receiving treatment with potent CYP3A4 inducters or medications "known to prolong" the QT interval as defined in Appendix II. Drugs that "may possibly prolong" the QT interval, as defined in Appendix II, are permitted if the patient has been stable on therapy for the period indicated for the specific medication.
10. Patients must agree to not donate sperm from the start of protocol treatment until at least 4 months after the last dose of protocol treatment.

Study Parameters

4.1 Therapeutic Parameters for AZD9291 Treatment

NOTE: In addition to the study parameters listed in the MATCH Master Protocol, the below parameters must also be performed for patients on AZD9291 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	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
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]			
ECHO/Nuclear Study	X				
Tumor biopsy and blood sample for MATCH Master Protocol[E]				X	