Cancer Research Consortium of West Michigan
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FAST FACTS

MATCH Treatment Subprotocol W: Phase II Study of AZD4547 in Patients with Tumors with Aberrations in the FGFR Pathway

AZD4547 80MG PO BID 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 FGFR 1-3 amplification, mutation or translocation as determined by the MATCH screening assessment. See Appendix II for a list of the FGFR gene alterations and corresponding Levels of Evidence.
3. Patients with squamous cell lung carcinoma, gastric cancer, gastroesophageal junction cancer that harbor FGFR amplifications will be excluded.
   - This is based on two trials that did not meet this endpoint in ORR in the relevant histologies (ASCO 2014 abstract #8035 & 2620) and also due to the fact that lung MAP trial is currently open for squamous cell lung cancers.
   - Mutations or fusions of FGFR 1-3 in the above mentioned histologies will still be eligible for the trial.
4. 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):
5. Patients must not have known hypersensitivity to AZD4547 or compounds of similar chemical or biologic composition.
6. Patients must have an ECHO or a nuclear study (MUGA or First Pass) within 4 weeks prior to registration to treatment 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.
7. Patients must have a pre-study eye exam by an ophthalmologist. See Section 3.4.2. Patients with current evidence of corneal or retinal disorder/keratopathy are excluded.
8. Patients must not have received prior FGFR specific inhibitors (e.g. BGJ398, erdafitinib, BAY1163877, LY2874455). Prior non-selective FGFR inhibitor treatment (e.g. Pazopanib, dovitinib, ponatinib, brivanib, lucitanib, lenvatinib) will be allowed.
9. Patients must not have any history of or current evidence of renal or endocrine alterations of calcium/phosphate homeostasis, or history of or current evidence of extensive tissue calcification (by evaluation of the clinician), including but not limited to, the soft tissue, kidneys, intestine, myocardium and lung with the exception of calcified lymph nodes and asymptomatic vascular calcification per investigators' judgment.
10. Patients must not be currently using medications that can elevate serum phosphorous and/or calcium levels.
    a. Medications that increase serum calcium should be avoided. Over the counter calcium supplements, antacids that contain calcium (Tums) and Vitamin D supplements (cholecalciferol and ergocalciferol) should be avoided. Prescription medications including lithium, hydrochlorothiazide and chlorthalidone must be used with caution.
    b. Medications that increase serum phosphate should be avoided. Over the counter laxatives that contain phosphate such as Fleets Oral or Fleets enema and Miralax should be avoided.