NOVARTIS

Product From for Pazopanib in Advanced Cancer

Medical Information *(Mandatory fields)*

1. Patient has histological evidence of advanced/metastatic cancer and received prior systemic therapy, unless it is considered unsuitable. — ◉ YES ○ NO

2. Patient has not received anti-cancer therapy within 14 days prior to the first dose of pazopanib **AND** all toxicities related to prior therapy have resolved to Grade 1 or less. — ◉ YES ○ NO ○ NA

3. Patient has adequate bone marrow and coagulation function as shown by: — ◉ YES ○ NO

Lab parameter	Adults (≥18 yrs)	Pediatric & young adults (< 18 yrs)
Absolute neutrophil count (ANC)	≥ 1.5 × 10^9/L	≥ 1.0 × 10^9/L
Platelets	≥ 100 × 10^9/L	≥ 75 × 10^9/L
Hemoglobin	≥ 9.0 g/dL	≥ 8.0 g/dL

4. Patient has adequate liver function as shown by: — ◉ YES ○ NO

Lab parameter	Adults (≥18 yrs)	Pediatric & young adults (< 18 yrs)
Total bilirubin	≤ 2.0 mg/dL	< 2.5 x ULN (unless abnormality is due to disease)
ALT	< 2.5 x ULN (≤ 5 x ULN in presence of liver metastases)	< 2.5 x ULN (unless abnormality is due to disease)
AST	< 2.5 x ULN (≤ 5 x ULN in presence of liver metastases)	Not applicable

5. Patient has a normal ECG defined as: — ◉ YES ○ NO

Parameter	Adults (≥18 yrs)	Pediatric and young adults (< 18 yrs)
Resting heart rate	50-90 bpm	Not applicable
QTcF	Male: < 450 ms Female: < 460 ms	< 480 ms
QTcB	Not applicable	< 480 ms

6. **Adults:** Patient has serum creatinine < 1.5 mg/dL — ◉ YES ○ NO ○ NA

7. Patient has clinically normal cardiac function based on the institutional lower limit of normal (LVEF assessed by MUGA or ECHO) **AND** no history of any one or more of the following cardiovascular conditions within the past 6 months? — ◉ YES ○ NO
   a. Cardiac angioplasty or stenting;

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b. Myocardial infarction; c. Unstable angina; d. Coronary artery bypass graft surgery; e. Symptomatic peripheral vascular disease; f. Class III or IV congestive heart failure, as defined by the New York Heart Association (NYHA).	
8. **Pediatric & young adults**: Patient with a known history of seizures should have well-controlled seizures and should not be receiving enzyme-inducing anti-convulsants	○ YES ○ NO ◉ NA
9. Patient is woman of childbearing potential and has a negative serum pregnancy test within 14 days prior to the start of pazopanib	○ YES ○ NO ◉ NA
10. Patient has any history of the following cardiac events: a. a cerebrovascular accident at any time in the past; b. a transient ischemic attack in the past 6 months; c. deep venous thrombosis (DVT) in past 6 months; d. pulmonary embolism in the past 6 months. *Note: Patients with recent DVT who have been treated with therapeutic anti-coagulating agents and remained stable for at least 6 weeks are eligible.*	○ YES ◉ NO
11. Patient has a history of clinically significant gastrointestinal disorders within 28 days prior to beginning pazopanib, including: a. own intraluminal metastatic lesions/s with risk of bleeding; b. other gastrointestinal conditions with increased risk of perforation; c. abdominal fistula; d. gastrointestinal perforation or intra-abdominal abscess.	○ YES ◉ NO
12. Patient has a history of a Grade 3 hemorrhage within 4 weeks of starting pazopanib.	○ YES ◉ NO
13. Patient has poorly controlled hypertension blood pressure as defined below: **Adults**: ≥ 140/90 mmHg **Pediatric & young adults**: > 95th percentile for age, height, and gender	○ YES ◉ NO
14. **Adults**: History or clinical evidence of central nervous system (CNS) metastases. Note: Patients who have previously-treated CNS metastases (surgery ± radiotherapy, radiosurgery, or gamma knife) **AND** must meet all 3 of the following criteria: e. asymptomatic and, f. have has no evidence of active CNS metastases for ≥ 6 months prior to treatment with pazopanib,	◉ YES ○ NO ○ NA

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g. have no requirement for steroids or enzyme-inducing anticonvulsants (EIAC)	
15. **Pediatric & young adults**: Patient has moderate to severe renal disease by institutional standards for their age.	☐ YES ☐ NO ☉ NA
16. Patient has an uncontrolled infection.	☐ YES ☉ NO
17. Patient has gross metabolic abnormalities.	☐ YES ☉ NO
18. Patient had prior major surgery or trauma within 28 days prior to first dose of pazopanib **AND/OR** presence of clinically significant non-healing wound, fracture, or ulcer.	☐ YES ☉ NO
19. Patient has known immediate or delayed hypersensitivity reaction or idiosyncrasy to drugs chemically related to pazopanib.	☐ YES ☉ NO

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