

## Inclusion Criteria

1. Male or female participants  $\geq 18$  years of age
2. Histologically confirmed diagnosis of TGCT (formerly known as pigmented villonodular synovitis [PVNS] or giant cell tumor of the tendon sheath [GCT-TS]). Tumor biopsy to confirm TGCT diagnosis will be required if no histology/pathology is available.
3. Disease for which surgical resection will potentially cause worsening functional limitation or severe morbidity as judged by surgical consultation or a multidisciplinary tumor board
4. Symptomatic disease with at least moderate pain per Brief Pain Inventory (BPI) Worst Pain or at least moderate stiffness per Worst Stiffness NRS item (defined as a score of 4 or more, with 10 describing the worst condition) within the screening period, prior to the first dose, and documented in the medical record
5. Participant should complete 14 consecutive days of questionnaires during the screening period.
6. An analgesic regimen, if used, needs to be stable as judged by the Investigator for at least 2 weeks prior to the first dose of study drug
7. Measurable disease per RECIST v1.1 with a minimum tumor size of 2 cm as assessed from MRI scans by a central radiologist
8. Adequate organ function and bone marrow reserve as indicated by the following laboratory assessments performed within 21 days prior to the first dose of study drug:
  - a. Bone marrow function: absolute neutrophil count (ANC)  $\geq 1500/\mu\text{L}$ ;
  - b. hemoglobin  $\geq 10$  g/dL; platelet count  $\geq$  lower limit of normal
  - c. Hepatic function: total serum bilirubin  $\leq$  upper limit of normal (ULN); serum AST/ALT  $\leq$  ULN
  - d. Renal function: serum creatinine  $\leq 1.5 \times$  ULN or creatinine clearance  $\geq 50$  mL/min based either on urine collection or Cockcroft-Gault estimation
9. Able to take oral medication
10. Participants of reproductive potential must:
  - a. Have a negative serum beta-human chorionic gonadotropin ( $\beta$ -hCG) pregnancy test at screening (female participants)
  - b. Agree to follow the contraception requirements outlined in the protocol
11. The participant is capable of understanding and complying with the protocol and has signed the informed consent form (ICF). A signed ICF must be obtained before any study-specific procedures are performed
12. Willing and able to complete the PRO assessments on an electronic device