An Open-label, Multi-center, Phase 2 Study of Denosumab in Subjects with Giant Cell Tumor of Bone (Amgen 20062004)

Status: Recruiting

Eligibility Criteria

Age: 12 years and over

Inclusion criteria: * Pathologically confirmed GCTB within 1 year before study enrollment * Measurable evidence of active disease within 1 year before study enrollment * Subjects with surgically unsalvageable disease (eg, sacral, spinal GCTB, or multiple lesions including pulmonary metastases) OR subjects whose planned surgery includes joint resection, limb amputation, hemipelvectomy or surgical procedure resulting in severe morbidity * Karnofsky performance status equal or greater than 50% (ie, Eastern Cooperative Oncology Group status 0, 1, or 2) * Adults or skeletally mature adolescents (ie, radiographic evidence of at least 1 mature long bone \[eg, humerus with closed growth epiphyseal plate\]) equal or greater than 12 years of age * Skeletally mature adolescents must weigh at least 45 kg * Before any study-specific procedure is performed, the appropriate written informed consent must be obtained Exclusion criteria: * Currently receiving other GCTB specific treatment (eg, radiation, chemotherapy, or embolization) * Concurrent bisphosphonate treatment * Known or suspected current diagnosis of underlying malignancy including high grade sarcoma, osteosarcoma, fibrosarcoma, malignant giant cell sarcoma * Known or suspected current diagnosis of non GCTB giant cell-rich tumors * Known or suspected current diagnosis of brown cell tumor of bone or Paget's disease * Known diagnosis of second malignancy within the past 5 years (subjects with definitively treated basal cell carcinoma and cervical carcinoma in situ are permitted) * Prior history or current evidence of osteonecrosis/osteomyelitis of the jaw * Active dental or jaw condition which requires oral surgery, including tooth extraction * Non-healed dental/oral surgery * Planned invasive dental procedure for the course of the study * Subject currently is enrolled in or has not yet completed at least 30 days since ending other investigational device or drug study(s), or subject is receiving other investigational agent(s) * Subject has known sensitivity to any of the products to be administered during dosing * Unstable systemic disease including active infection, uncontrolled hypertension, unstable angina, congestive heart failure, or myocardial infarction within 6 months before enrollment * Subject is pregnant or breast feeding, or planning to become pregnant within 5 months after the end of treatment * Female subject of child bearing potential is not willing to use two methods of highly effective contraception during treatment and for 5 months after the end of treatment * Subject has any kind of disorder that compromises the ability of the subject to give written informed consent and/or to comply with study procedures

Conditions & Interventions

More Information

Description: This is a phase 2, international, multi-center, open-label study in subjects with GCTB, receiving denosumab at a dose of 120 mg subcutaneously (SC) every 4 weeks (Q4W) with a loading dose of 120 mg SC on study days 8 and 15.
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