Samarium Optimized for Long-lasting Analgesia in Cancerous End-stage Bone Pain

NCT07197645

Status	RECRUITING
Phase	Phase 1
Sponsor	Telix Pharmaceuticals (Innovations) Pty Limited
Enrollment	33 participants

Key Eligibility Criteria

Inclusion (12)

- Participants have had disease progression while on anti-cancer treatment, and are not eligible for the treatments, or their lesions are not amenable to palliative EBRT.
- Participants must have a histologically confirmed diagnosis of malignancy at any time prior to their participation in this clinical trial with multiple metastatic bone lesions with at least 1 metastatic painful osteoblastic tumor that causes a minimum pain score of 4 on the NRS11.
- Participants must have bone cancer in one or more skeletal locations as identified by a 99mTc-diphosphonate bone scan within 60 days of dosing. At least one lesion must be osteoblastic. If described as osteosclerotic, radiology confirmation that the lesion is osteoblastic is required. Adequate organ function, including:
- Renal function, defined as a measured creatinine clearance (CrCl) e30 mL/min as per Cockroft Gault or based on radioisotope glomerular filtration rate (GFR).
- Hematologic function, defined as a platelet count of \>100,000 cells/mm3 and an Absolute neutrophil count (ANC) of \>1000 cells/mm3.

... and 7 more (see full listing online)

Exclusion (15)

- Participants are pregnant or breastfeeding.
- Participants who have received maximum tolerable radiation to the spinal cord, have untreated pathologic bone fracture, spinal cord compression, unstable spine, or imminent long bone fracture.
- Participants with a bone scan pattern showing diffuse, intense skeletal uptake with absent or faint kidney / bladder activity, typically indicating widespread bone metastases or high bone turnover from metabolic or hematologic diseases (Superscan) pattern on Technetium 99-m bone scan scintigraphy - defined as diffusely increased skeletal uptake with absent or markedly reduced renal and soft tissue visualization - are excluded from the study.
- Participants with impending or suspected or at high risk for spinal cord compression.
- Participants with neurogenic pain or significant pain associated with soft tissue lesions or other pain that, in the opinion of the Investigator, might interfere with the assessment of pain relief for bone tumors.

... and 10 more (see full listing online)

Locations (3 total)

Houston Metro Urology, Houston, Texas, United States
Oncology Consultants, Houston, Texas, United States
Excel Diagnostics and Nuclear Oncology Center, Houston, Texas, United States