

Bone & Osteoporosis

Introduction

Bone provides protection to visceral organs, storage of minerals, locomotive movement and are the locations of hematopoiesis. Structural integrity of bone can be affected by factors of aging, dietary imbalance, disuse, environmental contamination, infections, medicine, metabolic disorders, physical loading, radiation, smoking and trauma. Efficacy and safety data of the developing therapeutics to bone in animal models are required to predict the effects in human for excluding the toxicity of it.

Bone fragility increases with age in both genders, and most notably after menopause in female. Anti-resorptive agents are well established, such as bis-phosphonates and OPG. Anabolic agents are actively being developed. Besides PTH analogues and stem cells, molecules from BMP family and Wnt signal pathways, such as Smads, ERK, Dkk-1, Runx2, and beta-catenin are targets for therapeutics. Safety and efficacy data of bone in animal models (rodents and non-human primates) are required to predict the safety and the effects in phases of human clinical trials.

PharmaLegacy Models and Research Tools

At PharmaLegacy, our scientists have cumulated more than two centuries of experiences in bone physiopathology, especially in bone safety, metabolic bone diseases, osteoarthritis and osteoporosis. Our familiarity with IND/NDA and SOP driven GLP quality assurance operations can aid your regulatory submission.

In Vivo Models

Mouse

- Antigen, chemical and collagen induced arthritis for systemic and local modalities.
- Calvaria periosteal injection for assessing bone formation or resorption capability.
- Dietary alterations for body composition.
- Estrogen-deficient bone loss for screening anti-resorption or anabolic agents.
- Steroid-induced bone loss for seeking agents of osteopenia antagonist.



Rat

- Bone safety for evaluating therapeutic effects on skeletal integrity, short or long term.
- Disuse bone loss for examining anti-resorptive and anabolic agents.
- Dietary alterations for body composition.
- Estrogen deficient bone loss for screening anti-resorptive and anabolic agents.
- Renal osteodystrophy for seeking bone quality and quantity improvement agents.
- Steroid-induced bone loss for identifying agents of osteopenia antagonist.
- Testosterone deficient bone loss for screening anti-resorptive and anabolic agents.



Non-Human Primate

- Pharmacokinetic evaluation of dose range and short term effects on biomarkers of bone.
- Estrogen deficient bone loss for screening the therapeutic effects on biomarkers of bone.
- Bone safety for evaluating therapeutic effects on skeletal integrity, long term with biopsies.

Ex Vivo Models

- Biomechanics of bone properties.
- Serum and urine biomarkers of bone remodeling.
- Densitometry of pDEXA, micro-CT and pQCT on bone mineral.
- Static and dynamic histomorphometry of bone cells and tissue, and quality of bone matrix.

Orthopedics

Introduction

Orthopedics corrects injuries or disorders of the skeletal system and associated muscles, joints and ligaments. Modern technologies in tissue engineering have revolutionized tissue and organ repairs for recovery of function. Combinations of stem cells, small molecules and biologics in biocompatible scaffold are used to restore structural and functional deficit in bone, cartilage, facet joints, intervertebral disc, ligament/tendon, and teeth. Efficacy and safety data in animal models is required to predict the biological effects of the products in human.

PharmaLegacy Models and Research Tools

At PharmaLegacy, the scientists are abreast in the areas of animal models, biomaterials, biologics, surgical procedures, and tissue engineering. Our familiarity with IDE and 501k and SOP driven GLP quality assurance operations can aid your regulatory submission.

In Vivo Models

Bone Repair

- Bone void filler testing in rat, rabbit, mini-pig, dog and primate.
- Mini-pump delivery of test articles.
- Calvaria critical size defect in rat and rabbits.
- Osteoinduction in rats; muscle/subcutaneous.
- Periodontal bone repair in dog and primate.
- Segmental defect in long bone of rat, rabbit, dog and primate.
- Spine fusion in rat, rabbit and primate.



Cartilage Tissue Repair

- Full thickness in rat and rabbit.
- Intervertebral disc repair in rat, rabbit, mini-pig and dog.
- Intervertebral disc replacement in sheep/goat.
- Intra-articular particulate injection in rat, rabbit and sheep/goat.
- Meniscectomy and MCL transection in rat, rabbit and dog.
- Osteochondral defect in rat, rabbit, dog and sheep/goat.
- Pond Nuki model in rabbit and dog.



Dental Repair

- Direct and indirect dental pulp exposure in dog and primate.

Ligament/Tendon

- Achilles', ACL, patella and rotator cuff segmental defect repair in dog and sheep/goat.

Osteomyelitis

- Pyogen-induced and wear debris induced in rat, rabbit and dog.

Ex Vivo Models

- Biomechanics of bone/implant integration.
- Densitometry of pDEXA, micro-CT and pQCT on bone mineral.
- EXAKT cutting and grinding of bone/implant.
- Histopathology and histomorphometry of bone and/or cartilage repair and tissue reaction.

About PharmaLegacy Services

- World-class quality with increased speed and output at competitive cost.
- International GLP and QA-based operation.
- Electronic data management system (BioBook) for quality execution and maximum IP protection.
- AAALAC accredited Large capacity to house over 10,000 animals under SPF and conventional conditions.
- Availability of 4,000 non-human primates for research use.