



# Teriparatide: Turn-key Biosimilar Development

Celerion's extensive bioanalytical and clinical pharmacology experience with teriparatide enables us to provide a complete program for clinical development and registration of teriparatide biosimilars:

#### **Fully validated bioanalytical assays that meet rigorous regulatory validation requirements (Total development and validation ranges from \$200K - \$220K)\***

- Pharmacokinetic (PK) assay to measure the concentration of the originator products in plasma for use in pharmacokinetic biosimilarity studies and to document exposure in patient studies. It is the most sensitive assay (6 pg/mL) in the industry and no cross-reactivity to endogenous PTH(1-84)
- Three tier Anti-drug antibody (ADA) assay to measure extent of immune response to the biosimilar
- Cell-based neutralizing-drug antibody assay to assess presence of this effect-nullifying immune response
- Pharmacodynamic (PD) biomarker assays- Procollagen I Intact N-Terminal (P1NP), (Carboxy-Terminal Telepeptides of Type II Collagen (CTX-II) and calcium

#### **Pharmacokinetic study designed to demonstrate biosimilarity quickly (Cost range for equivalent sized study is \$1.25M - \$1.5M total)\***

- Double-blind crossover PK bioequivalence design to meet the 80 - 125% criteria for the 90% confidence intervals for C<sub>max</sub> and AUC
- 70 healthy subjects receiving single subcutaneous injections with a 3 day washout between treatment periods (35 sequence AB; 35 sequence BA)
- Measure for presence of ADAs up to 4 days after each dose

#### **Efficient conduct of studies in patients to demonstrate clinical similarity in drug response (Cost range for equivalent sized study is \$3M - \$5M total)\***

- Blinded, parallel group study in 90 - 100 patients (osteoporosis) per treatment group (originator versus biosimilar) 20 µg sc qd for 24 weeks to demonstrate clinical similarity in immunogenicity and in drug response (as needed by regulatory region):
  - ADA blood levels
  - Lumbar spine bone mineral density and bone turnover biomarkers
  - C<sub>max</sub> and AUC (0-4h) teriparatide
  - Safety and tolerability
- 26 - 30 sites (US or Europe depending on source of originator, Forteo or Forsteo) – recruitment and conduct 18 - 24 months

#### **Regulatory submissions for IND/CTA and NDA/MA (Cost range of \$30K to \$250K depending on services required)\***

**Ask us about our experience with your biosimilar.  
Contact us at [info@celerion.com](mailto:info@celerion.com)**

#### **Background**

The patent on the originating product, Forteo/Forsteo, expires in August, 2019 in both US and Europe.

The regulatory pathway for approval of a teriparatide in US and Europe is now defined. Two biosimilar versions of teriparatide have been approved by EMA and three by Indian regulators.

Teriparatide is the recombinant 34 amino acid portion of human parathyroid hormone (PTH). It is PTH receptor agonist that activates osteoclasts more than osteoblasts resulting in net growth of bone. It is valuable in treatment of osteoporosis in post-menopausal women and for men and post-menopausal women at high risk for bone fracture due to glucocorticoid-induced osteoporosis.

\*Costs include CRO, site and specialty vendor costs but do not include the cost of acquiring drug supply of the innovator biologic. These represent direct costs only for a typical study. Your actual study design and costs may vary.