



Corium International, Inc.

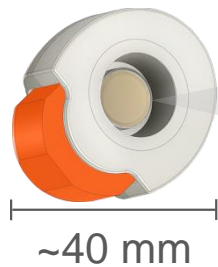
MicroCor hPTH(1-34) Phase 2a

Interim Topline Results

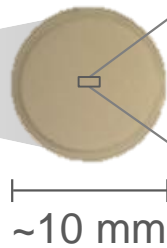
MicroCor Platform Overview



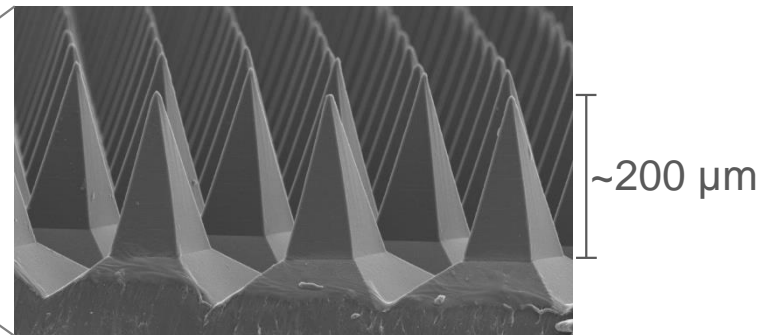
Applicator



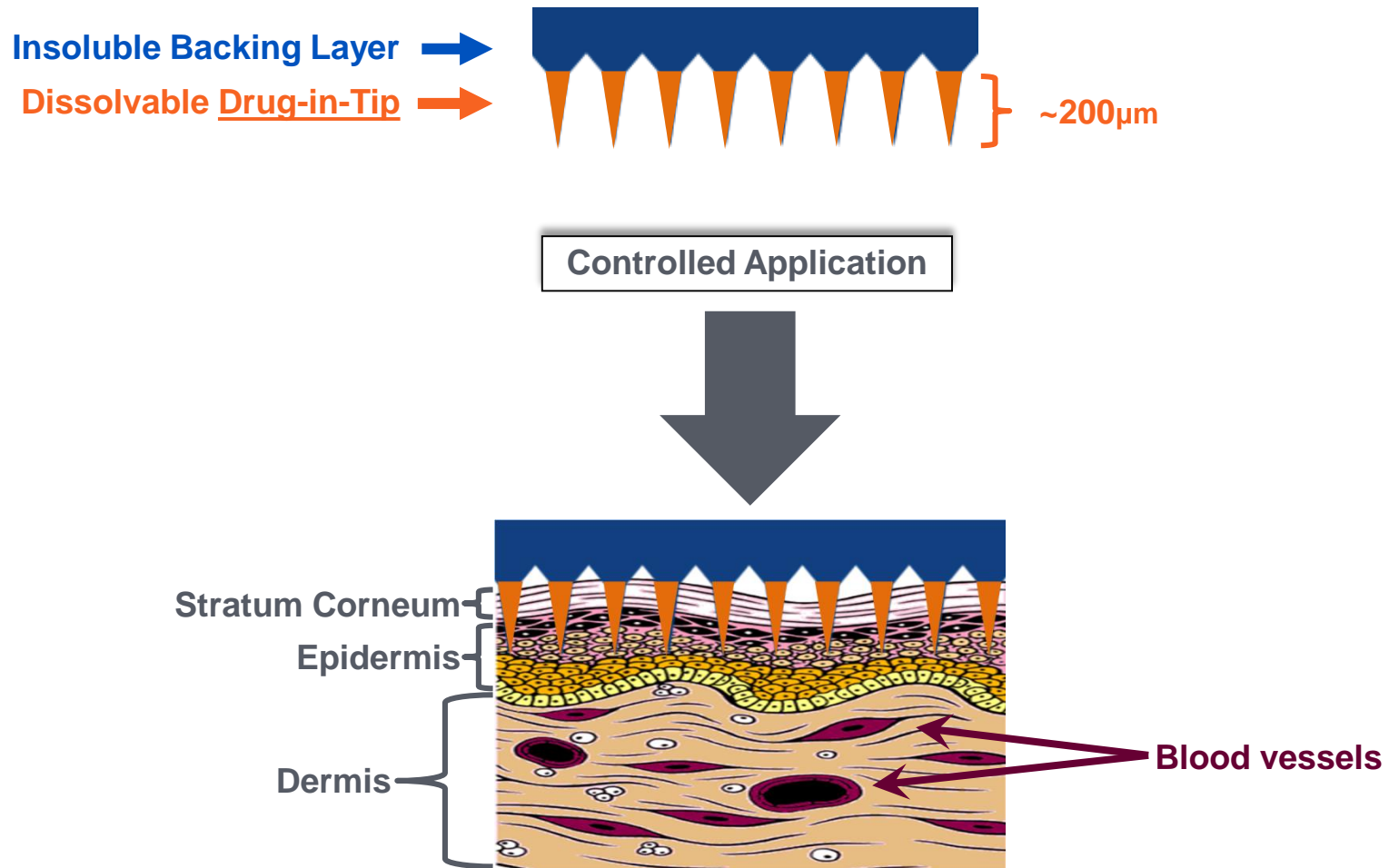
Array



Cross-Section



MicroCor Operation



Phase 2a Study Overview



- **Part A: PK only; FDA guidance to demonstrate PK in target age group**
 - Crossover design reduced variability among subjects
- **Part B: PD + PK; biomarkers evaluated to provide proof-of-concept**
 - Biomarker carry-over precluded crossover study design

Part A

Pharmacokinetics (PK)

18 Subjects

3 Days

In-clinic

2 MicroCor Doses
+ Forteo Injection

Part B

PK + Pharmacodynamics (PD)

21 Subjects

28 Days

Take-home

1 MicroCor Dose
or Forteo Injection

Phase 2a—Part A Design (PK Only)



- Single-dose, randomized, crossover study
- 18 healthy post-menopausal women (50-85 years of age)
- Per FDA guidance, two MicroCor doses to establish dose proportionality:
 - 16 mcg targeted to achieve C_{max} comparable to Forteo
 - 38 mcg targeted to achieve AUC* comparable to Forteo
- Forteo 20 mcg subcutaneous injection as comparator
- Three consecutive days of treatment, each subject receiving all three treatments
- Primary endpoint: compare MicroCor and Forteo PK
- Secondary endpoints: safety, tolerability, and dose proportionality

*AUC = Area Under the Curve, a measure of the total drug delivered to the bloodstream

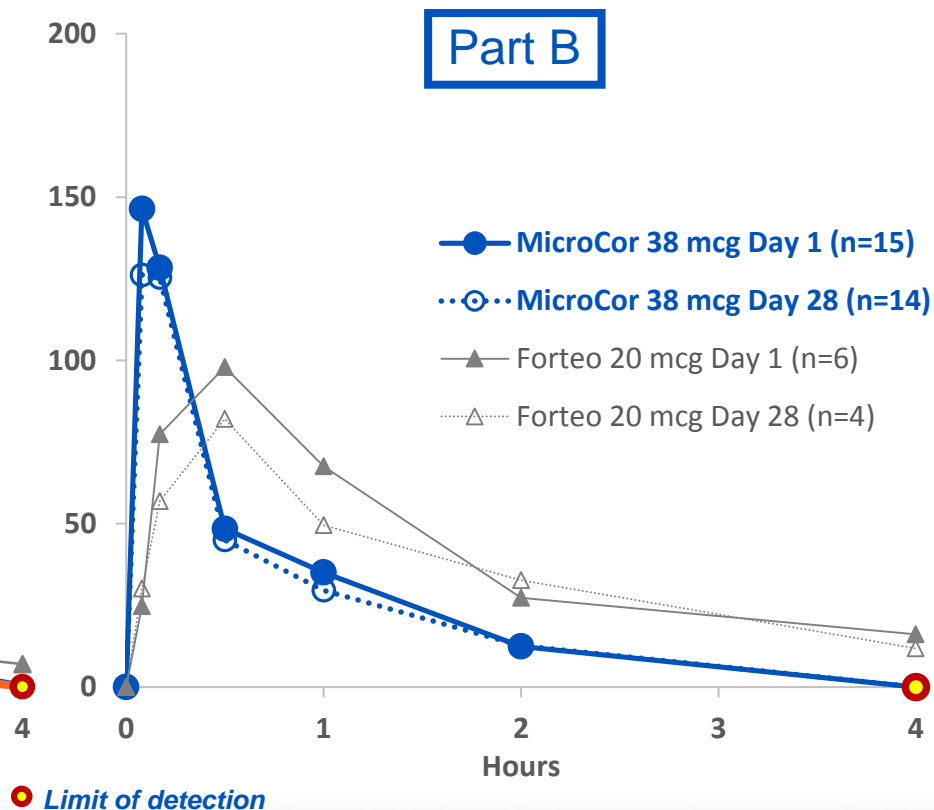
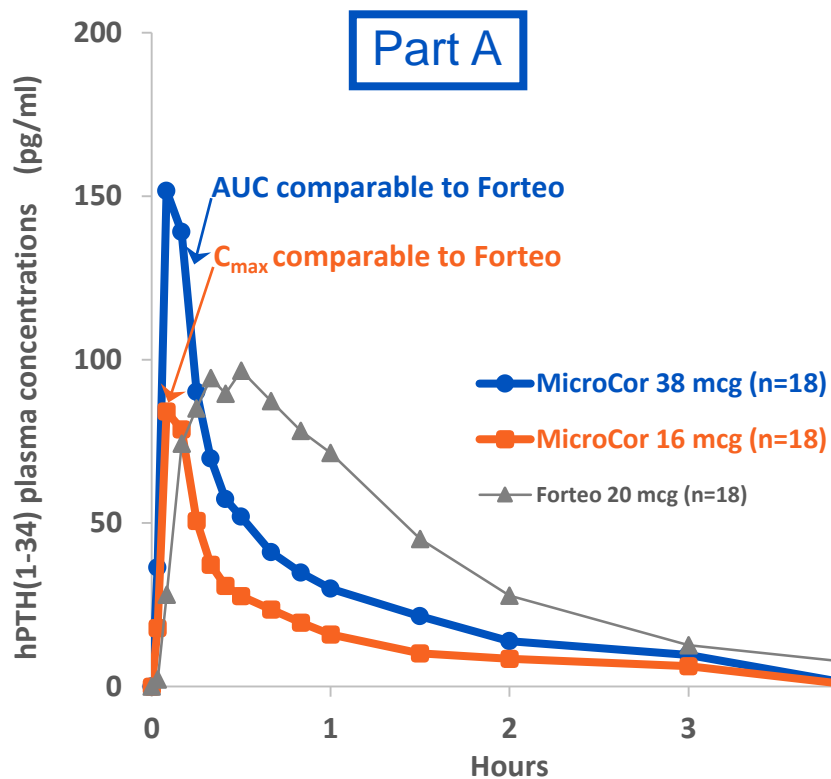
Phase 2a—Part B Design (PK/PD)



- Multiple-dose, randomized, parallel groups
- 21 healthy post-menopausal women (50-85 years of age)
- Two treatment groups:
 - 38 mcg MicroCor (n=15)
 - 20 mcg Forteo subcutaneous injection (n=6)
- Each subject dosed once per day for 28 consecutive days
- First 4 doses applied by clinic staff, remainder self-administered by subjects
- Primary endpoint: compare MicroCor and Forteo PK at Days 1 and 28
- Secondary endpoints: safety, tolerability, and changes in bone biomarkers

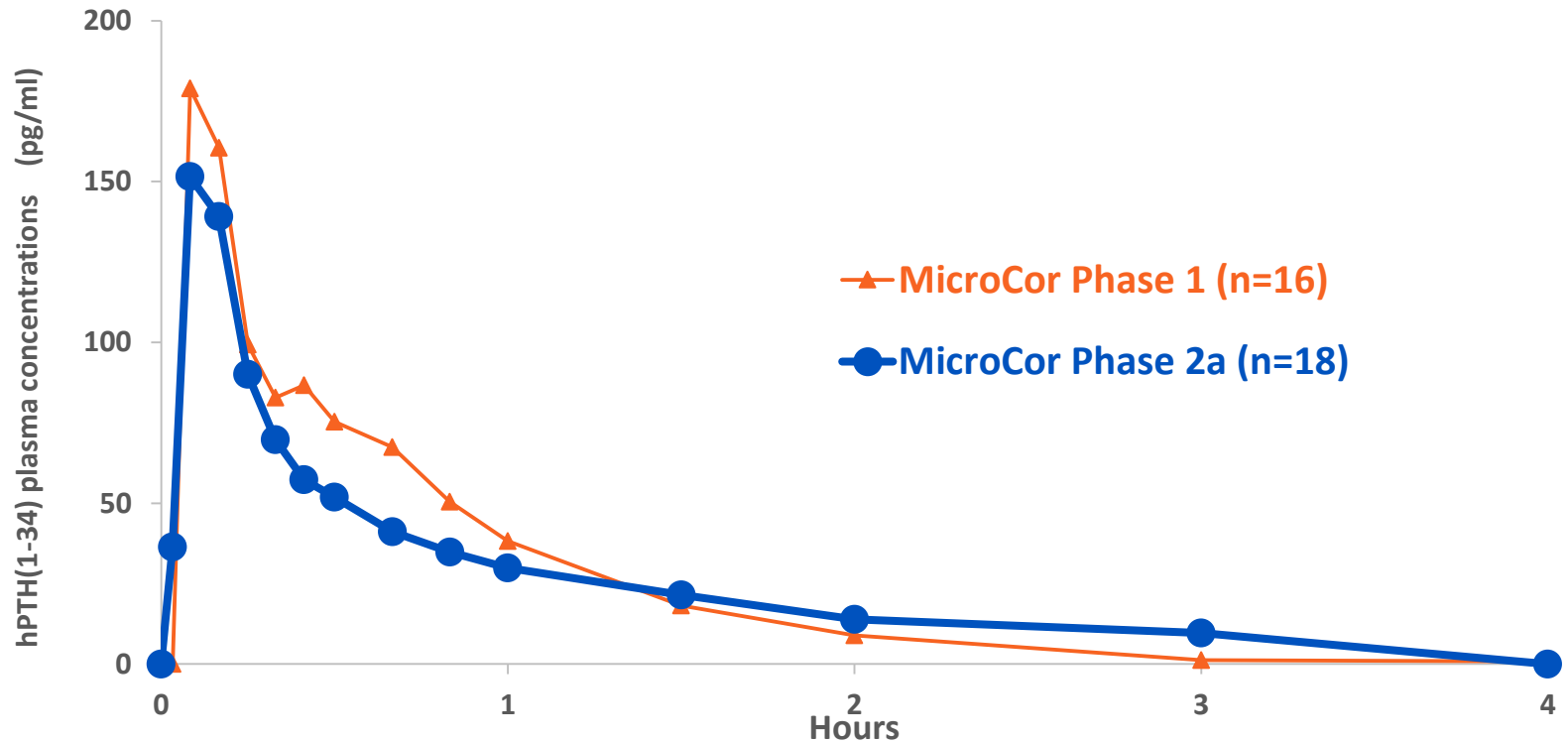
Rapid and Pulsatile Pharmacokinetics

- Dose proportional: *Supports dose selection for Phase 2B*
- No drug accumulation: *Consistent with the short half-life of PTH*



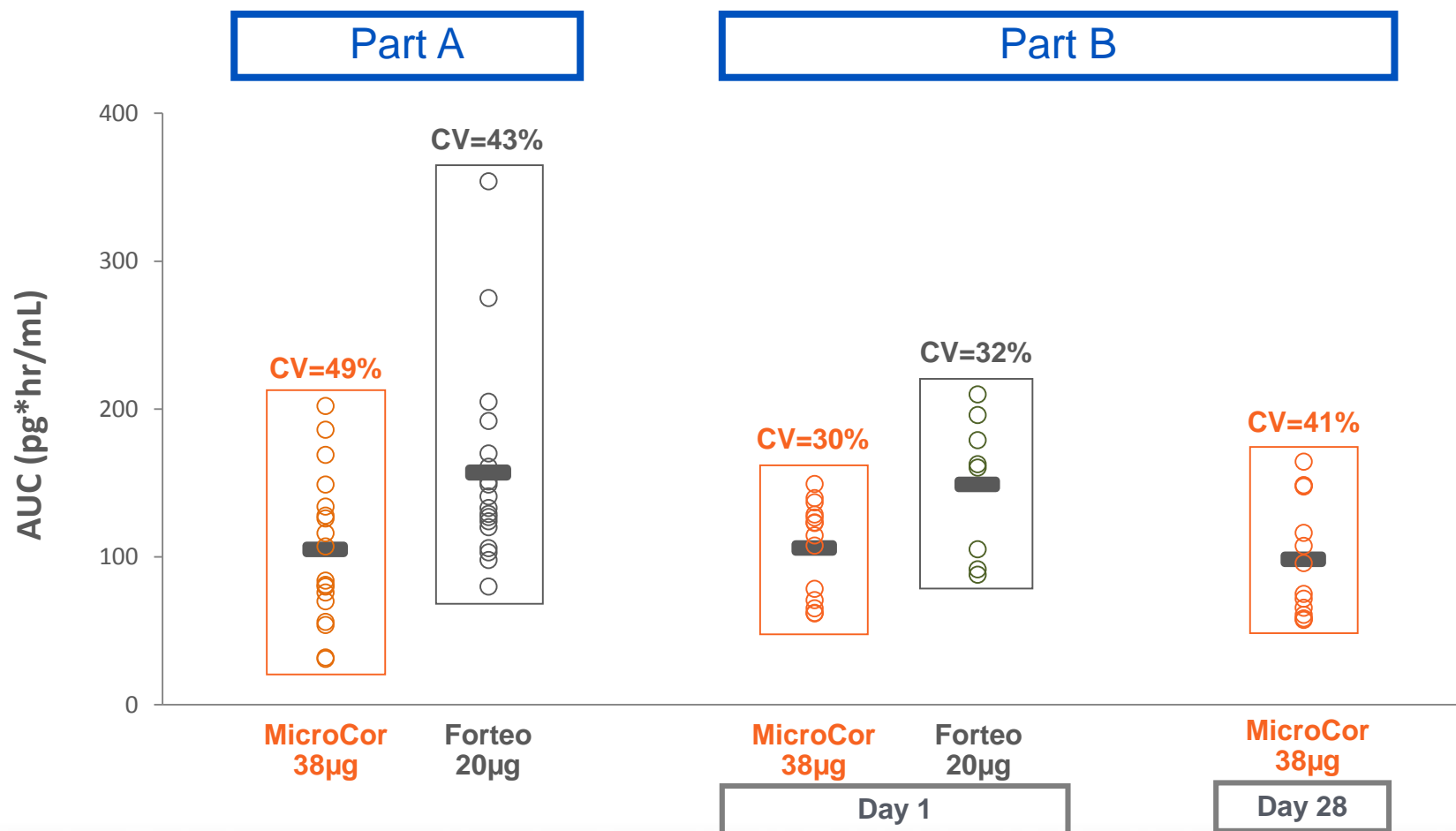
Phase 2a PK Profiles Similar to Phase 1

- PK profiles similar for younger (18-35) and older (50-85) subjects
- Phase 1 PK profile reviewed with FDA as basis for Phase 2 study design



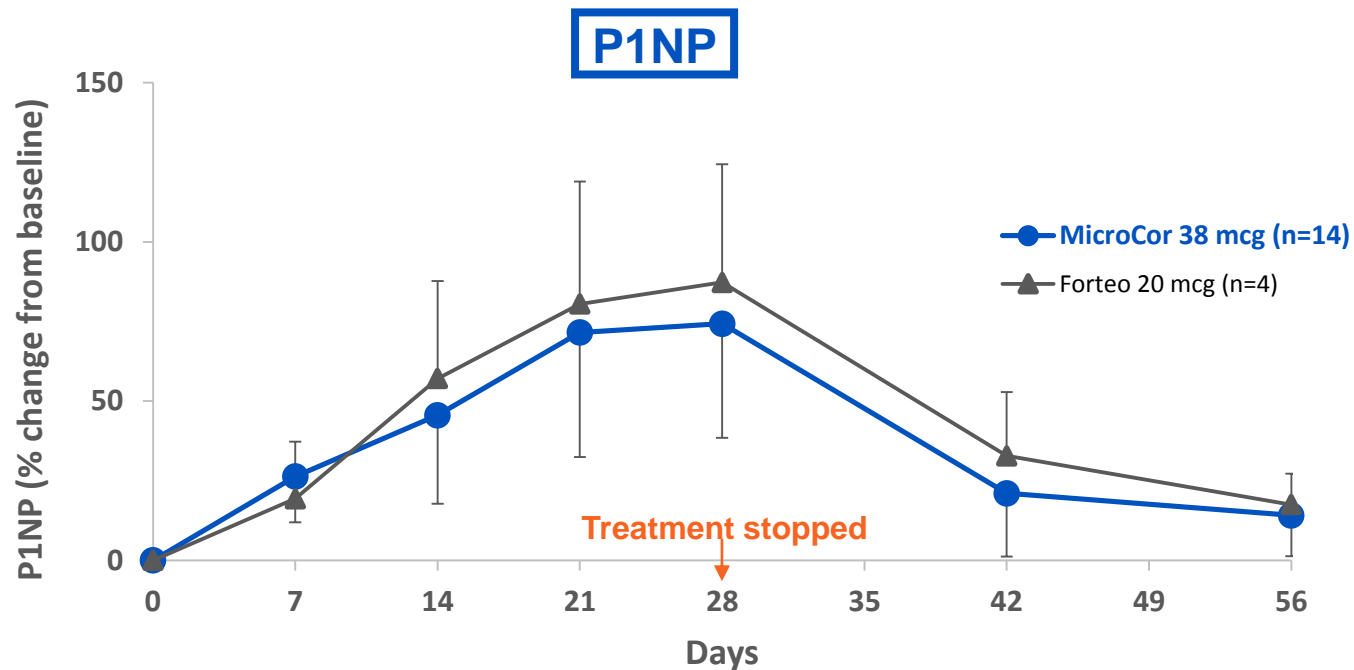
Reliable and Reproducible Dosing

- AUC variability in MicroCor PTH comparable to Forteo injections



Increase In Bone Formation Biomarker

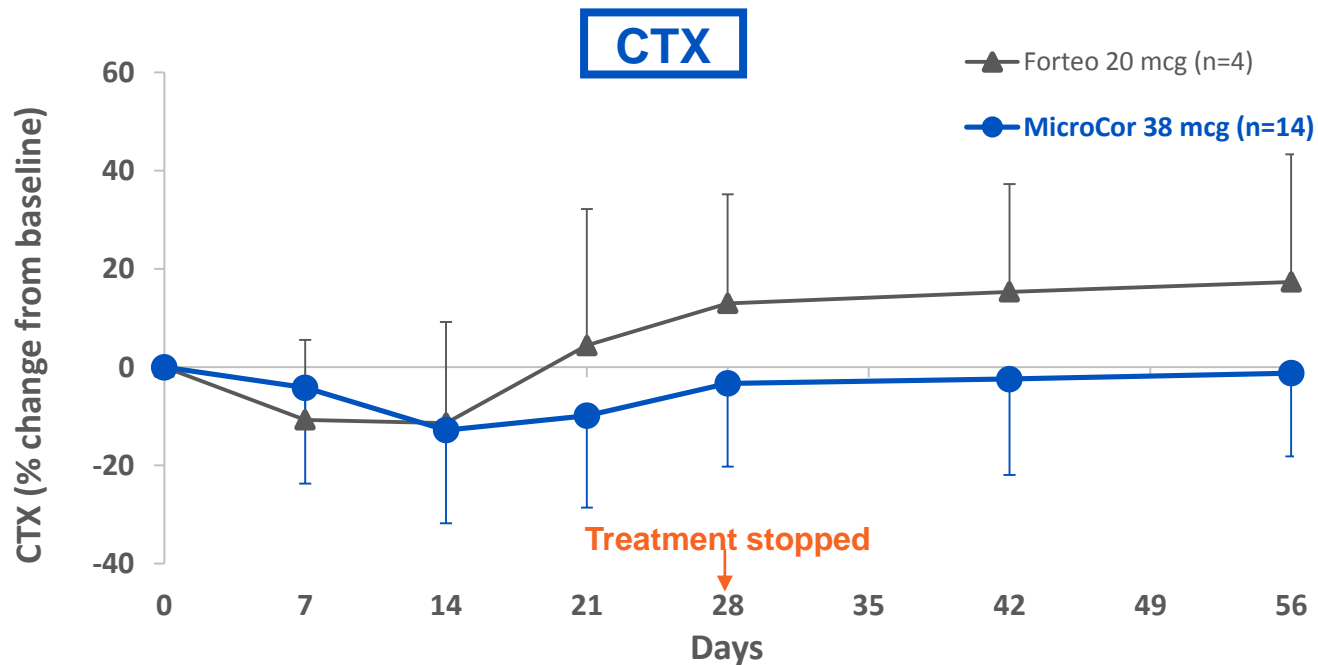
- Serum P1NP* levels indicative of bone formation activity
- Increase in P1NP with MicroCor similar to Forteo during 28-day treatment
- Marker is predictive of BMD response (primary endpoint in Phase 2b/3)



*P1NP – Procollagen Type 1 N-terminal propeptide

Little Change in Bone Resorption Biomarker

- Higher serum levels of CTX* are indicative of bone loss
- CTX levels with MicroCor essentially unchanged compared to baseline
- Forteo showed an increase in CTX starting at day 21



*CTX – collagen Type 1 cross-linked linked C-telopeptide

Excellent Safety and Skin Tolerability



- **545 MicroCor applications in Phase 2a showed excellent skin tolerability**
 - 95% of applications resulted in minimal (score of 1/8) skin irritation (erythema only)
 - Highest reported score was 2/8
 - Erythema was transient, limiting and self-resolving
 - No other application-related skin reactions reported/observed
 - No evidence of contact sensitization after 28 days of sequential daily use
- **Systemic safety**
 - No serious adverse events reported
 - Observed adverse events similar to Forteo; none unique to MicroCor
 - Lower frequency of drug-related adverse events compared to Forteo (64% vs. 83%)

Key Phase 2a Conclusions



- Excellent safety and skin tolerability
- Rapid and reproducible PK in target age group (50-85)
- Results confirmed PK profile seen in younger Phase 1 study age group (18-35)
- Bone biomarkers consistent with Forteo
- Ease and reproducibility of self-administration validated

Results support advancing into Phase 2b testing in osteoporotic patients

Planned Phase 2b Trial Design



- Efficacy and safety study in 150-200 post-menopausal osteoporotic women
- Three MicroCor doses with Forteo 20 mcg as active comparator
- Six-month study duration with daily self-administration of treatments
- Trial could commence in late CY 2016
- Partnering or co-development could affect timing

Primary Endpoint:	Changes in BMD at lumbar spine at 6 months
Secondary Endpoints:	Changes in BMD at hip, bone biomarkers, safety, and skin tolerability

A grayscale photograph of a hand with manicured nails holding a single, peeled segment of an orange. The segment is white with a bright orange rind. The background is a soft-focus, light gray surface.

Corium International, Inc.

Nasdaq: CORI

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