Reactivations repeated a total of 3 times with 2 weeks between each.

In contrast, as shown in the bar graphs, the knees of animals treated with Kenalog®-40 were inhibited following both Kenalog® and FX006 treatment, but recovered by Day 14.

Histopathological evaluation of the knees showed statistically significant improvement in gait scores through all three reactivations induced on Days 1, 14, and 28. Animals injected with 0.06 mg of FX006. All treatment groups had similar corticosterone levels at baseline that were initially reported following the labeled 40 mg IA dose in patients. Histopathological evaluation of the knees (2.5 hours after IA dosing), and subsequently on Days 14 and 28 (with no further dosing with treatments). FX006 was administered at doses of 0.28, 0.12 or 0.03 mg TCA and Kenalog® at 0.06 mg corticosterone) and plasma pharmacokinetics (PK) were characterized.

In a modified PGPS model of localized knee osteoarthritis in rats, the prolonged release of TCA from PLGA microspheres following a single IA injection of FX006 resulted in extended duration of efficacy and a significant improvement in histological scores of joint tissues compared to Kenalog® injection, the Cmax at this dose was 1/10th, and systemic exposure comparable to that provided in weight-bearing and gait (as a measure of knee pain), histopathology, pharmacodynamics (serum corticosterone) and pharmacokinetics (PK) were characterized.