PHARMACOKINETICS AND TOXICOKINETICS STUDIES OF A SUSTAINED RELEASE LIPOSOMAL FORMULATION OF DEXAMETHASONE SODIUM PHOSPHATE (TLC599) FOLLOWING INTRA-ARTICULAR INJECTION IN DOGS

Study#8351851: Following a single-dose IA injection of TLC599, DP concentration declined after 15 days but remained at similar level from 30 days to 120 days post-dose. Overall, the prolonged 120-day residence time of TLC599 in synovial joint was observed (Figure 2).

Abstract THU465 – Figure 2. Mean Concentration of DP in Dog Synovial Fluid.

Conclusion: TLC599, a novel extended-release liposome formulation of DSP, showed a long-lasting profile up to 120 days in synovial joint after a single IA injection in a preclinical dog study. In addition, no significant systemic exposure and accumulation of DP and DEX in dog plasma was observed following multiple-dose administration of TLC599. Animal studies indicate that TLC599 may be an effective and superior chronic treatment for OA.

REFERENCE:

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THE EVALUATION OF THE EFFECTIVENESS OF INTRA-ARTICULAR STEROID, TENOXICAM AND COMBINED STEROID-TENOXICAM INJECTIONS IN THE TREATMENT OF PATIENTS WITH KNEE OSTEARTHROSIS

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Background: Intra-articular corticosteroid injections are widely applied in the treatment of symptomatic knee osteoarthritis (OA). There is an evidence of short-term effects of intra-articular corticosteroid injection (up to 3-4 weeks), however there is no consensus for the long-term benefit of this treatment yet (1). Tenoxicam is an effective analgesic and anti-inflammatory drug for symptomatic treatment of OA. Additionally, apart from oral use, tenoxicam is also applied as an intra-articular treatment option to minimize gastrointestinal side effects of NSAIDs (2). Clinical evidence suggests that the combined use of NSAIDs and corticosteroids is synergistic (especially macular edema after cataract surgery in ophthalmology) (3).

Objectives: The aim of this study is to compare the effectiveness of intra-articular administration of these treatments and their combination and determine whether the combination of intraarticular steroid and tenoxicam was more effective for a long period rather than only tenoxicam and steroid injection alone in OA treatment.

Methods: 90 patients (56 female, 34 male) with diagnosis of knee osteoarthritis were randomly divided into three groups (30 patients per group): Group 1 were treated by intra-articular injection of triamcinolone hexacetonide. Group 2 were treated by intra-articular injection of triamcinolone hexacetonide with tenoxicam. The estimation of the severity of pain by the visual analog scale (VAS) was enrolled at baseline and 1, 3, 6 months post-injection. Additionally, the Western Ontario and McMaster Universities Index (WOMAC) was used to determine the outcome measures of pain, stiffness and physical functioning at baseline and 1, 3, 6 months post-injection.