A multicentre, randomized, placebo- and active-controlled trial comparing the efficacy and safety of topical ketoprofen in Transfersome® gel (IDEA-033) with ketoprofen-free vehicle (TDT 064) and oral celecoxib for knee pain associated with osteoarthritis.

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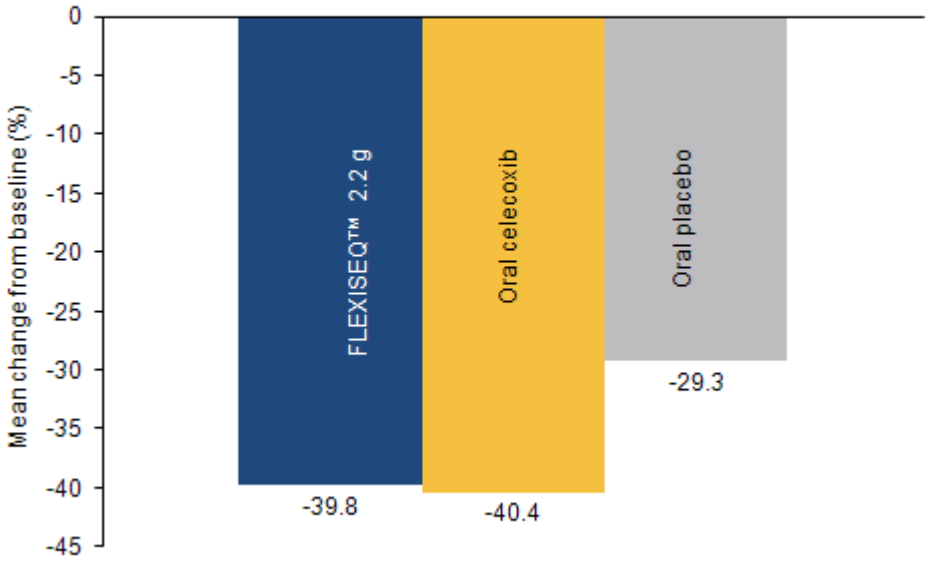
Summary

We are pleased to provide you with a summary of one of our key studies which was recently published in the prestigious clinical journal, Rheumatology. This study (CL-033-III-03) compared the use of FLEXISEQ™ (TDT 064) with 200 mg daily of oral celecoxib (the dose registered for OA) and also oral placebo. The 1399 patients with moderate OA-associated knee pain who were enrolled were typical of OA patients seen in clinical practice.

This summary reports the efficacy and safety data from the 2.2g dose of FLEXISEQ™ as this is the dose marketed. The study assessed pain, function and stiffness in the knee joint using the Western Ontario and McMaster Universities Arthritis Index (WOMAC), a globally recognised clinical assessment routinely used in OA trials. Patients treated with FLEXISEQ™ showed progressive and clinically relevant improvements in the WOMAC subscales for pain, function, and stiffness, comparable in size to those observed among patients receiving oral celecoxib and statistically superior to those observed in patients taking oral placebo. After 12 weeks' treatment, pain had improved by 39.8% from baseline, compared with 40.4% for oral celecoxib.



Reduced joint function and joint stiffness are also common complaints from patients with OA and this study demonstrated that FLEXISEQ™, used twice daily, improved function and stiffness by 37.0% and 35.9% respectively, compared to 38.2% and 37.9% respectively for oral celecoxib. Furthermore, confirmatory analyses demonstrated the statistically significant non-inferiority of FLEXISEQ™ versus oral celecoxib, and statistically significant superiority to oral placebo.

A similar proportion of patients in the FLEXISEQ™ group and the oral celecoxib group rated their response to therapy as 'fair', 'good' or 'excellent' (range: 68.0–73.0%). However, for comparison, in the oral placebo group, only 52.9% of patients rated their response as 'fair', 'good' or 'excellent'.

FLEXISEQ™ was well tolerated by the patients in this study. The majority of the AEs reported with FLEXISEQ™ were local skin reactions (reported in 5.9% patients), and treatment-related gastrointestinal disorders were reported at highest frequency among patients who received oral celecoxib (15.9% of patients). This was reflected in the substantially greater proportion of patients receiving oral treatment who required concomitant treatment with omeprazole. There were no serious treatment-related AEs reported.

The authors of this paper concluded that FLEXISEQ™ was superior to oral placebo in terms of pain reduction and comparable to oral celecoxib. They commented that the use of topical pain therapies instead of oral NSAIDs, or their combination with a lower dose of an oral NSAID, might be appropriate for some patients with OA to minimise systemic NSAID burden, thus reducing systemic AEs resulting from oral NSAID use.

The full text of this paper can be accessed:
http://rheumatology.oxfordjournals.org/content/early/2013/03/27/rheumatology.ket133.abstract.
Further publications of the clinical programme of FLEXISEQ™ studies are ongoing.