

Heel's Traumeel® and Zeel® T shown to reduce pain of OA of the knee by more than 60% in MOZArT trial – the first double blind, randomized, controlled clinical trial to assess efficacy and safety of intra-articular injections of Traumeel® and Zeel® T compared with placebo¹

Baden-Baden, Germany/Rome, Italy – Clinical data released at the 2015 European League Against Rheumatism (EULAR) congress show Traumeel® and Zeel® T co-administered intra-articular (IA) injections provide a new first line injection treatment option in the management of moderate to severe osteoarthritis of the knee, where oral pain management failed.

Treatment with Traumeel® and Zeel® T resulted in a clinically relevant reduction in pain for patients with OA of the knee over a three-month period, and in considerable improvement of function for patients with OA of the knee.¹

Lead author Carlos Lozada MD of University of Miami Miller School of Medicine, Miami, FL, explained, “The global burden of hip and knee OA is considerable.² The MOZArT study findings are, therefore, especially interesting since existing therapies, such as NSAIDs, don't always meet patients' needs in terms of pain relief and may also carry some tolerability risks.^{3,4} In our presentation, Traumeel® and Zeel® T were seen to produce a favorable risk benefit profile, adding a potentially useful option to our armamentarium when treating OA.”¹

Osteoarthritis of the knee is a chronic disease that causes moderate to severe pain in an estimated 250 million people worldwide, representing 83% of the total osteoarthritis disability burden.⁵ Oral treatments such as NSAIDs including selective COX-2 inhibitors may not be suitable for patients with comorbidities or who are at risk of developing serious adverse events or may end in treatment failure.^{3,4} Subsequent current intra-articular treatment options include corticosteroids and hyaluronic acid but clinical trial results and opinions on efficacy vary, while treatment costs can be high and duration of effect can be short.³

The MOZArT trial (**M**anagement of **O**steoarthritis of the **K**nee with **Z**eel **A**nd **T**raumeel Injections) was conducted across 24 centers involving 232 patients, and sought to evaluate the superiority of Traumeel® and Zeel® T co-administered intra-articular injections versus placebo intra-articular injections on the change in knee pain¹ based on WOMAC index (section A 1-5).⁶ Secondary objectives, among others, were to evaluate joint stiffness and change in physical function.

Overall, the Traumeel® and Zeel® T combination is an effective and safe first line injection treatment option and has the potential to provide significant improvement in patient activity levels due to the pain relief provided.

References

- 1 Lozada C, del Rio E, Reitberg DP, Smith R, Moskowitz RW. Risk-benefit of co-administered Traumeel® (TR14) and Zeel® (ZE14) intra-articular (IA) injections in patients with moderate-to-severe pain associated with OA of the knee (OAK). EULAR15-4268.
- 2 Cross M et al. The global burden of hip and knee osteoarthritis: estimates from the Global Burden of Disease 2010 study. *Ann Rheum Dis* 2014;73:1323–1330
- 3 McAlindon TE et al. OARSI guidelines for the non-surgical management of knee osteoarthritis. *Osteoarthritis Cartilage* 2014;22(3):363–388.
- 4 Bruyère O et al. An algorithm recommendation for the management of knee osteoarthritis in Europe and internationally: a report from a task force of the European Society for Clinical and Economic Aspects of Osteoporosis and Osteoarthritis (ESCEO). *Semin Arthritis Rheum* 2014;44(3):253–263.
- 5 Vos T et al. Years lived with disability (YLDs) for 1160 sequelae of 289 diseases and injuries 1990-2010: a systematic analysis for the Global Burden of Disease Study 2010. *Lancet* 2012;380(9859):2163–2196.
- 6 WOMAC Osteoarthritis Index <http://www.womac.org/womac/index.htm> (accessed 29 May 2015).

Notes to editors

- Traumeel® and Zeel® T showed statistically significant superiority to placebo in pain reduction and function on days 15, 43, 57, 71, 85 and 99 (primary end point day), and approached significance on day 29¹
- The MOZArT study used the WOMAC index (section A) to monitor change in pain:
 - WOMAC: Western Ontario and McMaster Universities Arthritis Index
 - Widely used and validated Instrument for measuring the continuum of pain
 - The WOMAC consists of 24 questions items divided into 3 categories (pain, stiffness, physical functioning)
 - WOMAC VAS (Visual Analogue Scale):
 - 100mm VAS version:
 - uses scale limits of no pain (0) and extreme pain (100) ends, respectively
 - patients point to a place on the scale that corresponds to the severity of their symptom
 - researcher measures the distance from zero in millimeters to calculate the score for that question
- MOZArT secondary objectives, among others, measured pain reduction and change in physical function by changes in WOMAC stiffness and physical function subscores, PGA/PhGA,* timed walking (pain after 50 foot walk test), and use of rescue medication

*PGA = patient global assessment/PhGA= Physician global assessment

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