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 placebo

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.

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. 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. 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.”

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. 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. 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.

The MOZArT trial (Management of Osteoarthritis of the Knee with Zeel And Traumeel 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 pain based on WOMAC index (section A 1-5). 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
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

Heel is a pharmaceutical company that develops, manufactures and distributes medicines based on natural substances. The company is a pioneer in the field of scientific research in natural healthcare. In cooperation with academic institutions, Heel actively fosters the concept of integrative medicine to improve patient care and health. The ‘Biologische Heilmittel Heel GmbH’ with its corporate headquarters located in Baden-Baden/Germany and a staff of nearly 1,400, achieved an annual turnover of 213 million Euros in 2014 – 65 percent of it outside of Germany. Heel medicines are available through subsidiaries and distribution partners in over 50 countries around the world. www.heel.com