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A disease modifying drug for osteoarthritis: Results of a phase II study

Osteoarthritis (OA) is the most common form of arthritis worldwide with rising incidence and prevalence in part due to ageing and obesity. In Western populations it is one of the most frequent causes of pain, loss of function, and disability in adults. In the US, Osteoarthritis affects 30% of the population with nearly 1 in 2 people expected to develop knee osteoarthritis by age 85. Over 40,000 total knee and hip replacement procedures were performed in 2013, the majority for OA, each costing between \$15,000-\$31,900. Despite its large disease burden, there are currently no approved disease-modifying drugs available which modify structural progression of OA. Conventional treatment of OA is mostly symptomatic and costly. Therefore, there is urgent need for a disease modifying osteoarthritis drug (DMOAD). Bisphosphonates have been evaluated as DMOAD. Zoledronic Acid (ZA) is the most potent bisphosphonate and is approved for prevention and treatment of osteoporosis, Paget's disease and certain bone cancers. A phase 2 randomized controlled trial of ZA in OA of knee in Australia (ZAP study, zoledronic acid for knee pain) showed efficacy at six months of ZA in decreasing bone marrow lesions in OA by MRI. This study describes the ability of a new formulation of ZA, VOLT01 (US patent # 13/791,685, US, WO PCT/US14/22169), to treat OA. In comparison, to ZA, VOLT01 showed superior efficacy in controlling osteoarthritis pain.

Biography

Ketan Desai, MD, PhD is the CMO of Levolta Pharmaceuticals and the Inventor of the Lead Compound, Volt01. He was trained at Washington University in Saint Louis and Baylor College of Medicine. He has been in the Pharmaceutical Industry for 18 years and started his own companies in 2006. The companies include a Radiology Company and Levolta Pharmaceuticals. He is a consultant for hedge funds and venture capitals.

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