Company Overview

Skelegen LLC is developing a novel, targeted osteoinductive agent for the enhancement of bone growth in spinal fusion procedures. The product consists of an osteoconductive bone graft scaffold paired with Jagged1, an osteoinductive protein known to stimulate bone growth. This combination provides the power of a biologic with a greatly enhanced safety profile when compared to competitive products.

Market Opportunity

Bone Morphogenetic Protein – 2 (BMP-2), also known as Medtronic’s Infuse, is the only osteoinductive biologic on the market that is approved for spinal fusion. Originally a wildly successful product with peak sales ~$900 Million, off-label marketing and a number of safety concerns including exuberant ectopic bone formation and in some cases death led to a sales slide to the current ~$470 Million per year. This sizeable known void in this market, along with the fact that surgeons still want to use a biologic with osteoinductive properties in spite of safety concerns, both point to an excellent opportunity for a fusion technology that grows bone with an enhanced safety profile.

Product

Skelegen’s technology utilizes the Notch Signaling pathway ligand, Jagged1, which potently induces osteoblast differentiation and bone mineral production. Jagged 1 is not part of the BMP family and is not a soluble growth factor. Instead it produces its effects as a surface bound cell-to-cell signaling molecule. Jagged1 must be adsorbed to a surface to induce a functional signal; ligand that is free-in-solution or that diffuses from the implant location is inactive. This greatly enhanced safety and performance feature does not depend on the design or manufacture of the device; it is a fundamental aspect of the biology. Jagged1 can likely be paired with any commercially available scaffold, and has been tested with several biomaterials. The Jagged1/biomaterial combination will be regulated through the PMA pathway as a combination device.

Team Information

Kurt Hankenson, DVM, PhD, Co-founder. Dr. Hankenson is Associate Professor and Associate Director of the Laboratory for Comparative Orthopaedic Research at Michigan State University. He is an expert in the field of cell signaling pathways and osteogenesis.

Michael Dishowitz, PhD, Co-founder. Dr. Dishowitz is an expert in bone tissue engineering and regenerative medicine. He has served as a consultant to the biotech industry, and advises and sits on the board of several early-stage startup companies.

Jaimo Ahn, MD, PhD, FACS, Co-founder. Dr. Ahn is Assistant Professor of Orthopaedic Surgery and Co-Director of Orthopaedic Trauma Fracture Service at the University of Pennsylvania. He is an expert in musculoskeletal trauma, regeneration and aging.

Sigmund Kulessa, MD, MBA, President. Dr. Kulessa has held multiple positions in business development and engineering at both large and small companies. He is keenly interested in translating technology from the lab into the marketplace.