Bone Therapeutics SA
www.bonetherapeutics.com

Paving the way in orthopedics and bone diseases

Bone Therapeutics has two innovative products in late-stage development for the treatment of delayed-union fractures, spinal fusion and knee osteoarthritis. The company is expanding its pipeline, including through research and development and commercialization partnerships, to help patients improve mobility.

Bone Therapeutics is a leading biotech company focused on helping patients improve their mobility and rebuild their lives with innovative products for high unmet medical needs in orthopedics and bone disease.

Bone-related disorders encompass pathologies ranging from orthopedic conditions, such as severe fractures, to spinal conditions, such as degenerative disc disease. Despite the growing number of biopharmaceutical and medical device companies in the field, there is still a need for further disruptive innovation.

Bone Therapeutics focuses on two major challenges: the production of allogeneic cell therapies that are easily distributed commercially, and the production of enhanced viscosupplements that offer analgesic effects with improved lubrication.

The company's lead clinical-stage programs are (1) an off-the-shelf, allogeneic cell therapy platform, ALLOB, for patients undergoing spinal fusion procedures and patients with delayed-union fractures, and (2) an enhanced viscosupplement, JTA-004, for the treatment of pain in knee osteoarthritis (KOA) (**Fig. 1**).

Bone Therapeutics is looking to further advance these programs through late-stage clinical development and to progress its orthopedics and bone disease preclinical pipeline. Key to these efforts is to strengthen and build new and existing research and development (R&D) and commercial partnerships.

"Bone Therapeutics is about excellent science combined with smart business," said Thomas Lienard, CEO of Bone Therapeutics. "Our ambition is to focus on rebuilding people's lives by being the leader in orthobiologics."

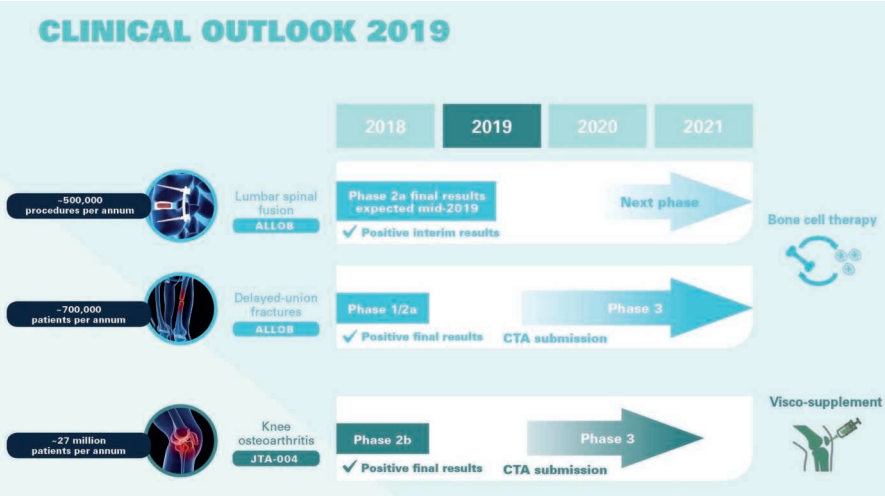

Fig. 1 | Bone Therapeutics' expanding pipeline. Advanced assets include ALLOB, an allogeneic cell therapy platform for spinal fusion and delayed-union fractures, and JTA-004, a patented, noncellular enhanced viscosupplement for the treatment of pain in knee osteoarthritis.

Going allo in delayed-union fractures

Each year, approximately 700,000 patients in the US, Europe and Japan fail to achieve bone union within three months after a severe fracture. Currently, a 'wait and see' approach is adopted for delayed-union fractures, delaying a patient's return to normal life. In some cases, fractures will resolve after a long period of time, but in many instances, the patient develops a nonunion, a permanent failure of healing that requires invasive surgery.

Bone Therapeutics has developed an allogeneic cell therapy platform, ALLOB, consisting of human allogeneic bone-forming cells that express master osteoblast genes and mesenchymal and bone matrix adhesion markers and are able to adhere, synthesize and mineralize new bone matrix. ALLOB is administered through a minimally invasive injection, directly to the site of the delayed-union fracture, to initiate bone formation and amplify the natural process of regeneration.

The company's production process maximizes yield, resulting in up to 100,000 doses of cryopreserved ALLOB per bone marrow donation. Compared with autologous approaches, an allogeneic cell therapy offers numerous advantages, including substantial reductions in overall production costs and simplified supply chain logistics that result in more cost-effective commercialization to large patient populations globally.

"We are very proud of the implementation of our improved and optimized production process for ALLOB, which will deliver consistency, scalability, cost effectiveness and ease of use, all of which are critical factors for the development and commercialization of a successful cell therapy product," said Lienard.

Combo approach to knee pain

Bone Therapeutics is developing JTA-004, a patented, noncellular enhanced viscosupplement for the treatment of pain in KOA, the most common chronic joint condition. KOA is caused by progressive breakdown of the protective cartilage in the knee joint, and symptoms include joint pain, swelling, stiffness and a limited range of motion.

No cure exists for KOA, and existing treatments focus on relieving and controlling pain, preventing disease progression, minimizing disability and improving quality of life. Severe KOA is usually resolved with invasive surgical interventions such as total knee replacement.

Viscosupplements are injectable solutions containing hyaluronic acid, a main component of the synovial fluid of the knee, and aim to provide added lubrication and protection to the cartilage of the arthritic joint. JTA-004 is a next-generation viscosupplement consisting of hyaluronic acid combined with an analgesic agent and an enriched protein solution. The resulting product protects the knee and provides analgesic activity and prolonged lubrication. JTA-004 has shown superiority over the leading viscosupplement in a phase 2 study.

Partnering in orthopedics and bone disease

The next steps for Bone Therapeutics' lead programs, ALLOB and JTA-004, include (1) reporting top-line data from the ALLOB phase 2a study in lumbar spinal fusion procedures, (2) submitting a clinical trial application (CTA) in Europe and the US for an ALLOB phase 2b/3 clinical trial in delayed-union fractures, and (3) filing a CTA in Europe and the US for a JTA-004 phase 3 clinical trial in KOA.

According to Lienard, "Bone Therapeutics is committed to further progress its late-stage clinical assets as well as its preclinical pipeline through a growing network of R&D and commercial partnerships."

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