Company name: Enlivex Therapeutics

Website : www.enlivex.com

CEO : Dr. Oren Hershkovitz

CATEGORY: Biotech/Pharma

- Evolving Trends in Orthopedic Innovation
- Immunology and Inflammation Reclaim top Priorities in BioPharma: Driver and Opportunities

Executive Summary

Enlivex (Nasdaq: ENLV) is a clinical stage macrophage reprogramming immunotherapy company developing AllocetraTM, a universal, off-the-shelf cell therapy designed to reprogram macrophages, into their homeostatic state. AllocetraTM is being developed for the treatment of multiple inflammatory indications including osteoarthritis and psoriatic arthritis, with a novel therapeutic mechanism which has the potential to redefine the way inflammatory diseases are treated. Enlivex is led by a seasoned management team who founded PROLOR and led it to a successful financial exit and partnership with Pfizer.

Core Technology

AllocetraTM is an off-the-shelf, cell-based therapy composed of mononuclear cells derived from non-HLA matched donors and induced to an apoptotic state. Administration of AllocetraTM introduces apoptotic cells into the target environment, triggering the modulation of macrophages, restoring their homeostatic state, and effectively rebalancing the immune system. This novel mechanism of action has the potential to redefine the way inflammatory diseases are treated. Most importantly, AllocetraTM offers an easy to use, flexible and cost effective cell therapy

Product Profile/Pipeline

Enlivex is evaluating AllocetraTM for the treatment of multiple indications including acute inflammatory diseases such as sepsis, and chronic inflammatory diseases like osteoarthritis. Enlivex is conducting clinical trials in moderate knee osteoarthritis, 1st CMC (Carpo-Meta-Carpal) osteoarthritis, TMJ (Temporomandibular Joint) osteoarthritis, and psoriatic arthritis. All indications are billion dollar markets defined as unmet medical conditions. Favorable safety profile demonstrated across several clinical studies and indications with initial efficacy data supporting the proposed MoA and the potential.

Business Strategy

As a drug-development company, Enlivex is seeking collaborations with mid to large pharmaceutical companies to advance its clinical pipeline into late-stage clinical trials and commercialization.

What's Next

With statistically significant 6-month data demonstrating durable pain reduction and functional improvement in knee osteoarthritis, Allocetra[™] continues to show strong efficacy and safety. The pipeline expansion into basal thumb osteoarthritis and psoriatic arthritis further broadens market potential, collectively targeting multi-billion-dollar markets. Topline readout from the ongoing its ongoing randomized, multi-country Phase I/II Allocetra[™] trial in patients with moderate to severe knee osteoarthritis is expected in Q3 2025 as well as additional clinical milestones.