

Israel's Moebius Medical & India's Sun Pharma receive fast track designation for osteoarthritis knee pain medicine

September 6, 2024 | News

Due to the inability of joint cartilage to self-heal, osteoarthritis is among the most challenging joint diseases to treat



India-based Sun Pharma and Israel-based Moebius Medical have announced that the US Food and Drug Administration (FDA) has granted Fast Track designation (FTD) to MM-II (Large Liposomes of DPPC and DMPC) for the treatment of osteoarthritis knee pain.

MM-II is a novel non-opioid product that uses a proprietary suspension of large, empty, multilamellar liposomes which are intended to reduce friction and wear on the joint and thus relieve joint pain. Data from a randomized, controlled, Phase 2b study (NCT04506463) showed that a single intra-articular injection of 3mL of MM-II provided greater pain relief than placebo for up to 26 weeks and were recently presented at EULAR 2024.

Sun Pharma and Moebius Medical, who have been jointly developing this product, have announced plans to initiate a Phase 3 clinical programme and to seek a CE Mark for the product in the European Union.

The US FDA's Fast Track programme is designed to facilitate the development and expedite the review of therapies intended to treat serious conditions and address unmet medical needs in order to potentially bring important new medicines to patients earlier. Among other benefits, companies whose investigational products are granted FTD are eligible for more frequent interactions with the FDA during clinical development and potentially accelerated approval and/or priority review.