



FOR IMMEDIATE RELEASE

Osteoarthritis Candidate MM-II Showed Durable Pain Relief in Global Phase 2b Study

- *Clinical data showed that a single intra-articular injection of MM-II provided durable pain relief up to 26 weeks vs placebo*
- *MM-II had a safety profile comparable to placebo*
- *Data presented at the OARSI 2023 World Congress on Osteoarthritis*

Mumbai (India) & Tel Aviv (Israel) – March 22, 2023: Sun Pharma (*Reuters: SUN.BO, Bloomberg: SUNP IN, NSE: SUNPHARMA, BSE: 524715, Sun Pharmaceutical Industries Limited, and includes its subsidiaries or associate companies*) and Israel-based Moebius Medical Limited recently announced the topline results of their Phase 2b, randomized, double-blind, placebo-controlled, single-administration, multiple-dose study evaluating the efficacy and safety of MM-II for the treatment of knee pain in participants with symptomatic knee osteoarthritis (NCT04506463).

Designed to guide the Phase 3 US FDA program, this study examined multiple doses of MM-II vs placebo, measuring changes in pain using standard pain measurement instruments, including the weekly average of daily knee pain and the Western Ontario and McMaster Universities Arthritis Index (WOMAC). The primary outcome measure was the change from baseline in WOMAC A pain score at Week 12. The study was conducted across 25 sites in the U.S., Europe, and Asia and enrolled 397 participants.

While the study did not achieve statistical significance on the primary outcome measure, it did show meaningful and sustained improvement across several clinical measures. In the target 3 mL dose, the reduction in the WOMAC A pain score from baseline to 12 weeks (primary endpoint) was larger for MM-II 3 mL vs placebo 3 mL (nominal $P = 0.047$; adjusted for multiplicity, $P = 0.085$). MM-II also showed a nominally significant and durable reduction in the weekly average of daily knee pain vs placebo starting at week 6 and enduring through week 26 (nominal $P = 0.008$ at week 12, $P = 0.007$ at week 26) for the 3 mL dose. Results of the WOMAC pain and function subscales, patient global assessment scores, use of rescue medication, and responder criteria all showed durable improvements for participants receiving MM-II 3 mL. MM-II was well tolerated with treatment-emergent adverse events reported in 2.6% of MM-II and 2.9% of placebo participants. Injection site reactions were similar in the treatment and control groups, 1.9% and 2.9%, respectively.

The results of the study were presented this past weekend at the 2023 Osteoarthritis Research Society International (OARSI) World Congress on Osteoarthritis held in Denver, CO, US. **Thomas J. Schnitzer, MD, PhD, a rheumatologist and professor of Medicine at Northwestern University**, who presented the study results, said that “the dearth of options for treating osteoarthritis, coupled with challenges we face from the reliance on opioids, puts MM-II in a unique position to offer a possible alternative to hyaluronic acid and steroid treatments. The data from this study show that MM-II has the potential to provide durable pain relief for our patients.”



"These encouraging data support MM-II's potential as a novel therapy for treating patients with osteoarthritis," said **Dilip Shanghvi, Managing Director of Sun Pharma**. "Pain related to osteoarthritis is a significant unmet need and urgently requires new agents which can improve patient outcomes. We believe MM-II has the potential to improve upon currently existing therapies in this space."

Moshe Weinstein, CEO of Moebius Medical, added: "With the durability of pain relief seen in this trial and the overall clean safety profile, MM-II has the potential to be a new option for patients with knee osteoarthritis and an alternative to steroid and hyaluronic acid injections. We look forward to working with our partner Sun Pharma to continue the development and commercialization of this promising product."

About MM-II

MM-II is a novel non-opioid product that consists of a proprietary suspension of large, empty, multilamellar liposomes that lubricate arthritic knee joints, thereby reducing friction and wear, consequently leading to joint pain reduction.

About Osteoarthritis

Osteoarthritis is one of the most common chronic health conditions and a leading cause of pain and disability among adults. Global estimates reveal that more than 100 million people are affected by osteoarthritis. More than 20 million people in the US suffer from knee osteoarthritis. The global market for products used for symptomatic relief of knee osteoarthritis pain (such as intra-articular hyaluronic acid) is about \$2 billion with a 6.5% compound annual growth rate; the US alone accounts for about 40% of this market.

About Moebius Medical

Moebius Medical is a clinical stage biotechnology company that is developing novel pain relief treatments for osteoarthritis. The company was founded in 2008 within the RAD Biomed Accelerator to develop products based on a patent-protected technology exclusively licensed from Yissum, the Hebrew University Technology Transfer Company; T3, the Technology Transfer arm of the Technion Institute; and by Hadasit, the Technology Transfer company of Hadassah Medical Center. In 2016, Moebius entered a joint collaboration with Sun Pharma in which Moebius is responsible for conducting certain preclinical studies and for product development and manufacturing through the end of Phase 2 studies, at which point Sun has the option to assume further product development and commercialization.

About Sun Pharmaceutical Industries Ltd. (CIN – L24230GJ1993PLC019050)

Sun Pharma is the world's fourth largest specialty generic pharmaceutical company and India's top pharmaceutical company. A vertically integrated business and a skilled team enable it to deliver high-quality products, trusted by customers and patients in over 100 countries worldwide. Its global presence is supported by manufacturing facilities spread across 6 continents and approved by multiple regulatory agencies, coupled with a multicultural workforce comprising over 50 nationalities. Sun Pharma fosters excellence through innovation supported by strong R&D capabilities across multiple centers. For further information, please visit www.sunpharma.com and follow us on Twitter @SunPharma_Live.



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For further details, please contact:

MEDIA

SUN PHARMA

Gaurav Chugh

Tel Direct: +91 22 4324 5373

Mobile: +91 98104 71414

Email: gaurav.chugh@sunpharma.com

MOEBIUS MEDICAL

Moshe Weinstein

Tel Direct: +972 3 768 4930

Email: bd@moebiusmedical.com

INVESTORS

SUN PHARMA

Dr. Abhishek Sharma

Tel Direct: +91 22 4324 2929

Mobile: +91 98196 86016

Email: abhi.sharma@sunpharma.com