



FOR IMMEDIATE RELEASE

Sun Pharma and Moebius Medical Announce Fast Track Designation Granted for MM-II for the Treatment of Osteoarthritis Knee Pain

Mumbai (India) & Tel Aviv (Israel) – September 06, 2024: 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 announced that the U.S. 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. Planning for confirmatory Phase 3 clinical trials for MM-II is underway.

The FDA's Fast Track program 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.

“As we enter Phase 3 development, we are very encouraged by the FDA’s decision to grant Fast Track designation to MM-II and recognize its potential to fill an unmet medical need for patients suffering from Osteoarthritis,” said Marek Honczarenko, MD, PHD, Senior Vice President, Head Global Development at Sun Pharma.

Moshe Weinstein, CEO of Moebius Medical, added, “This Fast Track Designation, which will enable FDA to review MM-II in an expedited manner, is an important milestone in the development of MM-II, and follows our recently released Phase 2b data, which showed MM-II’s potential to provide effective and durable treatment for patients with knee pain of Osteoarthritis.”

For more information on Fast Track Designation, please visit the FDA’s website at <https://www.fda.gov/patients/fast-track-breakthrough-therapy-accelerated-approval-priority-review/fast-track>.

About MM-II

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 program and to seek a CE Mark for the product in the European Union.

About Osteoarthritis

Osteoarthritis (OA) is the most common chronic degenerative joint disease, characterized by progressive wear of joint cartilage. Clinical manifestations of OA in the knee include, but are not limited to, pain in and around the joint and limited joint motion. Due to the inability of joint cartilage to self-heal, OA is among the most challenging joint diseases to treat, and currently no cure exists. The focus of current OA treatments is to reduce pain and improve function of the affected joints. Global estimates of OA exceed 100 million, and symptomatic OA afflicts more than 30 million Americans. Loss of joint function as a result of this condition is a major cause of work disability and reduced quality of life.

About Sun Pharmaceutical Industries Limited. (CIN – L24230GJ1993PLC019050)

Sun Pharma is the world's leading specialty generics company with a presence in Specialty, Generics and Consumer Healthcare products. It is the largest pharmaceutical company in India and is a leading generic company in the US as well as Global Emerging Markets. Sun's high growth Global Specialty portfolio spans innovative products in dermatology, ophthalmology, and onco-dermatology and accounts for over 18% of company sales. The company's vertically integrated operations deliver high-quality medicines, trusted by physicians and consumers in over 100 countries. Its manufacturing facilities are spread across six continents. Sun Pharma is proud of its multi-cultural workforce drawn from over 50 nations. For further information, please visit www.sunpharma.com and follow us on [LinkedIn](#) & [X](#) (Formerly Twitter).

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 licensed exclusively 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 to develop MM-II.

***Disclaimer:** Statements in this "document" describing Sun Pharma's and/or Moebius Medical's objectives, projections, estimates, expectations, plans or predictions, industry conditions, or events may be "forward-looking statements" within the meaning of applicable securities laws and regulations. Actual results, performance, or achievements could differ materially from those expressed or implied. Neither Sun Pharma nor Moebius Medical undertakes any obligation to update or revise forward-looking statements to reflect developments or circumstances that arise or to reflect the occurrence of unanticipated developments/circumstances after the date hereof.*

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