



## **Mapi Pharma Announces First Patient Recruited in Phase-I/II Study of Cariprazine Depot Once Monthly Injection**

NESS ZIONA, Israel – Sep. 17, 2025 – Mapi Pharma Ltd., a fully integrated, late-stage clinical development biopharmaceutical company focused on developing innovative long-acting depot injectable treatments, today provided an update on the clinical development program for its cariprazine once monthly injection. The company has enrolled the first patient into a Phase I/II study evaluating the product.

Mapi Pharma's injectable version of cariprazine, developed using its patented Depot technology, has demonstrated a long-acting release profile, for one monthly injection. The product is designed to address an unmet need in the treatment of schizophrenia and bipolar disorder.

Cariprazine is a well-established atypical antipsychotic approved for the treatment of schizophrenia and bipolar disorder. Current formulations of cariprazine have labels that specify daily oral dosing. For these indications, however, physicians generally prefer therapeutics that have long-acting formulations. Mapi's once-monthly injectable formulation has the potential to improve the treatment paradigm by achieving better compliance, reducing relapse risk, and simplifying disease management for patients and physicians.

Ehud Marom, Chairman and Chief Executive Officer, Mapi Pharma, commented, "This is the first clinical study we are initiating as part of a series of depot products Mapi is developing. We believe that, if approved, our once-monthly injectable Cariprazine could provide a valuable new treatment option for patients with schizophrenia and bipolar disorder, with the potential to improve long term outcomes."

Mapi has constructed dedicated production facilities for Cariprazine depot. The multinational Phase I/II trial, designed to evaluate dosing-safety and efficacy, is being conducted initially in Israel with plans to add centers in other countries. The study is being funded by an upfront payment received by Mapi from an undisclosed large pharmaceutical company following a recent development agreement between the parties. The terms of the agreement include a "Go-no-Go option" for the large pharmaceutical company to advance the product into a Phase III study as part of a definitive commercial agreement that the two companies are currently negotiating.

Mapi has intellectual property for its depot formulations of cariprazine that covers dose regimen from once weekly to every six months.



## About Mapi Pharma

Mapi Pharma is a clinical stage pharmaceutical company, engaged in development of high barrier-to-entry and high added-value life cycle management (“LCM”) products and AB Rated Depot injectable products that target large markets that include complex active pharmaceutical ingredients (“APIs”) and formulations. Mapi Pharma’s lead product is GA Depot which is partnered with Viartis (NASDAQ: VTRS) in an agreement under which Viartis was granted an exclusive license to commercialize the GA Depot injection product for Relapsing Forms of Multiple Sclerosis (RMS). Following successful Phase 3 results GA Depot was submitted for registration and is currently under FDA review. The Company is also marketing its own generic versions of Fingolimod (Gilenya®) and Apremilast (Otezla®) in specific geographic markets. Mapi’s portfolio also includes a leading development of Depot drugs for Schizophrenia, anti-cancer, GLP-1 for diabetes, weight control, Parkinson’s disease and potentially Alzheimer’s with innovative intellectual property. Mapi is built on strong chemical and pharmaceutical R&D capabilities and a deep understanding of the global market and of regulatory needs. Mapi is a global company with a Depot R&D center, API production and aseptic Depot manufacturing and a Fill & Finish for injectable Finished Dosage Forms facilities. Mapi has strong IP positions, filing numerous patent applications for APIs and formulations. For more information, please visit [www.mapi-pharma.com](http://www.mapi-pharma.com)

### Contacts:

Alex Mogle  
Vice President, Corporate Development  
Mapi Pharma  
+972 52 6080297  
[alex@mapi-pharma.com](mailto:alex@mapi-pharma.com)

Brian Ritchie  
Managing Director  
LifeSci Advisors, LLC  
[britchie@lifesciadvisors.com](mailto:britchie@lifesciadvisors.com)