Mapi Pharma Announces Initial Phase I/IIa Clinical Results Supporting Continued Development of Once-Monthly Cariprazine Depot

NESS ZIONA, Israel – Aug. 12, 2026 – Mapi Pharma Ltd. ("Mapi" or the "Company"), a late-stage clinical biopharmaceutical company specializing in long-acting injectable therapies, today announced initial clinical results from its on-going Phase I/IIa trial that support continued development of once-monthly Cariprazine Depot.

Cariprazine is a well-established atypical antipsychotic approved for the treatment of schizophrenia, bipolar I disorder and major depressive disorder (MDD). It is currently available only as a once-daily oral therapy. However, clinicians treating chronic psychiatric conditions generally prefer long-acting injectable (LAI) formulations of anti-psychotic medications, due to their ability to improve treatment adherence, reduce relapse risk and simplify long-term disease management.

Mapi Pharma is developing **Cariprazine Depot**, a once-monthly subcutaneous (SC) long-acting injectable formulation of cariprazine, using its proprietary depot technology. Designed to provide sustained drug release over one month, Cariprazine Depot has the potential to address an important unmet need by offering a convenient long-acting treatment option for patients with schizophrenia, bipolar disorder and MDD. Vraylar cariprazine capsules (marketed in the US by AbbVie and covered by a patent that will expire in 2029) generated net revenues of $3.6 billion in global sales in 2025, highlighting the significant commercial potential for an LAI formulation.

Phase I/IIa Clinical Study Design

The ongoing prospective, dose-escalating, open-label, multi-center, Phase I/IIa study is designed to evaluate the pharmacokinetics (PK), safety and tolerability of once-monthly SC injections of Cariprazine Depot in subjects eligible for treatment with oral cariprazine.

Following a washout period, participants received a single 22 mg subcutaneous injection of Cariprazine Depot. For more information on the design refer to ClinicalTrials.gov: NCT07185815.

Top-Line Results

Top-line results from Cohort 1 are now available. The results demonstrated that Cariprazine Depot exhibited a safety profile consistent with the established safety profile of oral cariprazine.

Key findings included:

- No serious adverse events (SAEs) were reported.
- All treatment-related adverse events associated with Cariprazine Depot were mild.
- Injection site reactions (ISRs) were mild, with injection site pain resolving rapidly (mean duration of less than one day).
- Treatment-related non-ISR adverse events occurred in fewer participants and were less frequent with Cariprazine Depot than with oral cariprazine. Each patient was treated at the beginning with oral cariprazine, and their data was analyzed.

Overall, once-monthly Cariprazine Depot administered as add-on therapy was safe and well tolerated. These encouraging results support the continued clinical development of Cariprazine Depot as a potential long-acting treatment option for patients requiring cariprazine therapy.

Ehud Marom, Chairman and Chief Executive Officer, Mapi Pharma, said, “We are excited to announce the excellent clinical results and are planning to submit an IND to the U.S. FDA by the end of 2026 with a partner who is expected to support the Phase 3 and lead marketing. Mapi will be responsible for drug manufacturing for clinical studies and the commercial supply from it’s GMP approved facilities. If successful in Phase 3, an NDA submission is planned for 2029”.

About Mapi Pharma

Mapi Pharma is a clinical-stage pharmaceutical company focused on the development of high-value, complex injectable therapies with significant barriers to entry. The Company’s portfolio includes long-acting depot formulations targeting large and growing markets, including central nervous system disorders and metabolic diseases. Key pipeline programs include long-acting formulations of Cariprazine, as well as GLP-1 therapies such as Semaglutide and Tirzepatide for diabetes and weight management. Mapi is also developing an AB-rated generic version of Naltrexone (Vivitrol®) and markets generic versions of Fingolimod (Gilenya®) and Apremilast (Otezla®) in select regions. Mapi combines deep expertise in chemistry, pharmaceutical development, and clinical execution with a strong intellectual property portfolio, including numerous granted patents primarily focused on formulations. The Company operates dedicated R&D and aseptic manufacturing facilities for long-acting injectable dosage forms. For more information, please visit www.mapi-pharma.com

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