PolyPid Successfully Completes Israeli Ministry of Health GMP Inspection, Advancing Towards Commercial Manufacturing Readiness for D-PLEX

Key Manufacturing Milestone Strengthens PolyPid's Position as it Advances Towards Global Commercialization of D-PLEX Following Successful SHIELD II Phase 3 Trial

PETACH TIKVA, Israel, Sept. 16, 2025 (GLOBE NEWSWIRE) — PolyPid Ltd. (Nasdaq: PYPD) ("PolyPid" or the "Company"), a late-stage biopharma company aiming to improve surgical outcomes, today announced the successful completion of a routine Good Manufacturing Practice (GMP) inspection by the Israeli Ministry of Health. The inspection, concluded earlier this week, marks the fourth consecutive successful GMP inspection of PolyPid's manufacturing facility.

The Israeli Ministry of Health operates under the EU-Israel Agreement on Conformity Assessment and Acceptance (ACAA) framework, whereby European regulatory authorities rely on these inspections for EU GMP compliance certification. This regulatory equivalence confirms that PolyPid's manufacturing facility meets the standards required for commercial production in the European market.

"Successfully completing this inspection demonstrates our consistent adherence to international GMP standards and validates our quality systems for commercial-scale manufacturing," said Dikla Czaczkes Akselbrad, Chief Executive Officer of PolyPid. "As we advance toward our planned New Drug Application ("NDA") submission for D-PLEX in early 2026, this inspection serves as crucial real-world preparation for the U.S. Food and Drug Administration ("FDA") facility inspection that will follow. With positive Phase 3 SHIELD II results in hand, confirming our manufacturing readiness represents another step toward bringing D-PLEX to patients."

The inspection comprehensively evaluated PolyPid's quality systems, manufacturing processes, and facility operations, confirming the Company's readiness to support commercial production of D-PLEX following regulatory approvals. We believe that this milestone further reinforces our path to commercialization as PolyPid prepares for potential market entry in both U.S. and European markets.

About D-PLEX

D-PLEX ¸ PolyPid's lead product candidate, is designed to provide local prolonged and controlled anti-bacterial activity directly at the surgical site to prevent surgical site infections ("SSIs"). Following the administration of D-PLEX into the surgical site, the PLEX (Polymer-Lipid Encapsulation matriX) technology pairs with Active Pharmaceutical Ingredients, enabling a prolonged and continuous release of the broad-spectrum antibiotic doxycycline, resulting in a high local concentration of the drug for a period of 30 days for the prevention of SSIs, with additional potential to prevent SSIs caused by antibiotic-resistant bacteria at the surgical site. D-PLEX recently demonstrated positive results in the Phase 3 SHIELD II trial, achieving a

statistically significant 58% relative risk reduction in SSI incidence following abdominal colorectal surgery with large incisions. D-PLEX received Breakthrough Therapy designation from the U.S. Food and Drug Administration for the prevention of SSIs in patients undergoing elective colorectal surgery.

About PolyPid

PolyPid Ltd. (Nasdaq: PYPD) is a late-stage biopharma company aiming to improve surgical outcomes. Through locally administered, controlled, prolonged-release therapeutics, PolyPid's proprietary PLEX (Polymer-Lipid Encapsulation matriX) technology pairs with Active Pharmaceutical Ingredients (APIs), enabling precise delivery of drugs at optimal release rates over durations ranging from several days to months. Following positive phase 3 results, New Drug Application (NDA) submission of D-PLEX , PolyPid's lead product candidate, for the prevention of abdominal colorectal surgical site infections, is expected in early 2026. In addition, the Company has an innovative pipeline in oncology, obesity and diabetes.

For additional Company information, please visit http://www.polypid.com and follow us on Twitter (X) and LinkedIn.

Forward-looking Statements

This press release contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act and other securities laws. Words such as "expects," "anticipates," "intends," "plans," "believes," "seeks," "estimates" and similar expressions or variations of such words are intended to identify forward-looking statements. For example, the Company is using forward-looking statements when it discusses the manufacturing facility's readiness for commercial production, the planned NDA submission for D-PLEX and timing thereof, preparation for FDA facility inspection, the Company's belief that this milestone further reinforces its path to commercialization and the potential for market entry in U.S. and European markets. Forward-looking statements are not historical facts, and are based upon management's current expectations, beliefs and projections, many of which, by their nature, are inherently uncertain. Such expectations, beliefs and projections are expressed in good faith. However, there can be no assurance that management's expectations, beliefs and projections will be achieved, and actual results may differ materially from what is expressed in or indicated by the forward-looking statements. Forward-looking statements are subject to risks and uncertainties that could cause actual performance or results to differ materially from those expressed in the forward-looking statements. For a more detailed description of the risks and uncertainties affecting the Company, reference is made to the Company's reports filed from time to time with the Securities and Exchange Commission, including, but not limited to, the risks detailed in the Company's Annual Report on Form 20-F filed on February 26, 2025. Forward-looking statements speak only as of the date the statements are made. The Company assumes no obligation to update forward-looking statements to reflect actual results, subsequent events or circumstances, changes in assumptions or changes in other factors affecting forward-looking information except to the

extent required by applicable securities laws. If the Company does update one or more forward-looking statements, no inference should be drawn that the Company will make additional updates with respect thereto or with respect to other forward-looking statements. References and links to websites have been provided as a convenience, and the information contained on such websites is not incorporated by reference into this press release. PolyPid is not responsible for the contents of third-party websites.

Company Contact:
PolyPid Ltd.
Ori Warshavsky
908-858-5995
IR@Polypid.com

Investor Relations Contact:
Arx Investor Relations
North American Equities Desk
polypid@arxhq.com