# PolyPid Announces Successful Commercial Good Manufacturing Practice (GMP) Audit by Israeli Ministry of Health

Successful Audit of the Company's State-of-the-Art Manufacturing Facility Represents a Key Milestone Toward Plan to Commercialize D-PLEX Globally

PETACH TIKVA, Israel, Sept. 21, 2023 — PolyPid Ltd. (Nasdaq: PYPD) ("PolyPid" or the "Company"), a late-stage biopharma company aiming to improve surgical outcomes, today announced that the Israeli Ministry of Health has completed a successful Good Manufacturing Practice (GMP) audit of the Company's manufacturing facility without any critical or major findings. The audit was conducted as part of the Ministry of Health's routine evaluation of PolyPid's manufacturing process for D-PLEX$_{100}$.

The audit concluded that PolyPid's manufacturing facility, process and quality system conform to the requirements of current GMP for medicinal products. This audit is also valid for Europe under the provisions of the Agreement on Conformity Assessment and Acceptance of industrial products (ACAA) between the European Union and Israel.

"We are pleased to achieve this important milestone which brings us one step closer to the potential commercialization of D-PLEX$_{100}$ globally," stated Dikla Czaczkes Akselbrad, PolyPid's Chief Executive Officer. "We can now produce D-PLEX$_{100}$ at scale in order to fulfill the expected commercial demand for the product. This successful audit underscores the viability, quality and high standards that PolyPid upholds in the manufacturing of D-PLEX$_{100}$ for clinical and commercial use in compliance with rigorous international standards."

## About D-PLEX$_{100}$

D-PLEX$_{100}$, PolyPid's lead product candidate, is designed to provide local prolonged and controlled anti-bacterial activity directly at the surgical site to prevent SSIs. Following the administration of D-PLEX$_{100}$ 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$_{100}$ received Breakthrough Therapy Designation from the U.S. Food and Drug Administration for the prevention of SSIs in patients undergoing elective colorectal surgery. D-PLEX$_{100}$ is currently in Phase 3 SHIELD II trial for the prevention of surgical site infections in patients undergoing open abdominal colorectal surgery with large incisions.

## 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. PolyPid's lead product candidate D-PLEX$_{100}$ is in Phase 3 clinical trial for the prevention of abdominal colorectal surgical site infections. In addition, the Company is currently in preclinical stages to test the efficacy of OncoPLEX for the treatment of solid tumors, beginning with glioblastoma.

For additional Company information, please visit http://www.polypid.com and follow us on Twitter 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 potentially commercializing D-PLEX$_{100}$ globally. 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 ("SEC"), including, but not limited to, the risks detailed in the Company's Annual Report on Form 20-F filed on March 31, 2023. 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.

**Contacts:**

PolyPid Ltd.
Ori Warshavsky
COO – US
908-858-5995
IR@Polypid.com

**Investors:**

Brian Ritchie
LifeSci Advisors
212-915-2578
britchie@lifesciadvisors.com