# PolyPid Announces Successful Completion of Manufacturing Process Validation for D-PLEX

*Company has Successfully Completed the Production of Three Process Validation Batches at Commercial Scale*

*Completes a Substantial Requirement Toward the Planned Submission of D-PLEX$_{100}$ NDA and MAA Regulatory Filings*

PETACH TIKVA, Israel, Sept. 19, 2023 — PolyPid Ltd. (Nasdaq: PYPD) ("PolyPid" or the "Company"), a late-stage biopharma company aiming to improve surgical outcomes, today announced the successful completion of the production of three process validation batches of D-PLEX$_{100}$ which have started stability program. This successful production process validation completes a substantial requirement toward the Company's planned submission of D-PLEX$_{100}$ New Drug Application (NDA) and Marketing Authorization Application (MAA) regulatory filings.

"The successful validation of the production process at commercial scale is the result of a significant facility expansion and scale-up that more than tripled the Company's capacity to manufacture D-PLEX$_{100}$ for the U.S., EU and global markets," stated Dikla Czaczkes Akselbrad, PolyPid's Chief Executive Officer. "Our in-house state-of-the-art GMP sterile production facility provides us with full control of D-PLEX$_{100}$ manufacturing from clinical stage to commercial supply and serves as a key competitive advantage going forward. Importantly, we have now evolved into a fully-integrated biopharmaceutical company."

PolyPid's ongoing Phase 3 SHIELD II trial of D-PLEX$_{100}$ for the prevention of surgical site infections (SSIs) is currently recruiting patients undergoing open abdominal colorectal surgery with large incisions. Top-line results are expected in mid-2024.

## 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$_{100}$ also received three Qualified Infectious Disease Product (QIDP) designations, and three Fast Track designations for the prevention of SSIs in patients undergoing elective colorectal surgery,

post-abdominal surgery incisional infection and for the prevention of sternal wound infection post-cardiac 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. 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 the expected competitive advantages resulting from the ability to have an in-house state-of-the-art GMP sterile production facility, the expected timing of top-line results from the Phase 3 SHIELD II trial of D-$PLEX_{100}$ for the prevention of abdominal colorectal SSIs and future regulatory submissions. 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.

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