PolyPid Announces Completion of Enrollment in Phase 3 SHIELD I Trial of D-PLEX for Prevention of Surgical Site Infections in Abdominal Surgery

- *Following Unblinded Interim Efficacy Analysis, Data Safety Monitoring Board Recently Recommended Concluding Study at 950 Patients, the Minimum Number of Patients Targeted*

- *Top-line Results Expected by End of Q3 2022; Potential NDA and MAA Submissions Targeted for H1 2023*

PETACH TIKVA, Israel, May 31, 2022 — PolyPid Ltd. (Nasdaq: PYPD) ("PolyPid" or the "Company"), a late-stage biopharma company aiming to improve surgical outcomes, announced today the completion of enrollment in the SHIELD I Phase 3 study of D-PLEX$_{100}$ for the prevention of surgical site infections (SSIs) in abdominal surgery. Following a review of unblinded efficacy data from the first 750 enrolled patients in the trial, the independent Data Safety Monitoring Board (DSMB) recently recommended concluding the study upon enrollment of 950 patients, which is the minimum number of targeted patients in the trial protocol.

"The conclusion of enrollment in the pivotal SHIELD I trial, the largest colorectal surgery clinical study conducted in more than a decade, represents an important milestone for our D-PLEX$_{100}$ development program and our company as a whole," stated Amir Weisberg, PolyPid's Chief Executive Officer. "We look forward to the availability of top-line results from SHIELD I by the end of the third quarter of 2022. Subsequent to these expected data, we intend to pursue a pre-NDA meeting with the FDA to discuss a rolling NDA submission, consistent with the Breakthrough Therapy Designation previously granted, with potential NDA and MAA submissions planned for the first half of 2023. We are also focused on further advancing commercial pre-launch activities, while expediting partnership discussions in and outside of the United States."

About SHIELD I

SHIELD I (Surgical site **H**ospital acquired **I**nfection pr**E**vention with **L**ocal **D**-PLEX) is a prospective, multinational, randomized, double blind Phase 3 trial designed to assess the efficacy and safety of D-PLEX$_{100}$ administered concomitantly with standard of care (SoC), which includes prophylactic systemic antibiotics, compared to a SoC alone arm, in prevention of post abdominal surgery incisional infection. The primary endpoint of the trial is the combination of incisional SSIs and mortality rate as measured by the proportion of subjects with either an SSIs event, as determined by a blinded and independent adjudication committee, or mortality for any reason within 30 days post-surgery. The trial has enrolled patients in more than 60 centers in the United States, Europe and Israel.

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 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. FDA 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, 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 trials for the prevention of soft tissue abdominal and sternal bone surgical site infections. In addition, the Company is currently in preclinical stages to test the efficacy of OncoPLEX for 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 Company's expectation to report top-line results of the SHIELD I Phase 3 study by the end of the third quarter of 2022, potential NDA submission to FDA and a European Union MAA filing targeted in the first half of 2023, the Company's intention to pursue a pre-NDA meeting with the FDA to discuss a rolling NDA submission and expedition of partnership discussions in and outside of the United States. 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 February 28, 2022. 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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