PolyPid Announces Peer-Reviewed Publication of Phase 2 Clinical Trial Results for D-PLEX in the Prevention of Surgical Site Infections in Abdominal Surgery

Intends to discuss the Clinical Outcomes and Next Steps for D-PLEX$_{100}$ for the Prevention of SSIs in Abdominal Surgery with the FDA and the EU Regulatory Authorities in Q1 2023

PETACH TIKVA, Israel, Sept. 19, 2022 — PolyPid Ltd. (Nasdaq: PYPD) ("PolyPid" or the "Company"), a late-stage biopharma company aiming to improve surgical outcomes, today announced the peer-reviewed publication of positive clinical data from the previously completed Phase 2 study of D-PLEX$_{100}$ for the prevention of surgical site infections (SSIs) in abdominal surgery. The paper, entitled, "A prospective, randomized assessment of a novel, local antibiotic releasing platform for the prevention of superficial and deep surgical site infections," was published in *Techniques in Coloproctology*, and can be found here.

The Phase 2 trial was a prospective, multicenter, randomized, controlled, single-blind, two arm study and was designed to assess the efficacy and the safety of D-PLEX$_{100}$ in addition to standard of care (SoC) in preventing superficial and deep SSIs in patients undergoing elective colorectal surgery. Efficacy was measured by the incidence of SSIs and mortality within 30 days post-surgery. SSIs were adjudicated by the endpoint adjudication committee, all of whom were blinded to study-group assignments. In addition, safety was assessed by the stratification and incidence of treatment-emergent adverse events.

One hundred and seventy-nine patients were evaluated in the per protocol population, 88 in the intervention arm [51 males, 37 females, median age 64.0 (range: 19-92) years] and 91 in the control arm [57 males, 34 females, median age 64.5 (range: 21-88) years]. The SSI rate (superficial and deep) within 30 day post-index surgery showed a 64% statistically significant relative risk reduction in the D-PLEX$_{100}$ plus SoC cohort at 8% infection rate [n=7/88] compared to 22% infection rate in the SoC alone cohort [n=20/91] (p=0.0115). There was no statistically significant difference in the incidence of treatment-emergent adverse events (TEAEs) between the two groups, and no difference in severity and incidence of serious TEAEs. No TEAEs in the D-PLEX$_{100}$ plus SoC cohort were deemed related to the study drug.

"We are pleased by the publication of the positive results from our Phase 2 study of D-PLEX$_{100}$," said Dikla Czaczkes Akselbrad, PolyPid's Chief Executive Officer. "The results of this trial were the basis of the Breakthrough Therapy Designation for D-PLEX$_{100}$ granted by the U.S. Food and Drug Administration (FDA) and a precursor to the Company's SHIELD I Phase 3 trial that concluded earlier this month. PolyPid is further evaluating the collective results of SHIELD I and the Phase 2 study, and intends to discuss the clinical outcomes and next steps for D-PLEX$_{100}$ for the prevention of SSIs in abdominal surgery with the FDA as well as the EU (European Union) regulatory authorities in Q1 2023."

The appropriate next steps for PolyPid's second Phase 3 trial of D-PLEX$_{100}$ for the prevention of SSIs in abdominal surgery, SHIELD II, which incorporates broader eligibility criteria and has enrolled over 200 subjects to date, will be evaluated following the discussion with the FDA and the EU regulatory authorities.

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 (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 trials for the prevention of soft tissue abdominal and sternal 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 its ongoing clinical trials, its intention to discuss the clinical outcomes and next steps for D-PLEX$_{100}$ for the prevention of SSIs in abdominal surgery with the FDA as well as the EU regulatory authorities in Q1 2023. 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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