PolyPid Hosts KOL Call to Discuss Significant Unmet Medical Need in Surgical Site Infections Prevention and Provides Update on its Ongoing SHIELD II Phase 3 Trial

After a Reduction in Surgical Site Infection (SSI) Rates During COVID, Rates are Now Increasing, Signaling a Return to Pre-COVID Levels

Known Procedure and Patient Risk-Factors Significantly Increase the Risk of SSIs and Impact Payer Costs

Approximately 250 Patients of a Planned Total of 600 Subjects Currently Enrolled in SHIELD II

Unblinded Interim Analysis to be Conducted Once Approximately 400 Patients Complete Their 30-Day Follow-up; Top-line Results Expected in the First Quarter of 2025

PETACH TIKVA, Israel, June 18, 2024 — PolyPid Ltd. (Nasdaq: PYPD) ("PolyPid" or the "Company"), a late-stage biopharma company aiming to improve surgical outcomes, today hosted a virtual Key Opinion Leader event discussing the significant unmet medical need in the prevention of surgical site infections (SSIs). The Company also provided an update on its ongoing SHIELD II Phase 3 trial for D-PLEX$_{100.}$

Charles E. Edmiston, Ph.D. (Emeritus Professor of Surgery, Division of Vascular Surgery, Medical College of Wisconsin), discussed several key topics surrounding SSIs. Key takeaways include:

- The return to higher pre-COVID SSI rates due to the increase in the number of elective surgeries conducted and the surgical environment normalizing to levels found prior to 2020.
- SSIs are under-reported, and up to 30-35% of colorectal infections are missed due to sub-optimal surveillance strategies.
- Procedural and patient-related risk factors such as smoking, alcohol abuse, type 2 diabetes and a high BMI have a significant negative impact on the risk of developing a SSI, and this increase in risk is compounded when patients have multiple risk factors.
- Long term cost to commercial payers of a single colorectal SSI event over a period of 24 months can range from $44,000 (superficial SSI) to $64,000 (deep SSI), with the cost for Medicare ranging from $20,000 to $45,000, respectively.
- Surgical care bundles in patients undergoing colorectal surgery significantly reduce the risk of SSIs. The 30-day high concentration release of antibiotics achieved with D-PLEX$_{100}$ has the potential to add additional benefit to infection prevention bundles.

"Studies show traditional evidence-based interventions have maximum benefit within the perioperative and immediate postoperative period. Building upon this, D-PLEX$_{100}$ supports

prolonged doxycycline concentrations within the surgical wound during and beyond this critical period and exceeds the minimum inhibitory concentration for the most common surgical wound pathogens regardless of length of the surgical incision," said Dr. Edmiston. "There remains an opportunity to improve upon the existing clinical standard of care to reduce the rate of SSIs in and beyond the colorectal surgical setting, improving the patient experience and lowering costs for payers."

PolyPid also provided an update on the enrollment of its ongoing Phase 3 SHIELD II trial of its lead product candidate, D-PLEX$_{100}$. The SHIELD II clinical study includes patients undergoing abdominal colorectal surgery with large incisions and has now enrolled approximately 250 patients of a planned total of approximately 600 subjects. Approximately 50 centers are currently open and recruiting patients. Top-line results are expected in the first quarter of 2025. The Company intends to conduct an unblinded interim analysis once a total of approximately 400 patients complete their 30-day follow-up, which is anticipated to occur in the fourth quarter of 2024.

About SHIELD II

SHIELD II (Surgical site Hospital acquired Infection prEvention with Local 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 SoC alone arm, in the prevention of post abdominal-surgery incisional infection in patients undergoing surgeries with incisions greater than 20 cm. The primary endpoint of the trial is measured by the proportion of subjects with either an SSI event as determined by a blinded and independent adjudication committee, reintervention, or mortality for any reason within 30 days post-surgery. Patient safety will be monitored for an additional 30 days. The trial will enroll patients in 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 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 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 potential benefits and advantages of D-PLEX$_{100}$, that there remains an opportunity to improve upon the existing clinical standard of care to reduce the rate of SSIs in and beyond the colorectal surgical setting, improving the patient experience and lowering costs for payers, total recruitment time into the study and the timing of the top-line results and an unblinded interim analysis. 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 6, 2024. 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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