

## **PolyPid Announces Publication in the American Journal of Surgery of Phase 2 Clinical Trial Post-hoc Analysis for D-PLEX in the Prevention of Surgical Site Infections in Abdominal Surgery**

*D-PLEX<sub>100</sub> Achieved in Phase 2 Trial Significant Reduction in SSIs in Patients with Multiple Preoperative Risk Factors Versus Standard of Care*

*Results Consistent with SHIELD I Phase 3 Post-hoc Analysis Demonstrating Significant Primary Endpoint Reduction in Patients with One or More patient related Risk Factors*

PETACH TIKVA, Israel, Jan. 03, 2023 — 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 a post-hoc analysis from the previously-completed Phase 2 study of D-PLEX<sub>100</sub> for the prevention of surgical site infections (SSIs) in abdominal surgery. The paper, entitled, “Reduction in Surgical Site Infections by Localized Administration with D-PLEX<sub>100</sub> in Patients with Multiple Risk Factors Undergoing Colorectal Surgery,” was published in the *American Journal of Surgery* 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<sub>100</sub> in addition to standard of care (SoC) in preventing superficial and deep SSIs in patients undergoing elective colorectal surgery. This post-hoc analysis was intended to evaluate the effect of D-PLEX<sub>100</sub> on SSI incidence in patients with multiple preoperative risk factors. Thirty-day SSI rates were examined in patients in the Intention-to-treat (ITT) population and in those with two or more patient related risk factors. Individual risk factor categories included diagnoses of diabetes, chronic obstructive pulmonary disease (COPD) or a history of smoking, obesity/overweight as defined as a body mass index (BMI) of 25 or more, hypertension, and peripheral vascular disease. The distribution of the assessed risk factors between the D-PLEX<sub>100</sub> plus SoC and SoC cohorts was approximately even.

Two hundred and one patients were evaluated in the ITT population, 101 in the intervention arm and 100 in the control arm. The study showed a 53% statistically significant relative risk reduction of the SSI rate (superficial and deep) within 30 days post-index surgery in the D-PLEX<sub>100</sub> cohort (N=10/101 [9.9%]) compared to SoC (N=21/100 [21%]; p = 0.033). In patients with two or more risk factors, the SSI rate in the D-PLEX<sub>100</sub> plus SOC cohort was 15.8% (6/38) compared to 37.5% (15/40) in the SOC alone cohort, demonstrating a statistically significant relative risk reduction of 58% (p = 0.042).

“The data from this post-hoc analysis are compelling, demonstrating that D-PLEX<sub>100</sub> may be an effective addition to current SSI bundles in patients with increased risk for surgical complications, including SSI,” said Oded Zmora, M.D., colorectal surgeon, Chair of Surgery at

Shamir Medical Center, Be'er Ya'akov, Israel and a co-author of this paper. "Importantly, these results are consistent with post-hoc analysis from the recently completed SHIELD I Phase 3 study, which showed that patients with one or more patient related risk factors could potentially benefit from D-PLEX<sub>100</sub> and may help address the high unmet need in this vulnerable patient population."

### **About D-PLEX<sub>100</sub>**

D-PLEX<sub>100</sub>, 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<sub>100</sub> 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<sub>100</sub> received Breakthrough Therapy Designation from the U.S. FDA for the prevention of SSIs in patients undergoing elective colorectal surgery. D-PLEX<sub>100</sub> 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<sub>100</sub> 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 that D-PLEX<sub>100</sub> may be an effective addition to current SSI bundles in patients with increased risk for surgical complications, including SSI, that patients with one or more patient related risk factors could

potentially benefit from D-PLEX<sub>100</sub> and may help address the high unmet need in this vulnerable patient population. 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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