PolyPid Announces Enrollment of 200th Patient in Ongoing SHIELD II Phase 3 Trial Evaluating D-PLEX for the Prevention of Abdominal Colorectal Surgical Site Infections

Study Approximately Half Enrolled to the Planned Unblinded Interim Analysis

Unblinded Interim Analysis to be Conducted Once Approximately 400 Patients Complete Their 30-Day Follow-up

Top-line Results Expected in Second Half of 2024

PETACH TIKVA, Israel, April 30, 2024 — PolyPid Ltd. (Nasdaq: PYPD) ("PolyPid" or the "Company"), a late-stage biopharma company aiming to improve surgical outcomes, today announced that it has enrolled the 200th patient in its ongoing SHIELD II Phase 3 trial for D-PLEX$_{100}$ for the prevention of surgical site infections in patients undergoing abdominal colorectal surgery with large incisions. The study is now approximately one-third enrolled and is anticipated to continue enrollment at a pace of 1.5 patients per center per month. There are currently approximately 40 centers open and the Company expects to add approximately 20 more centers over the next couple of months.

An unblinded interim analysis is anticipated to be conducted in mid-2024, once a total of approximately 400 patients complete their 30-day follow-up.

"Enrollment into SHIELD II has significantly ramped-up during the last two months and is now progressing at a consistently robust pace," said Dikla Czaczkes Akselbrad, PolyPid's Chief Executive Officer. "We continue to expect top-line results from SHIELD II in the second half of 2024. Importantly, the $16 million financing we successfully completed earlier this year extends our cash runway beyond the anticipated timing of the study's planned unblinded interim analysis, and we have the potential to secure an additional $19 million if the results of the unblinded interim analysis are positive and warrants are exercised, which would fund the Company to the start of a planned rolling New Drug Application ("NDA") submission for D-PLEX$_{100}$."

In January 2024, PolyPid closed a private placement financing (the "PIPE") for $16 million of gross proceeds. The PIPE syndicate was comprised of new and existing investors, including participation from new U.S. life sciences-focused investors, DAFNA Capital Management and Rosalind Advisors. The Company has the potential to secure an additional $19 million if the results of the unblinded interim analysis are positive and all warrants issued in the financing are exercised, which would fund PolyPid to the start of a planned rolling NDA submission for D-PLEX$_{100}$.

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 abdominal colorectal surgeries with large incisions. The primary endpoint of the trial is measured by the proportion of subjects with either a surgical site infection ("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 open 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 the expected timing for top-line results from the SHIELD II trial and of the unblinded interim analysis, the expected enrollment pace, the expectation to add approximately 20 more centers over the next couple of months, the planned NDA submission for D-PLEX$_{100}$, the Company’s expected cash runway and the potential to receive additional funds if warrants are exercised. 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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