PolyPid Announces FDA Agreement on the Design of SHIELD II Phase 3 Trial Evaluating D-PLEX for Prevention of Abdominal Colorectal Surgical Site Infections

Recruitment to Resume Imminently

Top-line Results Expected in Mid-2024

PETACH TIKVA, Israel, May 22, 2023 — PolyPid Ltd. (Nasdaq: PYPD) ("PolyPid" or the "Company"), a late-stage biopharma company aiming to improve surgical outcomes, today announced that the U.S. Food and Drug Administration (FDA) agreed to Company's SHIELD II Phase 3 trial design evaluating D-PLEX$_{100}$ for the prevention of abdominal colorectal surgical site infections (SSIs). The revised SHIELD II trial will recruit patients undergoing colorectal resection surgery with large incisions (> 20 cm).

Recruitment into the trial will resume imminently with the enrollment of an estimated 550 additional patients beyond the 40 patients already recruited into SHIELD II. Total recruitment time into the study is anticipated to be approximately 12 months and top-line results are expected in mid-2024. PolyPid also intends to conduct an unblinded interim analysis once a total of approximately 400 patients complete their 30-day follow-up.

"We are pleased with FDA feedback to our revised protocol and are excited to resume SHIELD II trial recruitment," stated Dikla Czaczkes Akselbrad, PolyPid's Chief Executive Officer. "Importantly, we view SHIELD II as a de-risked Phase 3 trial given the more focused patient population in which we've already generated highly positive data in SHIELD I, and the fact that it will not be conducted within the tight COVID-related restrictions that were in place throughout the duration of SHIELD I. We are also leveraging the key learnings from the SHIELD I trial, including firm knowledge of the best performing sites from SHIELD I in terms of recruitment, patient monitoring and good clinical practice."

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 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 a 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 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 resumption of recruitment for the SHIELD II Phase 3 trial and the timing of top-line results therefrom. 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 31, 2023. 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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