קסניה ונצ'ר קפיטל בע"מ
("החברה")

20 במאי 2021

לכבוד
רשות ניירות ערך
www.isa.gov.il

לכבוד
הבורסה לניירות ערך בת"א
www.tase.co.il

מהות האירוע: **פוליפיד בע"מ (להלן: "פוליפיד") – תשובה חיובית מפגישה עם ה - FDA**

החברה מתכבדת לדווח כי פוליפיד הודיעה כי בהמשך לפגישה שנערכה, הסכימו רשויות ה - FDA לבקשת פוליפיד לכך שמחקר אחד בשלב הפאזה השלישית (SHILD I) עשוי להספיק לקבלת אישור למוצר ה – D-PLEX$_{100}$ למניעת זיהומים בניתוחי המעי הגס.
גיוס החולים למחקר SHILD I מתקדם כמתוכנן, ועד היום גויסו למעלה מ – 200 חולים. תוצאות של ניסוי זה צפויות להתקבל בסוף 2021.

ההערכות שלעיל הינן בגדר מידע צופה פני עתיד, כהגדרת מונח זה בחוק ניירות ערך, התשכ"ח-1968, המבוסס על הערכות ותחזיות של פוליפיד. אין כל וודאות להתממשות הערכות אלו וזאת, בין היתר, בשל גורמים שאינם בשליטת פוליפיד.

למיטב ידיעת החברה, פוליפיד מפתחת טכנולוגית הובלת תרופות בשם PLEX אשר מאפשרת שחרור מקומי, מושהה ומבוקר של מינוני תרופה יעילים לאורך זמן. מוצר הדגל של פוליפיד הוא D-PLEX$_{100}$, אשר מאפשר שחרור מבוקר ולאורך זמן של אנטיביוטיקה, בכדי למנוע זיהומים שלאחר ניתוחי חזה ובטן. שתי האפליקציות של D-PLEX$_{100}$ נמצאות בשלב הפאזה השלישית של המחקר הקליני.
לפרטים נוספים אודות פוליפיד, ראו סעיף 9.3 לפרק א' לדוח התקופתי של החברה שפורסם ביום 26 במרץ 2021, מס' אסמכתא 2021-01-048501 (מידע זה מהווה הכללה על דרך ההפניה).

מצ"ב לדיווח זה, הדיווח שפרסמה פוליפיד באתר ה- NASDAQ.

בכבוד רב,

קסניה ונצ'ר קפיטל בע"מ

באמצעות: אלי סורזון, מנכ"ל וסמנכ"ל כספים

PolyPid Announces Positive FDA Type B Meeting Feedback for D-PLEX$_{100}$ Development Program

FDA Agreed that a Single Pivotal Phase 3 Study is Sufficient for Potential Approval of D-PLEX$_{100}$ for the Prevention of Surgical Site Infections in Colorectal Surgery.

- *Enrollment in Phase 3 SHIELD I Trial of D-PLEX$_{100}$ in Abdominal Surgery Continues to Advance; Over 200 Patients Enrolled to Date*

- *Top-line Results Expected by Year-end*

PETAH TIKVA, Israel, May 19, 2021 -- PolyPid Ltd. (Nasdaq: PYPD), a late-stage biopharma company aiming to improve surgical outcomes through locally administered, controlled, extended-release therapeutics, announced today it has received written responses from the U.S. Food and Drug Administration (FDA) to a Type B meeting request that the Company submitted regarding its development plan for D-PLEX$_{100}$.

The FDA indicated that PolyPid's proposal for a single Phase 3 pivotal study (SHIELD I), provided the study results are adequate, would provide sufficient evidence of clinical efficacy and safety to support approval of D-PLEX$_{100}$ for the prevention of surgical site infections (SSIs) in colorectal surgery. The Type B meeting was requested following PolyPid's receipt of Breakthrough Therapy Designation from the FDA for D-PLEX$_{100}$ for the prevention of SSIs in patients undergoing elective colorectal surgery.

"We appreciate the thoughtful feedback from the FDA regarding our clinical program, and we are thrilled with the acceptance of our proposed development plan for the potential approval of D-PLEX$_{100}$, which also reduces overall anticipated costs for the program," said Amir Weisberg, PolyPid's CEO. "PolyPid is dedicated to tackling the issue of SSIs that accounts for 20 percent of all healthcare-acquired infections in the U.S., resulting in extended hospital stays and readmission, costing up to $10 billion in annual medical costs. We will use the responses provided to progress our SHIELD I trial which continues to enroll patients at the expected rate, with over 200 patients enrolled to date, and we anticipate the availability of top-line results by the end of 2021."

Launched in July 2020, SHIELD I is a prospective, multinational, multicenter, randomized, double blind Phase 3 trial designed to assess the efficacy and safety of D-PLEX$_{100}$ for the prevention of incisional SSIs post-abdominal surgery. The primary endpoint of the trial is the combination of incisional SSIs and mortality rate as measured by the proportion of subjects with either an SSI event, as determined by a blinded and independent adjudication committee, or mortality for any reason within 30 days post-surgery. The trial will enroll a minimum of 616 patients, with a maximum

of about 900 patients, as defined by the adaptive study design, in more than 60 centers in the United States, Europe and Israel.

About D-PLEX$_{100}$

PolyPid's lead product candidate, D-PLEX$_{100}$, is a novel drug product candidate 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 technology enables a prolonged and constant release of the broad-spectrum antibiotic doxycycline, resulting in high local concentration of the drug for a period of four weeks for the prevention of SSIs, with additional potential to prevent SSIs caused by antibiotic-resistant bacteria at the surgical site. D-PLEX$_{100}$ has received Breakthrough Therapy Designation from the U.S. Food and Drug Administration (FDA) for the prevention of SSIs in patients undergoing elective colorectal surgery. D-PLEX$_{100}$ has also received two Qualified Infectious Disease Product (QIDP) designations as well as two Fast Track designations for the prevention of 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, extended-release therapeutics. PolyPid's proprietary PLEX (Polymer-Lipid Encapsulation matriX) technology pairs with medications, enables precise delivery of drugs at effective 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 sternal and abdominal surgical site infections (SSIs).

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, plans to use the guidance provided by the FDA to progress with its SHIELD I program, the timing of top-line results of the SHIELD I trial, and the size and design of the SHIELD I trial. 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 5, 2021. 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.