PolyPid Granted Breakthrough Therapy Designation from FDA for D-PLEX for the Prevention of Surgical Site Infections in Colorectal Surgery

PETAH TIKVA, Israel, Nov. 24, 2020 — PolyPid Ltd. (Nasdaq: PYPD), a Phase 3 clinical-stage biopharmaceutical company focused on developing targeted, locally administered and prolonged-release therapeutics using its proprietary PLEX technology, today announced that D-PLEX$_{100}$ has received Breakthrough Therapy Designation from the U.S. Food and Drug Administration (FDA) for the prevention of surgical site infections (SSIs) in patients undergoing elective colorectal surgery.

Breakthrough Therapy Designation is an FDA process designed to expedite the development and review of drugs that are intended to treat a serious or life-threatening condition so patients may have access to therapies through FDA approval as soon as possible. This designation is granted based on preliminary clinical evidence indicating that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints.

“The Breakthrough Therapy Designation in the field of anti-infective drugs is rather rare, and further supports the urgency to develop new innovative therapies to prevent SSIs,” said Amir Weisberg, PolyPid’s CEO. “It also reflects on the promising clinical data of D-PLEX$_{100}$ in the prevention of SSIs in complex surgical settings, such as colorectal abdominal surgeries. We are looking forward to working closely with the FDA to make D-PLEX$_{100}$ available to surgeons and patients as quickly as possible. Our ongoing Phase 3 pivotal studies in abdominal surgery – SHIELD I and SHIELD II – are on track.”

The Breakthrough Therapy Designation for D-PLEX$_{100}$ is based on conclusive positive results from a Phase 2 clinical trial evaluating D-PLEX$_{100}$ for the prevention of surgical site infections (SSIs) in abdominal colorectal surgery. The Phase 2 clinical trial was a prospective, multicenter, randomized, controlled two arm study in 201 patients and demonstrated that the local administration of D-PLEX$_{100}$ resulted in a statistically significant decrease in SSIs of 59 percent in the Intent to Treat (ITT) population (p=0.0086), and a decrease of 69 percent in the Per Protocol population (n=179; p=0.0024), as compared to the standard of care alone.

D-PLEX$_{100}$ previously received two Fast Track Designations from the FDA for the prevention of post-abdominal surgery incisional infections and for the prevention of sternal wound infections post-cardiac surgery, as well as two Qualified Infectious Disease Product designations (QIDP’s) in the same indications.

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 treat antibiotic-resistant bacteria at the surgical site. D-PLEX$_{100}$ has received two Qualified Infectious Disease Product (QIDP) designations as well as two Fast Track designations from the FDA for the prevention of post-abdominal surgery incisional infection and for the prevention of sternal wound infection post-cardiac surgery.

About PolyPid

PolyPid is a Phase 3 clinical-stage biopharmaceutical company focused on developing targeted, locally administered and prolonged-release therapeutics using its proprietary PLEX (Polymer-Lipid Encapsulation matriX) technology. PolyPid's product candidates are designed to address diseases with high unmet medical needs by pairing PLEX with drugs to deliver them directly to precise sites in the body at predetermined release rates and over durations ranging from several days to several months. PolyPid's lead product candidate, D-PLEX$_{100}$, is in Phase 3 clinical trials for the prevention of sternal SSIs and abdominal SSIs. PolyPid's technology and products are based on the inventions and the professional leadership of Dr. Noam Emanuel, the Founder and the Chief Scientific Officer of the company.

For additional company information, visit www.polypid.com.

Forward-looking Statements

This press release contains forward-looking statements within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995 and other Federal 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, PolyPid is using forward-looking statements in this press release when it discusses the potential of D-PLEX$_{100}$ to prevent SSIs, timing, subject matter and frequency of communications with the FDA, and providing a safe and effective solution for surgeons and their patients as quickly as possible. Because such statements deal with future events and are based on PolyPid's current expectations, they are subject to various risks and uncertainties. Also, while PolyPid has received Fast Track Designation for D-PLEX$_{100}$ for the prevention of surgical site infections, and Breakthrough Therapy Designation for the prevention of SSIs in colorectal surgery, it cannot guarantee that it will be able to maintain such designation due to reasons within our outside of its control. Actual results, performance or achievements of PolyPid could differ materially from those described in or implied by the statements in this press release. The forward-looking statements contained or implied in this press release are subject to other risks and

uncertainties, including those discussed under the heading “Risk Factors” in PolyPid’s final prospectus dated June 25, 2020, filed pursuant to Rule 424(b)(4) with the Securities and Exchange Commission (“SEC”), and in any subsequent filings with the SEC. Except as otherwise required by law, PolyPid undertakes no obligation to publicly release any revisions to these forward-looking statements to reflect events or circumstances after the date hereof or to reflect the occurrence of unanticipated events. 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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