PolyPid Granted Fast Track Designation from FDA for D-PLEX for Prevention of Surgical Site Infections in Abdominal Surgery

PETAH TIKVA, Israel, Aug. 03, 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 Fast Track Designation from the U.S. Food and Drug Administration (FDA) for the prevention of post abdominal surgery incisional infections.

The FDA's Fast Track designation is a process designed to facilitate the development and expedite the review of drugs to treat serious and life threatening conditions and fill an unmet medical need. Fast Track designation allows for early and frequent communication with the FDA throughout the entire drug development and review process, and allows for a rolling review of a D-PLEX$_{100}$'s New Drug Application ("NDA"). It also enables eligibility for Accelerated Approval and Priority Review, if relevant criteria are met.

"Receiving Fast Track designation from the FDA represents an important achievement for our promising D-PLEX$_{100}$ development program," said Amir Weisberg, PolyPid's CEO. "We view the Fast Track designation as important regulatory validation of the novelty of our PLEX technology and the high clinical unmet need that currently exists in the ability to prevent surgical site infections in complex surgical settings such as abdominal surgeries. We recently initiated our SHIELD I Phase 3 clinical trial of D-PLEX$_{100}$ for the prevention of post-abdominal surgery incisional infections, and look forward to the opportunity to provide a safe and effective solution for surgeons and their patients as quickly as possible."

About D-PLEX$_{100}$

PolyPid's lead product candidate, D-PLEX$_{100}$, is a novel product candidate designed to provide local prolonged 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 up to 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 from the FDA for the prevention of sternal wound infection post-cardiac surgery and for the prevention of post-abdominal surgery incisional infection.

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 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, whether D-PLEX$_{100}$ will be eligible for rolling review of its NDA and/or priority review 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, 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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