PolyPid Announces FDA Acceptance of NDA with Priority Review for D-PLEX

PDUFA target action date of November 28, 2026, approximately one quarter ahead of Company's previously communicated guidance

FDA identified no Filing review issues

Acceptance triggers $15 million milestone payment, completing $30 million in upfront and near-term milestone payments under recently announced U.S. and Canada commercialization partnership

PETACH TIKVA, Israel, July 29, 2026 (GLOBE NEWSWIRE) — PolyPid Ltd. (Nasdaq: PYPD) ("PolyPid" or the "Company"), an innovative biopharmaceutical company dedicated to elevating treatment effectiveness, right where care begins, today announced that the U.S. Food and Drug Administration ("FDA") has accepted for filing the New Drug Application ("NDA") and granted the NDA a Priority Review for D-PLEX$_{100}$ for the prevention of surgical site infections ("SSIs") in patients undergoing abdominal colorectal surgery. The FDA did not identify any filing review issues and set a Prescription Drug User Fee Act ("PDUFA") target action date of November 28, 2026, approximately one quarter ahead of the Company's previously communicated first quarter 2027 guidance. Priority Review shortens the FDA's target review timeline from ten months to approximately six months.

"The FDA's acceptance of our NDA with Priority Review, arriving with no filing review issues and an accelerated action date, is a defining regulatory milestone for PolyPid in our development of D-PLEX$_{100}$ as a potential new option to patients for the prevention of surgical site infections, pending the outcome of FDA's review," said Dikla Czaczkes Akselbrad, Chief Executive Officer of PolyPid. "We believe this outcome reflects the quality of our regulatory submission and the rigor of our development program for D-PLEX$_{100}$. Together with our commercial partner Azurity, we are fully aligned on supporting the Agency's review, and on bringing D-PLEX$_{100,}$ if approved, as a new option to patients for the prevention of SSIs following abdominal colorectal surgery."

The FDA's acceptance of the NDA triggers a $15 million milestone payment from Azurity Pharmaceuticals ("Azurity"), completing the $30 million in upfront and near-term milestone payments previously announced under the exclusive commercial partnership signed on July 17, 2026.

The Company will continue to support the FDA's review of the NDA through the November 28, 2026 PDUFA action date, ahead of a potential U.S. commercial launch of D-PLEX$_{100}$ by Azurity in early 2027.

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 with the goal of preventing abdominal surgical site infections ("SSIs"). Following the administration of D-PLEX$_{100}$ into the surgical site, PolyPid's delivery technology, Kynatrix, is designed to pair 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. In the Phase 3 SHIELD II trial, D-PLEX$_{100}$ recently demonstrated positive results in achieving its primary end point and a 60% (p= 0.0013) relative risk reduction at the secondary end point in SSI incidence following abdominal colorectal surgery with large incisions. 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.

About PolyPid

PolyPid Ltd. (Nasdaq: PYPD) is an innovative biopharmaceutical company dedicated to elevating treatment effectiveness, right where care begins. The Company develops long-acting, controlled-release drugs designed to deliver therapy precisely at the site of care, addressing critical unmet medical needs across a wide and diverse pipeline spanning surgical care, metabolic diseases, and beyond. PolyPid's lead product, D-PLEX , successfully met its primary and all key secondary endpoints in the landmark Phase 3 SHIELD II trial for the prevention of surgical site infections. Guided by a commitment to precision and innovation, PolyPid is redefining how therapies perform and raise the standard of patient care. For additional Company information, please visit http://www.polypid.com and follow us on Twitter (X) 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 anticipated timing of the FDA's review and potential approval of the D-PLEX NDA, the PDUFA target action date, the potential impact of Priority Review on the FDA's review timeline, D-PLEX$_{100}$ as a potential new option to patients for the prevention of surgical site infections, pending the outcome of FDA's review, and the Company's and Azurity's expectations regarding the timing of a potential U.S. commercial launch of D-PLEX . 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, including, but not limited to, the risks detailed in the Company's Annual Report on Form 20-F filed on February 25, 2026. 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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