PolyPid Receives PDUFA Fee Waiver from FDA for D-PLEX ‘s New Drug Application

FDA Grants $4.3 Million Small Business Waiver, Enabling Focus on Commercialization Preparations

Company On Track to Initiate NDA Submission by the End of this Month

PETACH TIKVA, Israel, March 17, 2026 (GLOBE NEWSWIRE) — PolyPid Ltd. (Nasdaq: PYPD) (“PolyPid” or the “Company”), an innovative biopharmaceutical company dedicated to improving patient outcomes by elevating treatment effectiveness, right where care begins, today announced that the U.S. Food and Drug Administration (FDA) has granted a small business waiver of the Prescription Drug User Fee Act (PDUFA) fee of approximately $4.3 million for the New Drug Application (NDA) for D-PLEX , the Company’s lead product candidate for the prevention of surgical site infections (SSIs) in abdominal colorectal surgeries.

This meaningful waiver advances PolyPid toward its upcoming NDA submission initiation and enables the Company to focus its resources on commercialization preparations, following the successful Phase 3 SHIELD II trial which demonstrated a 60% (p=0.0013) relative risk reduction in surgical site infections and met its primary and all key secondary endpoints. The Company remains on track to submit the first sections of its rolling NDA by the end of this month, following positive feedback from the FDA during the pre-NDA meeting communication completed in December 2025.

“We are pleased to receive this PDUFA fee waiver days before our planned NDA submission,” said Dikla Czaczkes Akselbrad, Chief Executive Officer of PolyPid. “Following our landmark Phase 3 SHIELD II results and productive engagement with the FDA on our rolling NDA review approach, we continue to make significant progress toward bringing D-PLEX to market. With D-PLEX seeking to address a significant unmet need in a major surgical infection prevention market, we are in advanced stages of commercial partnership discussions for the U.S. market while preparing for what we expect to be a transformative year for PolyPid.”

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 to prevent surgical site infections (“SSIs”). Following the administration of D-PLEX$_{100}$ into the surgical site, PolyPid’s delivery technology, Kynatrix, pairs 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. D-PLEX$_{100}$

recently demonstrated positive results in the Phase 3 SHIELD II trial, achieving a statistically significant 60% (p= 0.0013) relative risk reduction 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 initiation and progress of the rolling NDA submission for D-PLEX , the Company's expectations regarding potential approval of D-PLEX , the potential benefits and clinical impact of D-PLEX for the prevention of SSIs, the Company's plans and preparations for potential commercialization, including commercial partnership discussions for the U.S. market, and the Company's expectations regarding the continued advancement of D-PLEX toward potential market introduction. 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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