

## **PolyPid Initiates D-PLEX NDA Submission to the FDA**

*PolyPid Submits First Modules as Part of Rolling NDA Review; Completion expected in Second Quarter of 2026*

*U.S. Commercialization Partnership Negotiations on Track*

PETACH TIKVA, Israel, March 31, 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 it has initiated a New Drug Application (“NDA”) submission to the U.S. Food and Drug Administration (the “FDA”) for D-PLEX for the prevention of surgical site infections (“SSIs”) in patients undergoing colorectal surgery.

The NDA is being submitted under the FDA’s Fast Track designation, which allows for rolling review. The submission includes the Chemistry, Manufacturing and Controls (CMC) and nonclinical sections of the NDA, with additional components, including the clinical section, expected to be submitted in the second quarter of 2026.

“This submission marks a pivotal milestone for PolyPid as we advance D-PLEX into its regulatory approval phase,” said Dikla Czaczkes Akselbrad, Chief Executive Officer of PolyPid. “Following the positive results from our successful Phase 3 SHIELD II trial and constructive feedback from our previously announced pre-NDA meeting with the FDA, we are pleased to initiate the NDA submission. We are highly focused on executing toward potential approval and commercialization, with the goal of bringing D-PLEX to patients undergoing surgery, while advancing discussions for a U.S. commercialization partnership.”

### **About D-PLEX**

D-PLEX, PolyPid’s lead product candidate, is designed to provide local prolonged and controlled anti-bacterial activity directly at the surgical site to prevent SSIs. Following the administration of D-PLEX 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 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 received Breakthrough Therapy Designation from the FDA 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 progress of the rolling NDA submission for D-PLEX and the expected timing thereof, the Company's expectations regarding potential approval of D-PLEX, and potential commercial partnership for the U.S. market. 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.

### **Company Contact:**

PolyPid Ltd.

Ori Warshavsky  
908-858-5995  
IR@Polypid.com

**Investor Relations Contact:**

Arx Investor Relations  
North American Equities Desk  
polypid@arxhq.com

