PolyPid Completes New Drug Application Submission to FDA for D-PLEX

If approved, D-PLEX$_{100}$ would address a critical unmet medical need in the prevention of surgical site infections

PDUFA target action date currently planned for the first quarter of 2027

PETACH TIKVA, Israel, June 01, 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 the successful completion of its New Drug Application ("NDA") submission on a rolling review basis to the U.S. Food and Drug Administration ("FDA") for D-PLEX$_{100}$, the Company's lead product candidate for the prevention of surgical site infections ("SSIs") in patients undergoing colorectal surgery. The Company anticipates a potential FDA decision in the first quarter of 2027 under the Prescription Drug User Fee Act ("PDUFA") review timeline.

The NDA is supported by positive results from the Company's pivotal Phase 3 SHIELD II trial that met its primary endpoint and all key secondary endpoints, and demonstrated a 60% relative risk reduction in SSIs compared to standard of care (p=0.0013). D-PLEX$_{100}$ has been granted Breakthrough Therapy, Fast Track, and Qualified Infectious Disease Product ("QIDP") designations by the FDA, supporting eligibility for Priority Review.

"Completing the NDA submission for D-PLEX$_{100}$ is a defining milestone for PolyPid and the culmination of years of disciplined clinical and regulatory work," said Dikla Czaczkes Akselbrad, Chief Executive Officer of PolyPid. "With the full application now before the FDA, we are focused on supporting the agency's review, finalizing our U.S. commercial partnership discussions, and preparing for the potential approval and launch of a novel approach to the prevention of SSIs."

About D-PLEX$_{100}$

D-PLEX$_{100}$ is PolyPid's lead product candidate, designed to prevent surgical site infections following abdominal colorectal surgery. Built on the Company's proprietary Kynatrix™ technology, D-PLEX$_{100}$ is administered locally at the surgical site at the time of wound closure and delivers a sustained, controlled release of doxycycline for approximately 30 days, with minimal systemic exposure. In the Phase 3 SHIELD II trial, D-PLEX$_{100}$ met its primary endpoint and key secondary endpoints, demonstrating a 60% relative risk reduction in SSIs compared to standard of care (p=0.0013). D-PLEX$_{100}$ has been granted Breakthrough Therapy, Fast Track, and Qualified Infectious Disease Product (QIDP) designations by the FDA.

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$_{100}$, 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 raises 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 its anticipation about the potential FDA decision and the timing thereof, benefits and advantages of D-PLEX$_{100}$, the Company's focus on supporting the FDA's review, finalization of its U.S. commercial partnership discussions, and preparation for the potential approval and launch of a novel approach to the prevention of SSIs. 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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