

PolyPid Announces Positive FDA Pre-NDA Meeting Minutes for D-PLEX Supporting NDA Submission

NDA to be Submitted on a Rolling Basis, Beginning Early 2026

PETACH TIKVA, Israel, Dec. 03, 2025 (GLOBE NEWSWIRE) — PolyPid Ltd. (Nasdaq: PYPD) (“PolyPid” or the “Company”), a late-stage biopharma company aiming to improve surgical outcomes, today announced that it has received a formal pre-New Drug Application (“NDA”) meeting minutes from the U.S. Food and Drug Administration (“FDA”) supporting the NDA submission of D-PLEX₁₀₀, the Company’s lead product candidate for the prevention of surgical site infections in abdominal colorectal surgeries.

The FDA agreed that the Company’s existing clinical data package, including results from the Phase 3 SHIELD II trial, appears adequate to support NDA submission and review. The FDA also agreed to a rolling NDA review, allowing PolyPid to submit the first completed sections in early 2026.

Based on the FDA’s Pre-NDA meeting written response, the Company concludes that the objectives of the pre-NDA meeting have been accomplished and has determined that the in-person meeting, originally scheduled for December 3, 2025, is no longer necessary.

“We are pleased with the pre-NDA meeting feedback we received from the FDA, which confirmed agreement on the content and format for our planned NDA submission, and appreciate the agency’s collaborative engagement throughout this process,” said Dikla Czaczkes Akselbrad, Chief Executive Officer of PolyPid. “The agreement on the adequacy of the clinical data package for submission, combined with our Breakthrough Therapy designation, validates our regulatory strategy and keeps us firmly on track to bring this potentially transformative treatment to patients.”

About D-PLEX₁₀₀

D-PLEX₁₀₀, 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-PLEX₁₀₀ into the surgical site, the PLEX (Polymer-Lipid Encapsulation matrix) technology 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-PLEX₁₀₀ recently demonstrated positive results in the Phase 3 SHIELD II trial, achieving a statistically significant 58% ($p < 0.005$) relative risk reduction in SSI incidence following abdominal colorectal surgery with large incisions. D-PLEX₁₀₀ 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 a late-stage biopharma company aiming to improve surgical outcomes. Through locally administered, controlled, prolonged-release therapeutics, PolyPid's proprietary PLEX (Polymer-Lipid Encapsulation matrix) technology pairs with Active Pharmaceutical Ingredients (APIs), enabling precise delivery of drugs at optimal release rates over durations ranging from several days to months. Following positive phase 3 results, New Drug Application (NDA) submission of D-PLEX₁₀₀, PolyPid's lead product candidate, for the prevention of abdominal colorectal surgical site infections, is expected in early 2026. In addition, the Company has an innovative pipeline in oncology, obesity and diabetes.

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 expected NDA submission and timing thereof, that the Company's clinical data package appears adequate to support NDA submission and review, and that the agreement on adequacy of the clinical data package for submission, combined with its Breakthrough Therapy designation, validates its regulatory strategy and keeps the Company firmly on track to bring this potentially transformative treatment to patients. 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 26, 2025. 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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