

PolyPid gets a second QIDP designation for D-PLEX100

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PolyPid Ltd., an Israeli, clinical-stage biopharmaceutical company focused on developing and commercializing novel, locally administered therapies, announced that the United States Food and Drug Administration (FDA) has granted a second Qualified Infectious Disease Product (QIDP) designation to D-PLEX₁₀₀ for the prevention of post-abdominal surgery incisional infection.

D-PLEX₁₀₀, PolyPid's lead product candidate, had previously received both QIDP designation and Fast Track status from the FDA for the prevention of sternal wound infection post cardiac surgery, one of the most devastating complications with a mortality rate of up to 40 percent when deep sternal infection occurs. Plans are currently underway for PolyPid to commence their Phase 3 clinical trial in cardiac surgery in the second half of 2019.

"This additional QIDP designation for D-PLEX₁₀₀ in abdominal surgery expands significantly the potential surgical population that may benefit from D-PLEX₁₀₀," said Amir Weisberg, PolyPid's Chief Executive Officer. "Abdominal surgeries, and especially those involving colorectal resection are notorious for their high rates of surgical site infections (SSIs), and the need for preventive solutions is acute. At this time, we remain focused on completing the Phase 2 study of D-PLEX₁₀₀ in abdominal surgery for which we plan to report top-line results in the second half of this year"