PolyPid Initiates First Phase 3 Clinical Trial of D-PLEX100 for the Prevention of Post-Abdominal Surgery Incisional Infections

PETAH TIKVA, Israel, July 1, 2020 — PolyPid Ltd. (Nasdaq: PYPD), a Phase 3 clinical-stage biopharmaceutical company focused on developing targeted, locally administered and prolonged-release therapeutics using its proprietary PLEX technology, today announced that the first patient has been enrolled and randomized in the SHIELD I (**S**urgical site **H**ospital acquired **I**nfection pr**E**vention with **L**ocal **D**-plex) trial, the Company's first of two Phase 3 clinical trials of its lead product candidate D-PLEX$_{100}$, for the prevention of post-abdominal surgery incisional infection (soft tissue).



"We are very pleased with the initiation of our SHIELD I trial, one month after the submission of an amendment to our Investigational New Drug application to the U.S. Food and Drug Administration (FDA) on May 29, 2020 " said Amir Weisberg, PolyPid's CEO. "Enrollment of the first patient in this trial represents a significant milestone for our D-PLEX$_{100}$ development program. Abdominal surgery is the second surgical model to enter Phase 3 development for D-PLEX$_{100}$. We believe that this trial, combined with the second Phase 3 clinical trial in this indication that is planned to start approximately 6 months from now, represents a key advancement toward our U.S. regulatory approval strategy and our ability to provide a novel solution for surgeons and their patients as expeditiously as possible."

"D-PLEX$_{100}$ has shown promise in a previous Phase 2 clinical trial by significantly decreasing surgical site infections (SSI) in abdominal surgery with colorectal resection, one of the most complex surgical setting for SSIs" said Dr. Anthony Senagore, colorectal surgeon and a medical advisor to PolyPid. "The need for additional preventive solutions is acute, especially with the emergence of antibiotic resistant bacteria, and so we look forward to evaluating D-PLEX$_{100}$ in the SHIELD-I trial as a potential solution for our surgical patients."

SHIELD I is a prospective, multinational, multicenter, randomized, double blind Phase 3 trial designed to assess the efficacy and safety of D-PLEX$_{100}$ administered concomitantly with the

Standard of Care (SoC), compared to a SoC-treated control arm, for the prevention of post-abdominal surgery incisional infection. The primary endpoint of the trial is the infection rate, as measured by the proportion of subjects with at least one abdominal target incisional infection event within 30 days post abdominal surgery, determined by a blinded independent adjudication committee. The trial will enroll a minimum of 616 patients, with a maximum of about 900 patients, as defined by the adaptive study design, in approximately 50 centers in the United States, Europe and Israel.

About D-PLEX$_{100}$

PolyPid's lead product candidate, D-PLEX$_{100}$, is a novel product candidate designed to provide local prolonged anti-bacterial activity directly at the surgical site to prevent SSIs. Following the administration of D-PLEX$_{100}$ into the surgical site, the PLEX technology enables a prolonged and constant release of the broad-spectrum antibiotic doxycycline, resulting in high local concentration of the drug for a period of up to four weeks for the prevention of SSIs, with additional potential to treat antibiotic-resistant bacteria at the surgical site. D-PLEX$_{100}$ has received two Qualified Infectious Disease Product (QIDP) designations from the FDA for the prevention of sternal wound infection post-cardiac surgery and for the prevention of post-abdominal surgery incisional infection.

About PolyPid

PolyPid is a Phase 3 clinical-stage biopharmaceutical company focused on developing targeted, locally administered and prolonged-release therapeutics using its proprietary PLEX (Polymer-Lipid Encapsulation matriX) technology. PolyPid's product candidates are designed to address diseases with high unmet medical needs by pairing PLEX with drugs to deliver them directly to precise sites in the body at predetermined release rates and over durations ranging from several days to several months. PolyPid's lead product candidate, D-PLEX$_{100}$, is in Phase 3 clinical trials for the prevention of sternal SSIs and abdominal SSIs. PolyPid's technology and products are based on the inventions of Dr. Noam Emanuel, the Founder and the Chief Scientific Officer of the company.

For additional company information, visit www.polypid.com.

Forward-looking Statements

This press release contains projections and other forward-looking statements regarding future events or our future financial performance. All statements other than present and historical facts and conditions contained in this release, including any statements regarding our future results of operations and financial positions, business strategy, plans and our objectives for future operations, the conduct and timing of our clinical trials, our research, development and regulatory plans for our product candidates and preclinical pipeline, the

potential for these product candidates to receive regulatory approval from the FDA or equivalent foreign regulatory agencies and whether, if approved, our product candidates will be successfully commercialized and marketed, are forward-looking statements (within the meaning of the Private Securities Litigation Reform Act of 1995, Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended). These statements are only predictions and reflect our current beliefs and expectations with respect to future events and are based on assumptions and subject to risk and uncertainties and subject to change at any time. Actual events or results may differ materially from those contained in the projections or forward-looking statements. Forward-looking statements in this release are made pursuant to the safe harbor provisions contained in the Private Securities Litigation Reform Act of 1995.

This press release shall not constitute an offer to sell or the solicitation of an offer to buy, nor shall there be any sale of these securities in any state or jurisdiction in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of such state or jurisdiction.

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