PolyPid Announces Positive Preclinical Data of its Intra-tumoral OncoPLEX in Brain Cancer

- *Positive Results in Two Animal Models of Glioblastoma Multiform (GBM) demonstrated that Single Local Treatment of OncoPLEX Significantly Inhibited Tumor Growth and Prolonged Survival*

- *Company Expects a Pre-IND Meeting with the U.S. FDA by Year End and Potential Initiation of Phase 1/2 Clinical Trial of OncoPLEX in Brain Tumors in 2022*

PETAH TIKVA, Israel, Sept. 13, 2021 — PolyPid Ltd. (Nasdaq: PYPD), a phase 3 biopharmaceutical company focused on developing targeted, locally administered, and prolonged-release therapeutics using its proprietary PLEX technology, today announced positive preclinical data in two key Glioblastoma Multiform (GBM) animal models of its OncoPLEX intra-tumoral cancer therapy program.

OncoPLEX utilizes the Company's novel PLEX technology to provide controlled local exposure to docetaxel, one of the most widely used chemotherapy agents, for a few weeks in the intra-operative tumor resection setting, to potentially reduce local tumor recurrence, tumor spreading and prolong patient survival.

The OncoPLEX intra-tumoral cancer therapy program was evaluated in brain tumors for tumor growth and survival in two Glioblastoma Multiform (GBM) animal models. Key results included:

- OncoPLEX induced strong inhibition of tumor growth and recurrence in a partially resected human glioblastoma subcutaneous mouse model. A single local OncoPLEX application induced 98% tumor growth inhibition (day 41 post operation) compared to the untreated control ($p<0.001$), and 66% compared to multiple injections of systemic chemotherapy treatment arm ($p=0.0165$). The day 41 survival rate for OncoPLEX was much higher than the systemic treated mice, or untreated with 60%, 20%, and 10% survival, respectively.
- OncoPLEX was also tested in a GBM brain rat model. OncoPLEX, applied locally next to the non-resected tumor in the brain, showed a 40% survival rate at day 23 following the beginning of treatment, as compared to a 0% survival rate in the standard systemic treatment arm (Temozolomide 33.5 mg/kg, 5 treatment days), the placebo arm (OncoPLEX without Docetaxel) and in the untreated control arm. Only OncoPLEX significantly enhanced the overall survival compared to both the placebo arm and to the untreated arm ($p<0.02$).
- Dose response was demonstrated for OncoPLEX in the different animal models.
- Local application of OncoPLEX in a rat brain model evidenced good safety profile at the

different doses studied.

“The growing set of data from our OncoPLEX preclinical studies continue to look promising,” said Dr. Noam Emanuel, PolyPid’s co-founder and Chief Scientific Officer. “GBM is one of the most aggressive forms of brain cancer which carries a poor prognosis with current therapy, mainly due to the limited ability of existing approaches to penetrate the blood brain barrier. The novel prolonged intra-tumoral OncoPLEX treatment could provide substantial benefit for patients with these devastating tumors that often cannot be fully resected surgically. Based on the encouraging anti-cancer results of OncoPLEX in various animal models generated to date, including in tumors that are highly resistant to docetaxel, we believe that OncoPLEX warrants further evaluation in the clinical setting. As such, we intend to conduct a pre-Investigational New Drug (IND) meeting with the U.S. FDA by year-end with the objective of initiating a Phase 1/2 clinical trial in 2022.”

About OncoPLEX

OncoPLEX is PolyPid’s lead intra-tumoral product candidate in Oncology. OncoPLEX utilizes the Company’s novel PLEX technology to provide controlled local exposure to docetaxel, one of the most widely used chemotherapy agents, directly at the tumor site for few weeks to potentially reduce local tumor reoccurrence, the potential spreading of cancer cells, and ultimately improve the overall survival rate of cancer patients. Local delivery of drugs directly into the tumor site, especially in difficult to access tumors such as in the brain, may significantly improve the clinical outcome. The OncoPLEX intra-tumoral cancer therapy program has been evaluated successfully in various animal tumor models, including colon carcinoma and glioblastoma.

About PolyPid

PolyPid Ltd. (Nasdaq: PYPD) is a phase 3 biopharma company aiming to improve surgical outcomes through locally administered, controlled, extended-release therapeutics. PolyPid’s proprietary PLEX (Polymer-Lipid Encapsulation matriX) technology pairs with medications, enables precise delivery of drugs at effective release rates, over pre-determined durations ranging from several days to months. PolyPid’s lead product candidate D-PLEX$_{100}$ is in Phase 3 clinical trials for the prevention of abdominal and sternal surgical site infections (SSIs).

For additional company information, please visit polypid.com and follow us on Twitter 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 statements relating to the timing of a pre-IND Meeting with the U.S. FDA, the timing of trials, and the potential benefits of OncoPLEX, and all statements (other than statements of historical facts) that address activities, events, or developments that the Company intends, expects, projects, believes, or anticipates will or may occur in the future. 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 ("SEC"), including, but not limited to, the risks detailed in the Company's Annual Report on Form 20-F filed on March 5, 2021. 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 and social media platforms 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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