

קסניה ונצ'ר קפיטל בע"מ ("החברה")

23 בדצמבר 2020

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מהות האירוע:

פוליפיז בע"מ (להלן: "פוליפיז") – תוצאות פרה קליניות חיוביות של OncoPLEX

החברה מתכבדת לדווח כי פוליפיז הודיעה כי התקבלו תוצאות חיוביות בניסוי של OncoPLEX במודל עכברים לטיפול בגידולים סרטניים של המעי הגס. OncoPLEX, המבוסס על טכנולוגיית PLEX של פוליפיז, מספק חשיפה מקומית, ממושכת ומבוקרת של Docetaxel, שהינו אחד מהטיפולים הכימותרפיים הנפוצים ביותר.

הניסוי הדגים שיפור בטיפול בגידול, הפחתה משמעותית בהישנות הגידול, וכן הפחתה ברעילות, ביחס לשיטת הזרקת הטיפול הכימותרפי המקובלת.

בכוונת פוליפיז להשלים ניסויים פרה קליניים נוספים בגידולים סרטניים שונים, ולהתחיל פאזה ראשונה של ניסוי קליני בשנת 2022.

ההערכה שלעיל הינה בגדר מידע צופה פני עתיד, כהגדרת מונח זה בחוק ניירות ערך, התשכ"ח-1968, המבוסס על הערכות ותחזיות של פוליפיז. אין כל וודאות להתממשות הערכה זאת, בין היתר, בשל גורמים שאינם בשליטת פוליפיז.

למיטב ידיעת החברה, פוליפיז מפתחת טכנולוגית הובלת תרופות בשם PLEX אשר מאפשרת שחרור מקומי, מושהה ומבוקר של מינוני תרופה יעילים לאורך זמן. מוצר הדגל של פוליפיז הוא D-PLEX₁₀₀, אשר מאפשר שחרור מבוקר ולאורך זמן של אנטיביוטיקה, בכדי למנוע זיהומים שלאחר ניתוחי חזה ובטן. שתי האפליקציות של D-PLEX₁₀₀ נמצאות בשלב הפאזה השלישית של המחקר הקליני.

לפרטים נוספים אודות פוליפיז, ראו סעיף 9.3 לפרק א' לדוח התקופתי של החברה שפורסם ביום 3 בפברואר 2020, מס' אסמכתא 012867-01-2020 (מידע זה מהווה הכללה על דרך ההפניה).

מצ"ב לדיווח זה, הדיווח שפרסמה פוליפיז באתר ה-NASDAQ.

בכבוד רב,

קסניה ונצ'ר קפיטל בע"מ

באמצעות: אלי סורזון, מנכ"ל וסמנכ"ל כספים



PolyPid Announces Positive Preclinical Data from OncoPLEX Intra-Tumoral Cancer Therapy Program

Single Local Treatment of OncoPLEX Showed Improved Overall Survival and Significantly Less Tumor Recurrence, and Reduced Systemic Toxicity Compared to Multiple Injections with Standard Systemic Chemotherapy in a Syngeneic Mouse Model for Solid Tumors of Colon Carcinoma

Company Intends to Complete an IND Package with Additional Preclinical Studies in Various Solid Tumor Types, Followed by the Initiation of a Phase 1 Clinical Trial in 2022

PETAH TIKVA, Israel, December 22, 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 positive preclinical data from its OncoPLEX intra-tumoral cancer therapy program. OncoPLEX utilizes the Company's novel PLEX technology to provide prolonged and controlled local exposure to docetaxel, one of the most widely used chemotherapy agents, in the intra-operative tumor resection setting. OncoPLEX is designed for the delivery of sustained, significant concentrations of docetaxel locally within the tumor site for a few weeks, potentially reducing local tumor recurrence and tumor metastatic spreading.

In a syngeneic mouse model for solid tumors of colon carcinoma, a single local application of OncoPLEX at the intra-operative setting post tumor resection compared to the group treated with six cycles of systemic docetaxel treatment with 2-4 days gap between cycles, generated the following key results:

- OncoPLEX arm showed 25% overall tumor recurrence at the end of the study (day 39 post-surgery) compared to 75% in the systemic treatment arm, and 100% in the untreated control arm.
- OncoPLEX arm demonstrated 75% overall tumor free survival at the end of the study (day 39 post-surgery), compared to 25% in the systemic treatment arm, and 0% in the untreated control arm.
- OncoPLEX arm demonstrated 75% overall survival at the end of the study (day 39 post-surgery), compared to 50% in the systemic treatment arm, and 0% in the untreated control arm.

Dose response was also demonstrated for OncoPLEX in these studies.

Systemic toxicity was lower following the local application of OncoPLEX versus systemic docetaxel. Additional data in a pharmacokinetic model showed that the

maximal plasma concentration of docetaxel was >10 times lower with OncoPLEX than with systemic docetaxel.

“We believe the benefits of our PLEX platform, including the ability to generate constant and high local concentration of drug over a prolonged period, can also potentially be leveraged as an anti-cancer therapy” said Dr. Noam Emanuel, PolyPid’s Chief Scientific Officer. “We are very encouraged by these preclinical data, as they support our belief that direct local application of OncoPLEX in the intra-operative tumor resection setting has the potential to be a promising new type of adjuvant therapy to reduce local tumor recurrence and to prevent postoperative metastatic spreading by cancer cells that escape resection, as seen in many oncology patients across different solid tumors.”

Based on these compelling preclinical results, PolyPid intends to conduct additional preclinical safety studies of OncoPLEX in various type of solid tumor resections, in order to complete a preclinical package for the filing of pre-Investigational New Drug meeting request with the U.S. Food and Drug Administration in 2021 and potentially initiate a Phase 1 clinical trial in 2022.

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-PLEX₁₀₀, 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 and the professional leadership 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 forward-looking statements within the meaning of the “safe harbor” provisions of the Private Securities Litigation Reform Act of 1995 and other Federal 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, PolyPid is using forward-looking statements in this press release when it discusses the potential of its products and that it intends to conduct additional preclinical safety studies of OncoPLEX in various type of solid tumor resections, in order to complete a preclinical package for the filing of pre-Investigational New Drug meeting request with the U.S. Food and Drug Administration in 2021 and potentially initiate a Phase 1 clinical trial in 2022. Actual results, performance or achievements of PolyPid could

differ materially from those described in or implied by the statements in this press release. The forward-looking statements contained or implied in this press release are subject to other risks and uncertainties, including those discussed under the heading “Risk Factors” in PolyPid’s final prospectus dated June 25, 2020, filed pursuant to Rule 424(b)(4) with the Securities and Exchange Commission (SEC), and in any subsequent filings with the SEC. Except as otherwise required by law, PolyPid undertakes no obligation to publicly release any revisions to these forward-looking statements to reflect events or circumstances after the date hereof or to reflect the occurrence of unanticipated events. 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.