



NASDAQ: PYPD
Corporate Presentation

January 2025

Cautionary Note Regarding Forward Looking Statements

This presentation of PolyPid Ltd. (the “Company”) 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 our objectives, plans, and strategies, the expected timing of trials, the research, development, and use of our platform technologies, technologies, products and product candidates, potential benefits and advantages of our products and product candidates, 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, expected timing of completion of patient recruitment and top-line results of the SHIELD II study and US addressable market. 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 with the SEC on March 6, 2024. 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.

PolyPid Overview

Late clinical
stage biopharma
company

Unique LOCAL
Prolonged Delivery of
APIs

Polymer-Lipid
Encapsulation matrix
(PLEX) Platform

Lead Product D-PLEX₁₀₀ in
Phase 3 trial

OncoPLEX Next Big
Opportunity for Solid
Tumors

176

granted and
pending patents⁽¹⁾

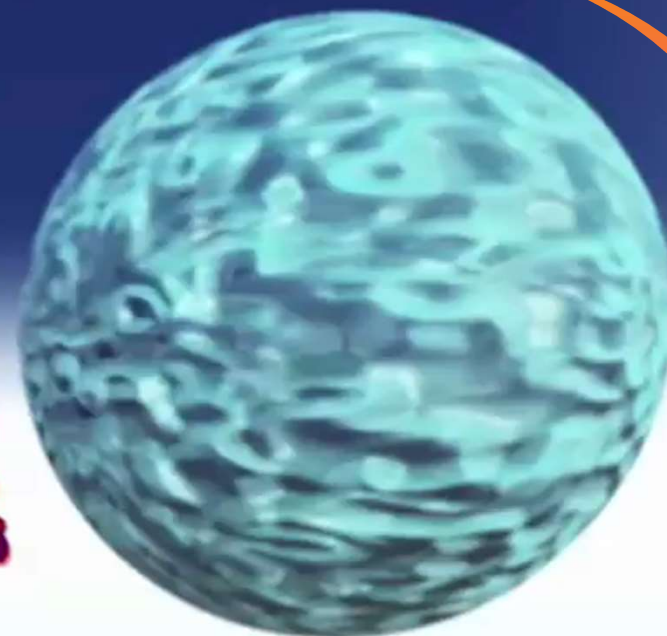
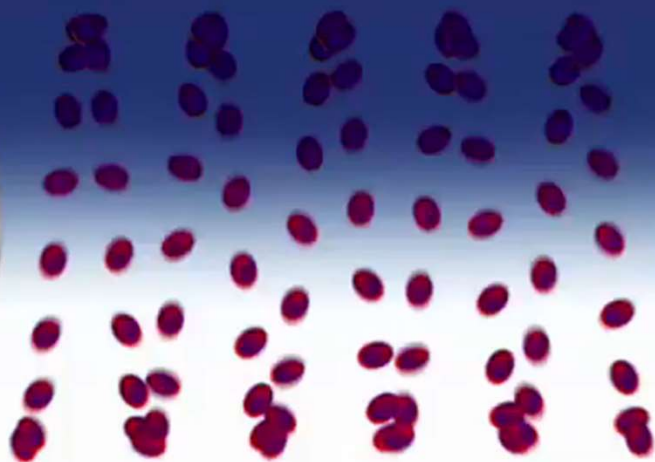
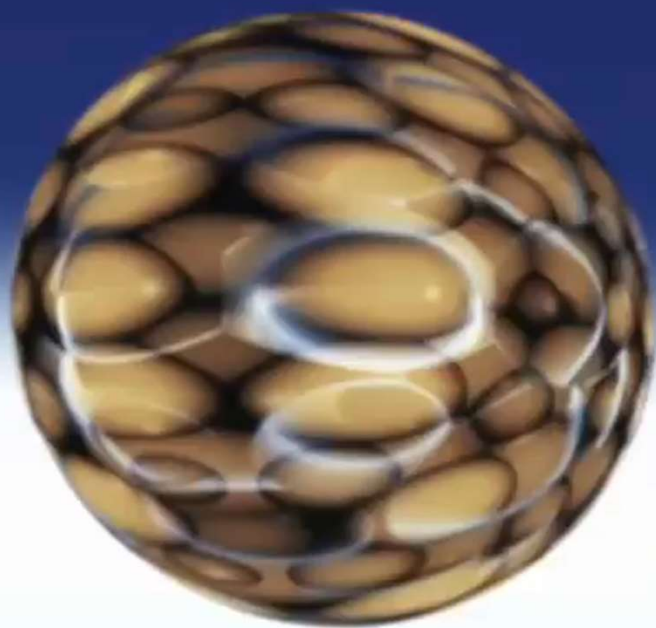
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employees⁽¹⁾

HQs

Global: Petach Tikva, Israel
US: New Jersey

NASDAQ: PYPD



LIPIDS

POLYMERS

Robust Pipeline with Multiple Near- and Longer-Term Inflection Points

Product candidate and indication	Preclinical	Phase 1	Phase 2	Phase 3	Key milestones
D-PLEX₁₀₀ Prevention of Surgical Complications Prevention of SSI in Colorectal Abdominal Prevention of SSI in Abdominal Surgery Prevention of SSI in Orthopedic Surgery	SHIELD I pivotal study in abdominal colorectal surgery				SHIELD I study completed
	SHIELD II abdominal colorectal surgeries with large incisions				SHIELD II Topline expected by 2Q 2025
				PK + Safety Study	2026
				Post-Approval Efficacy Study	2027/2028
OncoPLEX Post Surgical Tumor Resection (Adjuvant) Intratumoral Solid Tumors (Neoadjuvant)					Pre-IND meeting completed (FDA) for GBM Pre-clinical stage

D-PLEX₁₀₀ is a Potential First-in-class for the prevention of SSIs

Indication:

Prevention of abdominal incisional SSI

Doxycycline (broad spectrum antibiotic)

FDA 505(b)(2) regulatory pathway

Administered directly into the surgical site for prolonged 30 days release

~12M Surgeries addressable market in US

Breakthrough Therapy, Fast Track, and QIDP designations

~12M procedures

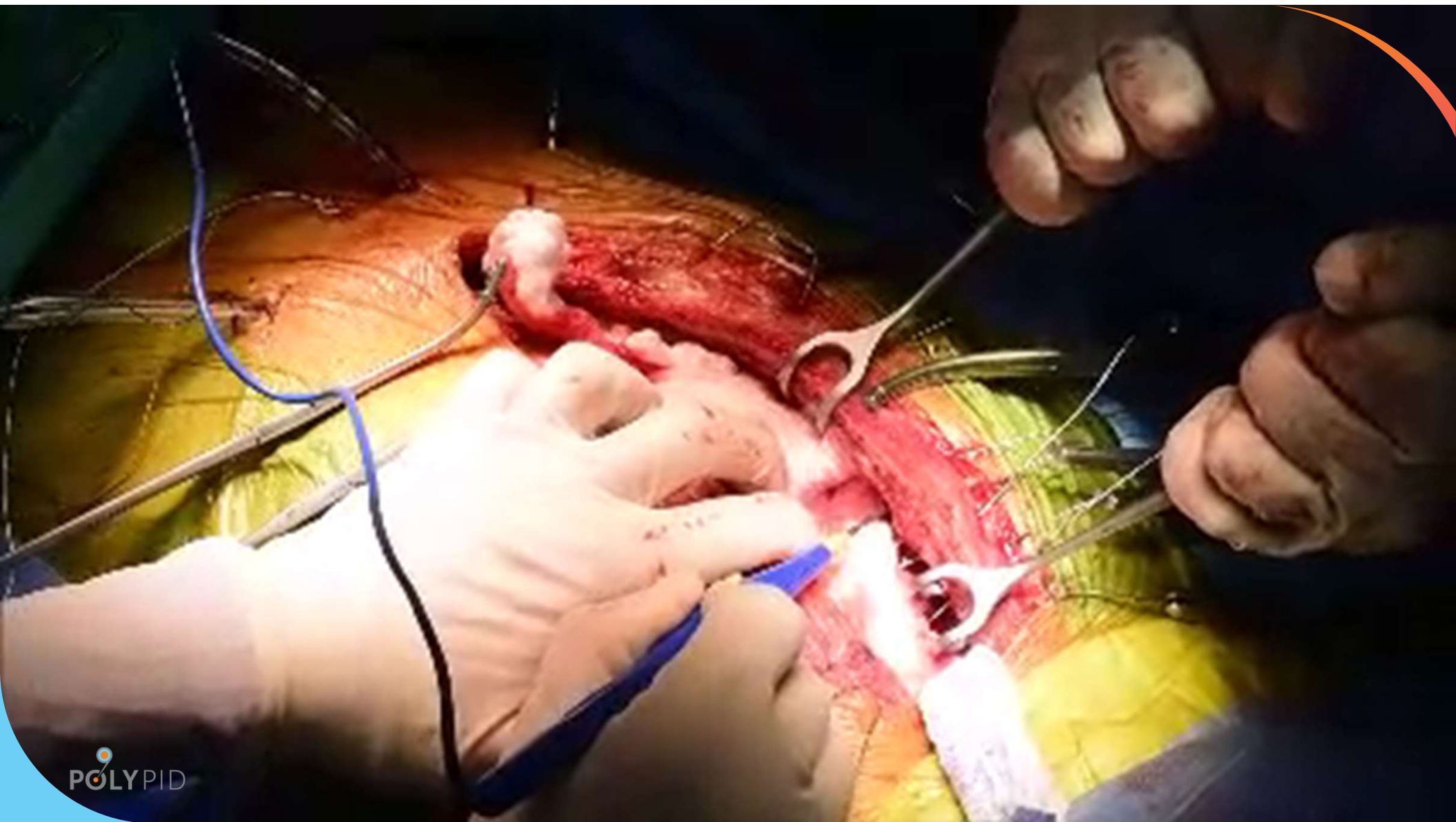
Orthopedic **5.0M**

Abdominal **4.5M**

Gyn & Uro **2.5M**

Sternum **0.5M**

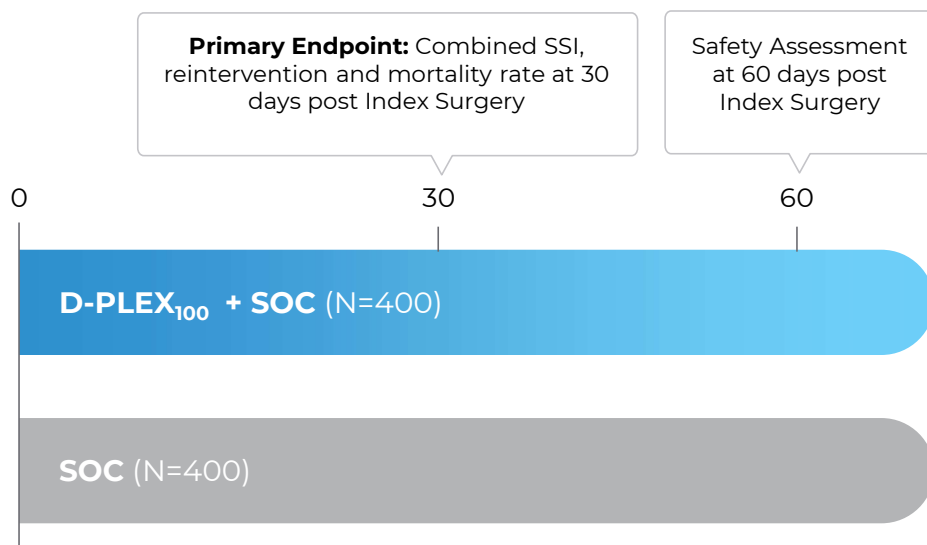




Study Design and Timeline

SHIELD II

SSI PREVENTION WITH D-PLEX₁₀₀



Surgeries with large surgical incision

Total of 800 patient trial.

Sample size is based on Interim Analysis review of the data by the Data Safety Monitoring Committee (DSMB)

Current timing assumptions

- Last patient in: Q1 2025
- Topline results: Q2 2025

Actions taken to de-risk SHIELD II

- Focused on population where SHIELD I was successful
- Conservative statistical assumptions on SSI rates
- Implemented lessons-learned: performed detailed debriefing with the site PIs, kept only high-performing sites
- Strengthened clinical ops team

The Interim Analysis is an Opportunity to Re-size the Trial and Ensure it has Sufficient Power to Confirm Treatment Benefit

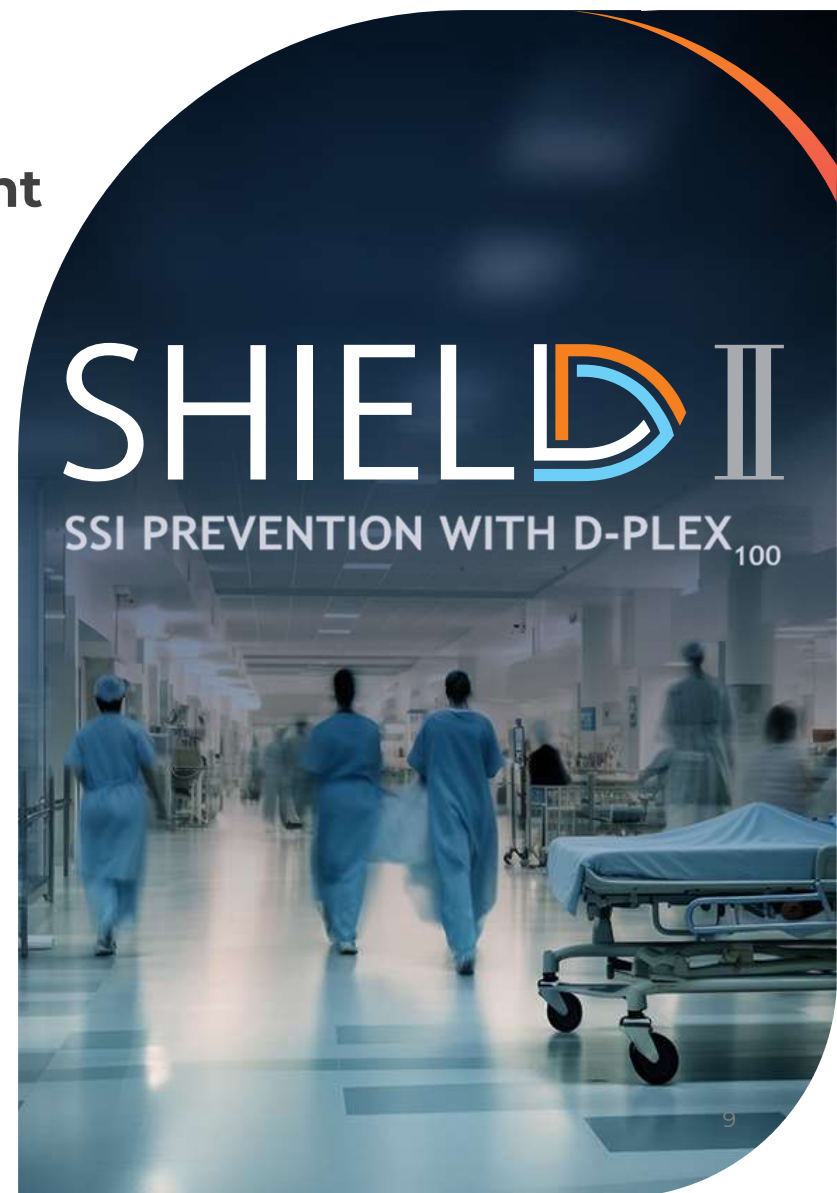
Unblinded interim efficacy analysis by DSMB at 430 patients recommended expanding the sample size to 800 patients - **the first stop after the minimum planned number of patients**

We view this DSMB's recommendation as a **very favorable outcome**, as it is suggestive of **positive efficacy signals** from D-PLEX₁₀₀

The study is now **significantly de-risked** - futility option is now removed

No safety issues related to D-PLEX₁₀₀ have been observed in SHIELD II to date

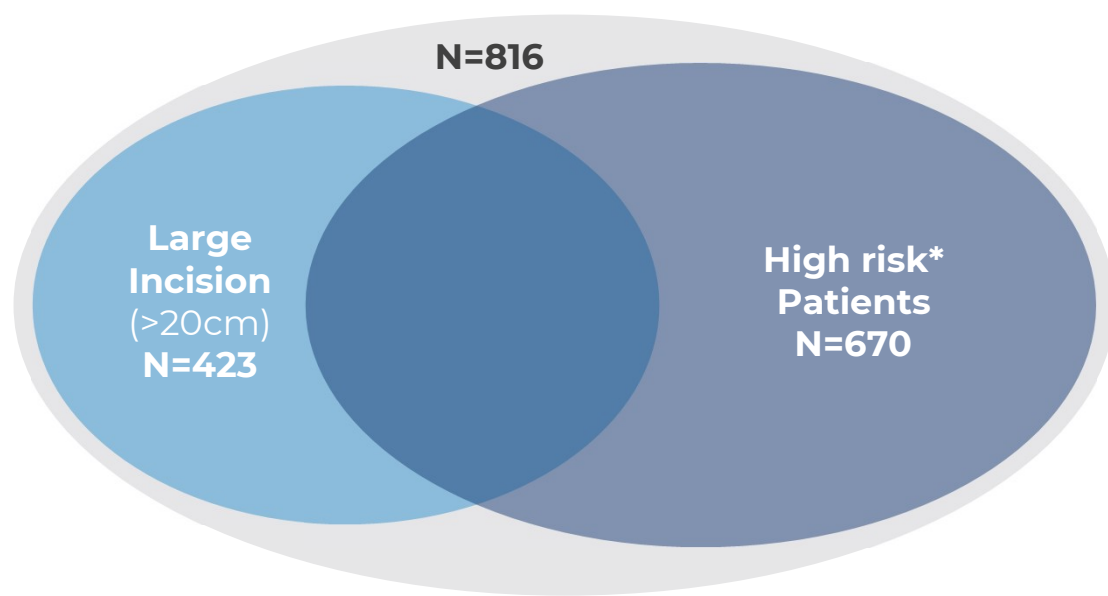
SHIELD  II
SSI PREVENTION WITH D-PLEX₁₀₀



SHIELD I: Deep Dive into the Large-Incision Subgroup

Parameter	D-PLEX (N=212)	Control (N=211)	Effect
Primary endpoint	17 (8%)	37 (17.5%)	54% (p=0.0032)
Key Secondary Efficacy Endpoints			
Infection rate during 30 days post abdominal surgery	9 (4.4%)	19 (9.7%)	55%
Number of subjects with at least 1 score of ASEPSIS >20	2 (1.0%)	5 (2.6%)	62%
Additional Efficacy Endpoints			
Incidence of SSSI rate during 30 days post surgery	9 (4.4%)	17 (8.7%)	49%
Incidence of DSSI rate during 30 days post surgery	0	2 (1.0%)	100%
Mortality rate within 30 days post abdominal surgery	6 (2.8%)	10 (4.7%)	40%
Time to adjudicated SSI during 30 days post index surgery (days)	8.0 (4, 28)	5.0 (1, 13)	NA
Number of subjects treated with IV Antibiotic as treatment for adjudicated SSI	1 (11.1%)	9 (47.4%)	77%
Number of subject with any surgical re-interventions	9 (4.4%)	19 (9.7%)	55%

D-PLEX₁₀₀ Effect on in Patients w/ SSI Risk Factors*



816 Patients

had a large incision and/or high-risk factors (comorbidities)

37% Reduction

of the primary endpoint (p=0.0162)



Target Market at Launch is >7M Surgeries in US & Europe*



12M

US total addressable market in-patient surgical procedures



4.4M

Abdominal Surgeries

8M

Europe total addressable market in-patient surgical procedure



3M

Abdominal Surgeries

7,400K**
Core Target Surg. Procedures

* Assuming additional safety and PK Study for US ; Expected Abdominal Indication in Europe based on SHIELD 2 phase 3 trial

**Source IQVIA PM&I Global FlexView. Internal analysis

Demonstrated Economic Benefits will be Essential for Market Access and Sales Uptake

Direct cost

SSI costs ~\$25K/patient¹ on average

- Prolonged length of stay and higher readmission rates
- Re-operation in some cases (to debride and remove infected / necrotic tissues)

Indirect cost

CMS 1-3% penalty on all the yearly Hospital Medicare reimbursement

Reputational cost

Hospital SSI rates are public information and have direct influence on hospital ranking by CMS and U.S. News best hospitals ranking



1. Stone PW. Economic burden of healthcare-associated infections: an American perspective. Expert Rev Pharmacoecon Outcomes Res. 2009 Oct;9(5):417-22.

D-PLEX₁₀₀ is eligible
for NTAP program
up to 75%
reimbursement
of cost of drug



Global Go-to-market Strategy

Partnerships with leading pharma companies with established hospital-focused commercial capabilities and resources

Agreement highlights

Includes European Economic Area and UK

Potentially receive over \$115 million in upfront and milestone payments as well as royalties on net sales

\$2.7 million upfront payment paid upon signature of licensing agreement



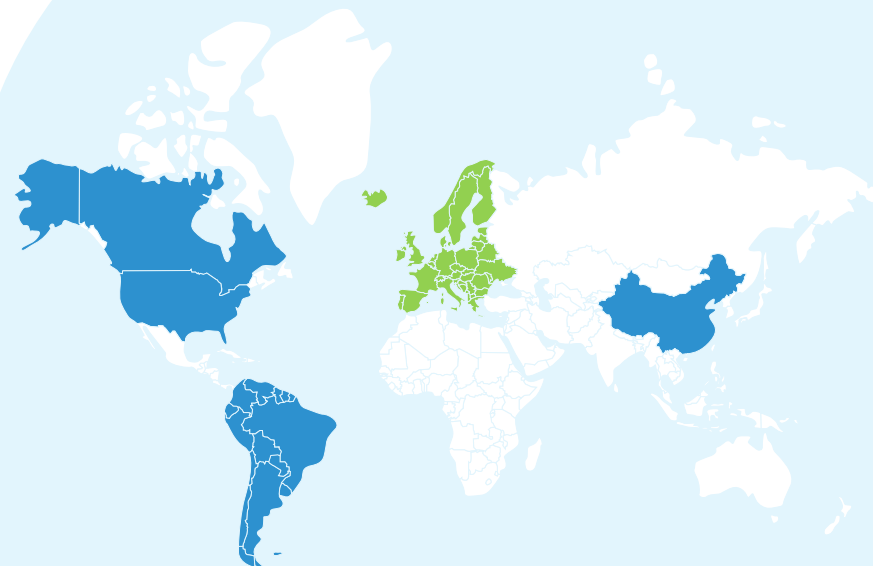
Focused on abdominal and cardiac indications

Signed licensing agreement includes transfer price, development and sales-related milestone payments and royalties

Development-related milestones for a total of up to \$25 million



*Announced August 3rd, 2022



Next-in-line
US, Canada, China and South America

- Partnered territories w/ Advanz Pharma
- Next-in-line

R&D Collaboration Agreement with Immunogenesis for Controlled and Prolonged Intratumoral Delivery

- Houston-based company founded by Dr. Michael Curran, Associate Professor of Immunology at the MD Anderson Cancer Center
- Combined Immunogenesis potent anti-tumor STING agonist with PolyPid's technology to enhance treatment for solid tumors
- Aim to overcome shortcoming of STING agonists molecules, which are susceptible to rapid clearance



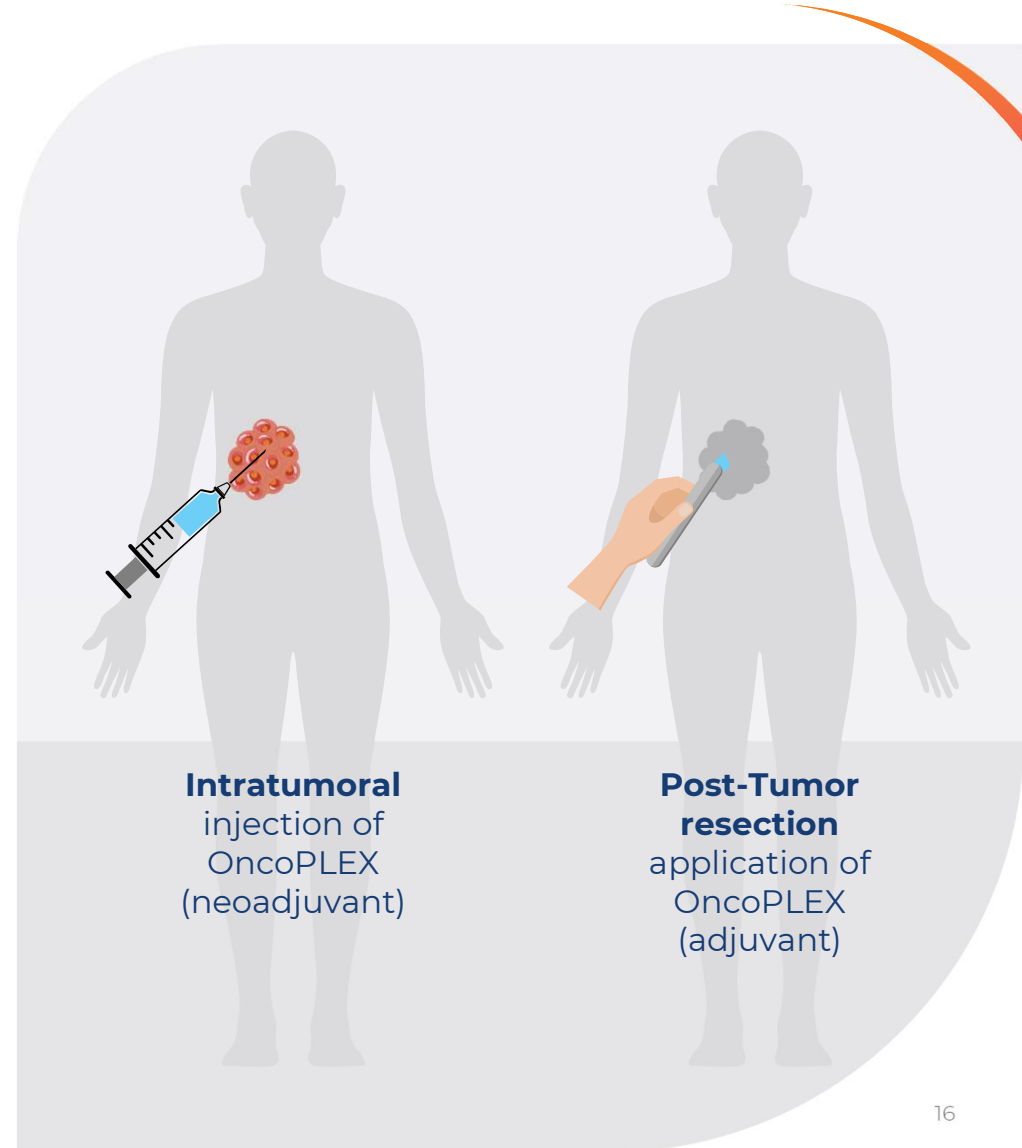
OncoPLEX - The Next Big Opportunity @ PolyPid

New approach for solid tumors - every year, 1.6 million new cases of solid tumors in the U.S. alone

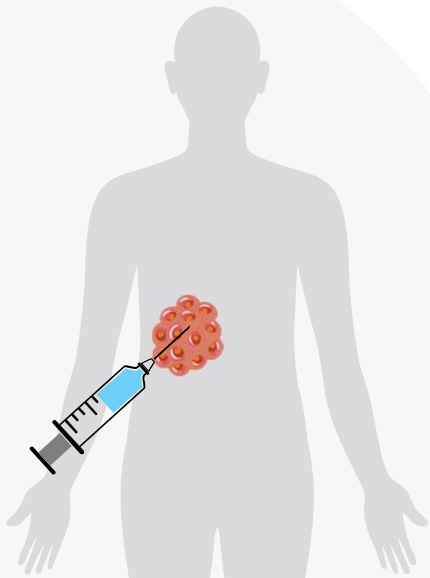
Prolonged 3wks release of docetaxel: intratumoral (neoadjuvant) and post surgical resection of the tumor (adjuvant)

Evaluated successfully in various animal models

Pre-IND meeting (FDA) completed for GBM

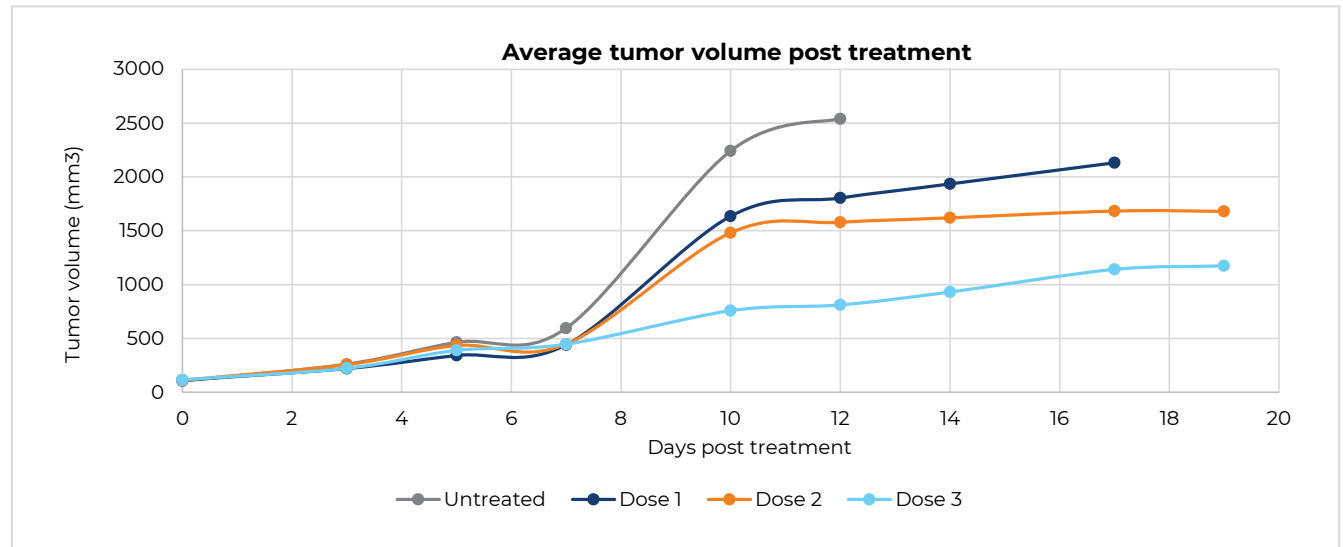


Single Intratumoral Injection of OncoPLEX reduced tumor growth



B16 murine melanoma:
Dose response

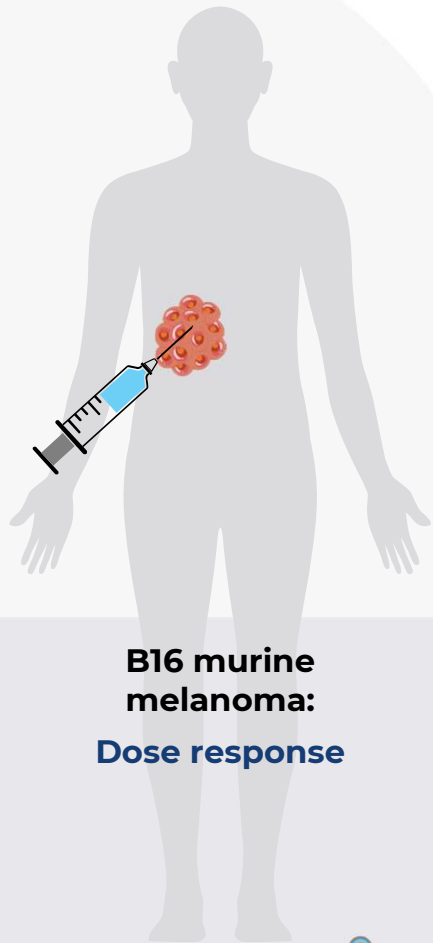
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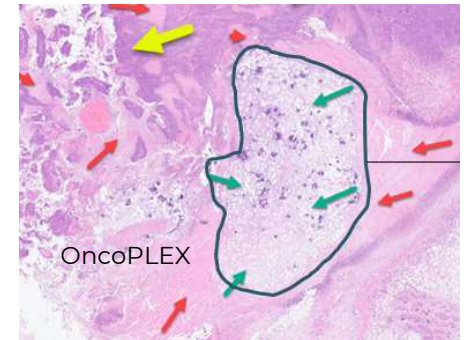
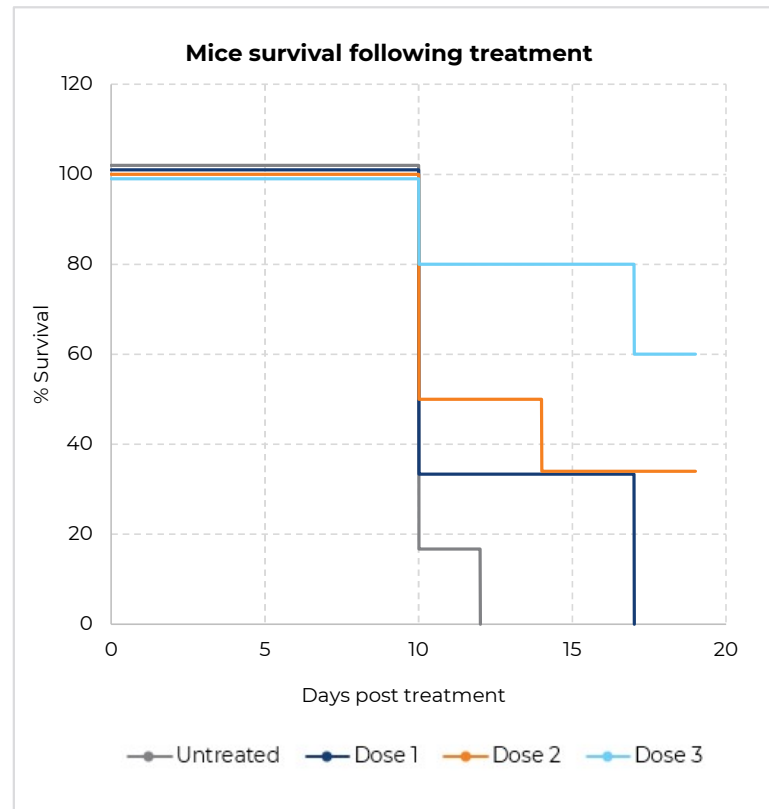
Key Takeaways

- OncoPLEX spheres remain anchored to the injection site over the entire period
- The prolonged and constant release mechanism allows the released drug to generate an effective microenvironment far from the injection site

60% Survival at Day 19 for the Most Effective Dose



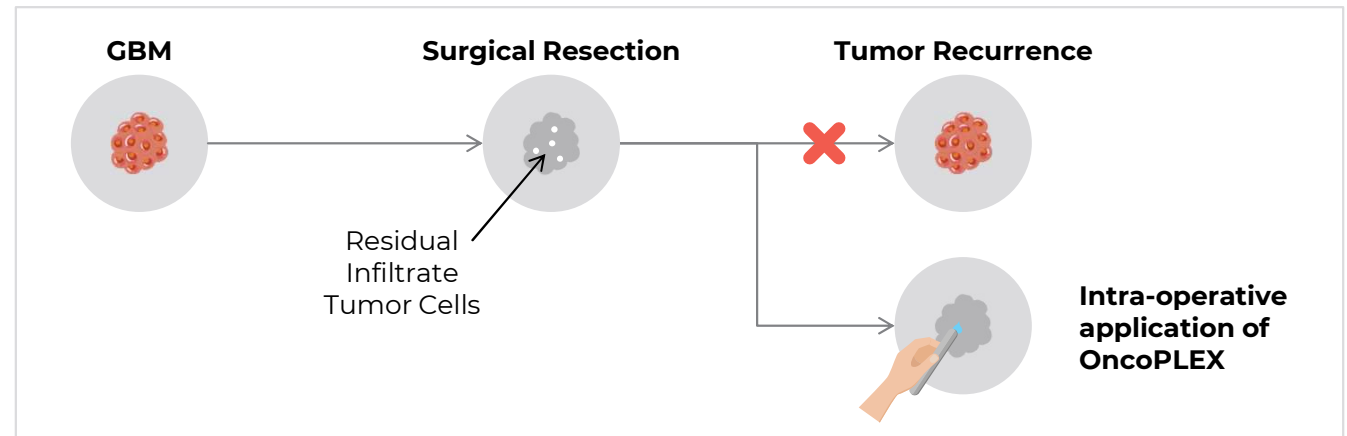
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OncoPLEX Focal Deposits are mostly Surrounded by **Necrotic Tumor Tissues and Inflammation**

Post-Surgical Resection in GBM & Other Solid Tumors

- Prolonged 3wks. local release of Docetaxel directly in the tumor resection pocket
- Evaluated successfully in various animal models
- 98% tumor growth inhibition (day 41) in resected GBM tumor mouse model compared to the untreated control ($p < 0.001$)
- 60% survival (day 41) in resected GBM tumor mouse model vs 20% for the systemic treated mice ($p = 0.0165$)
- 75% overall tumor free survival in resected colon carcinoma tumor mouse model compared to 25% for the systemic docetaxel arm
- Pre-IND meeting in GBM completed (FDA)



State-of-the-Art Manufacturing Facility

PolyPid was granted Manufacturer Authorization and Good Manufacturing Practice – **GMP - certification** by Israel's MoH and EU qualified person for its state-of-the-art ~18,000 square feet (~1,700 m²) manufacturing facility.

Investment

machinery, qualifications and validations

Supply capacity

expected to meet commercial demand for the first 4-5 years from launch



Financials

Stock Information

Listing	NASDAQ
Ticker	PYPD
52-week range ¹	\$2.95-\$9.20
Market cap ¹	\$32 M

Share Structure

Shares outstanding	10.2 M
Pre-funded warrants	1.6 M @ \$0.0001 exercise price
Warrants	1.7 M @ \$3.61 exercise price
Warrants	6.7 M @ \$4.00 exercise price
Warrants	3.4 M @ \$5.50 exercise price
Options	1.8 M @ \$6.73 WAEP



¹. As of November 12, 2024

Top Holders



Analyst coverage



Balaji Prasad



Roy Buchanan



Brendon Folkes



Chase Knickerbocker



Raghuram Selvaraju

Key Accomplishments

Raised over \$65 million from existing and new life science-focused investors

Signed a commercialization agreement for Europe - deal worth >\$110 million in milestone payments plus royalties and transfer price

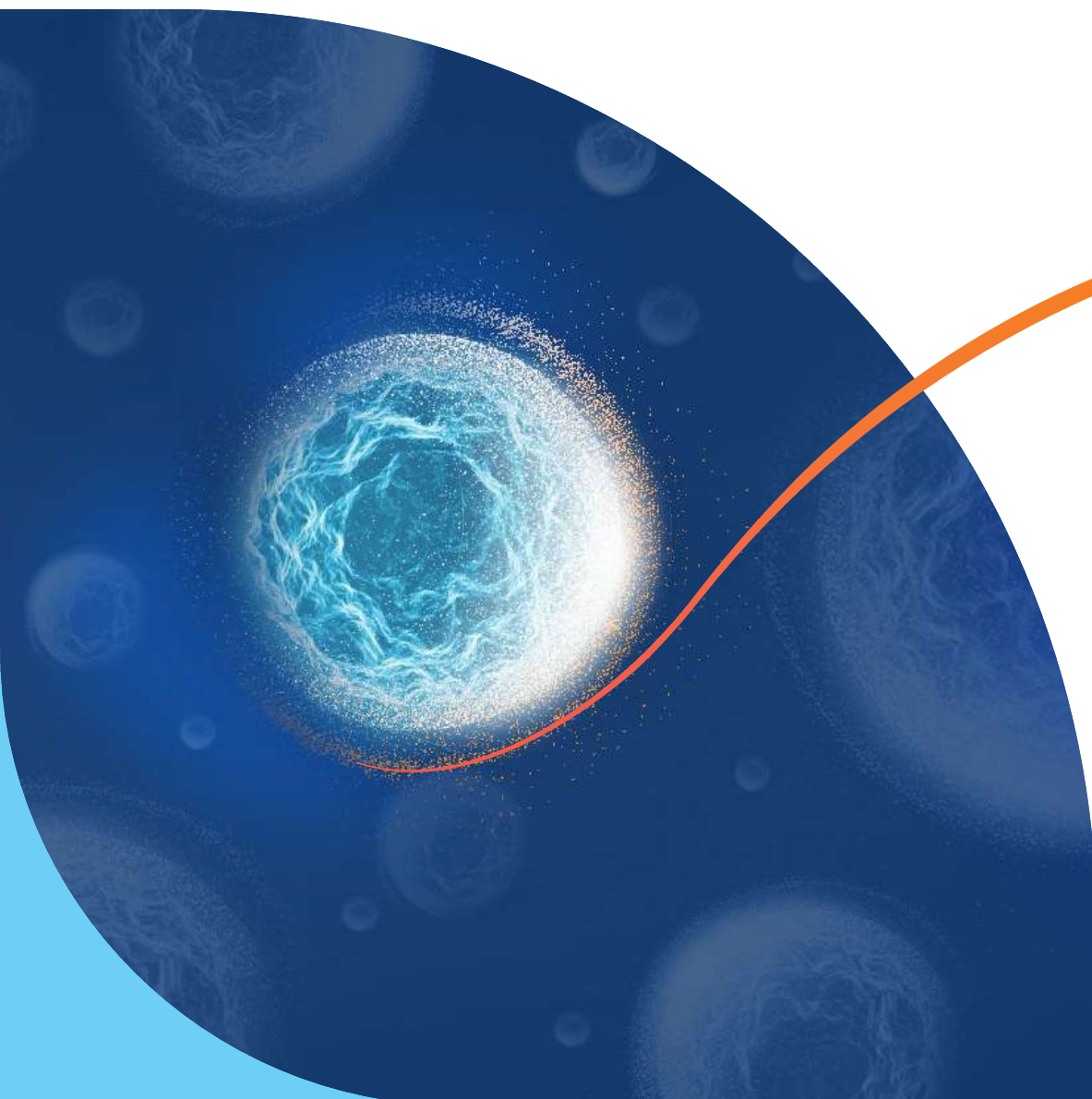
Completed the largest Phase 3 trial in prevention of SSI in colorectal resection in over a decade

Advanced the development of OncoPLEX including pre-IND studies

Initiated a second Phase 3 for prevention of SSI in abdominal colorectal resection with large incisions – top line expected by Q2 2025

Completed process validation for D-PLEX₁₀₀ and passed cGMP inspection – manufacturing facility ready for EU launch





THANK YOU

Polypid.com

PLEX based product typical presentation



Solid spheres

Micron range in diameter

Dry format (powder) and sterile

Ready to use

Each particle contains

the PLEX formulation & the Pre-Encapsulated API/APIs

The PLEX formulation

is predesigned to achieve the needed release characteristics

The dry powder can be

prepared for administration by either:

Hydration into a paste, to be applied locally into the wound/tumor bed during the surgery

Injected ($\geq 21G$) as a paste, or as a dry powder – Once or multiple applications



Recognizes the Potential Value of D-PLEX₁₀₀ in SSI



3 Fast Track Designations

More frequent meetings with the FDA to discuss the development plan

Eligible for accelerated approval and priority review, if relevant criteria are met

Rolling Review

3 Qualified Infectious Disease Product (QIDP) Designations

All the benefits of Fast Track

Additional 5-years of market exclusivity

Improved CMS add-on payment, increase of the NTAP from 50% to 75%

Breakthrough Therapy Designation

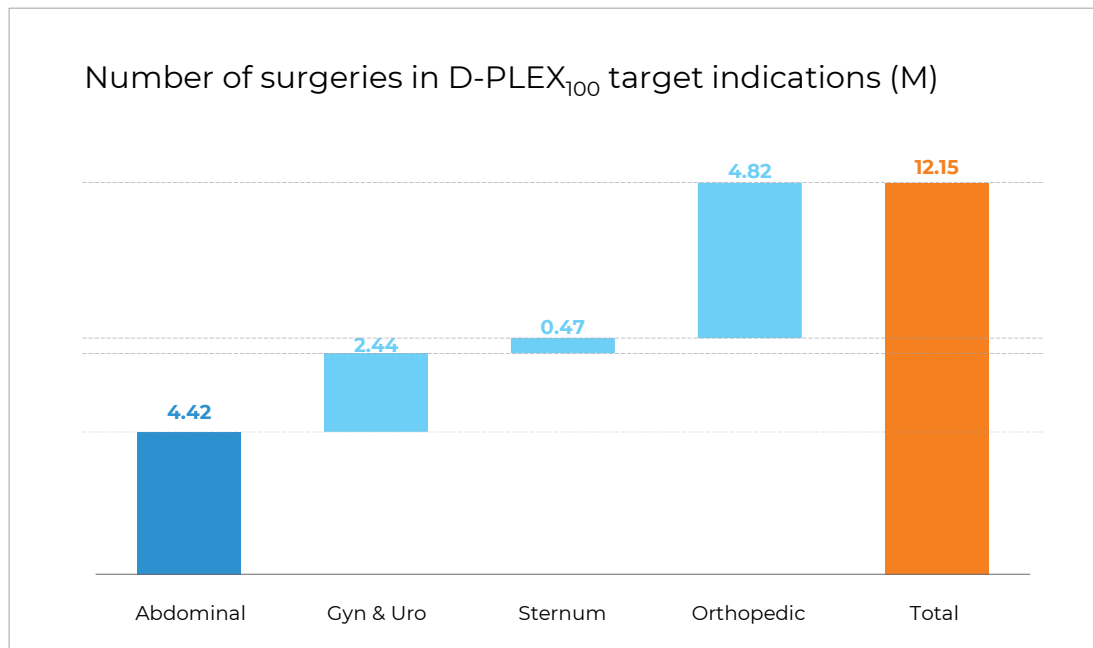
All the benefits of Fast Track

Intensive guidance from FDA on an efficient drug development program

Organizational commitment from FDA involving senior managers

Total US Addressable Market

US TAM for D-PLEX₁₀₀ is Over
12.2M Procedures



Source: IQVIA PM&I Global FlexView. Internal analysis



Main drivers of surgery volumes

Abdominal surgeries

- Herniorrhaphies – 2.1M / year
- Cholecystectomies – 616K / year
- Colorectal resection – 544K / year

Gynecology & Urology surgeries

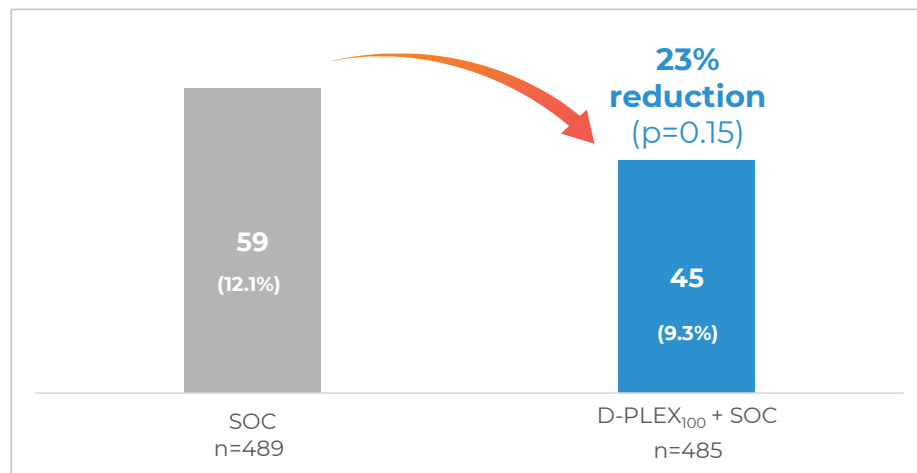
- Hysterectomies – 660K / year
- Oophorectomies – 1.1M / year

Orthopedic surgeries

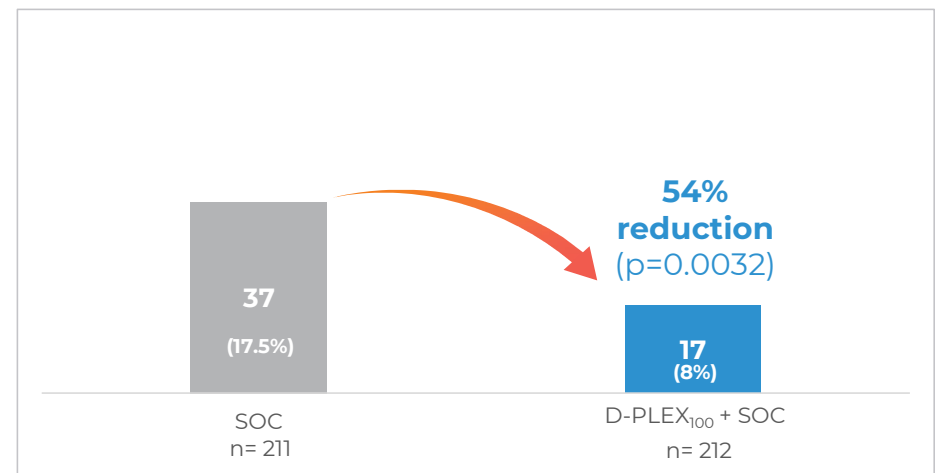
- Joint replacement – 1.8M / year
- Long bone fraction – 2M / year
- Spine procedures – 1M / year

SHIELD I Topline Results

All cohort (primary endpoint*, ITT)



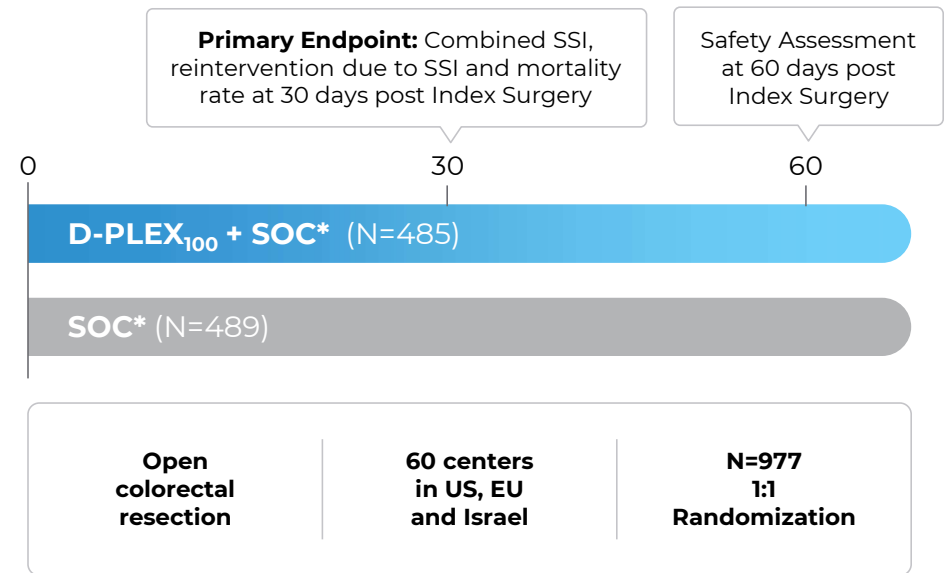
Large incisions complex surgeries – pre-specified subgroup analysis (primary endpoint, incisions >20cm)



SHIELD I Study was the Largest Phase 3 Study of Infection Prevention in Colorectal Surgery in Over a Decade

Assess efficacy and safety of D-PLEX₁₀₀ for prevention of deep and superficial incisional SSI after elective abdominal colon surgery

(prospective, multicenter, randomized, controlled, two arm, double-blind study)



*SOC - Standard of Care