

NASDAQ: PYPD SHIELD II Topline Results

June 9, 2025

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SHIELDS II SSI PREVENTION WITH D-PLEX₁₀₀

Scope

- Assess the efficacy and safety of D-PLEX₁₀₀ in the prevention of post abdominal surgery incisional infection
- Prospective, multinational, randomized, controlled, twoarm, double-blind study
- Global trial, ~60 sites in US, Europe, and Israel

Patient Population

- Patients undergoing elective abdominal colorectal surgery with incision length > 20 cm
- ITT cohort: 798 patients
- Randomization 1:1



Standard of Care (SoC)

- IV antibiotic only / IV antibiotic with mechanical bowel prep / IV antibiotic with oral antibiotics combined with mechanical bowel
- 1st, 2nd or 3rd generation cephalosporin family plus metronidazole given within 60 minutes prior to surgery and discontinued at a maximum of 24hour post index surgery
- Each site used the same pre-defined SoC for all its subjects during the study





SHIELD II Demographics & Surgery Characteristics (ITT Cohort)

Parameter	D-PLEX₁₀₀ (N=405)	SoC (N=393)
Age (yrs)	67.0	68.0
Female (%)	44.0%	37.9%
BMI (Kg/m²)	26.2	26.4
Charlson co-morbidity index	4.0	5.0
Surgery duration (hrs)	2.4	2.3
Indication for index surgery (%)		
Cancer	86.2%	91.1%
Inflammatory Bowel Disease (IBD)	2.0%	0.3%
Other	11.9%	8.7%
Preoperative IV antibiotics given prior to index surgery (%)	100%	99.5%



Primary Efficacy Endpoint

The Primary Efficacy Endpoint is the combination of the following events measured for 30 days from index surgery:

- **1. Surgical Site Infections (SSI)**, deep & superficial, as approved by adjudication committee
- 2. All-cause mortality

3. Reintervention

Re-opening through the same target surgical incision, used for the original index surgery, in the operation room



D-PLEX₁₀₀ Showed Statistically Significant Reduction in the Primary Efficacy Endpoint

POLYPID

Primary Efficacy Endpoint

(ITT cohort)



Key Secondary Efficacy Endpoint #1

Surgical Site Infection rate – intention to treat population:

At least one abdominal incisional surgical site infection event, occurring within 30 days post abdominal (index) surgery in the population **of subjects with incision length >20 cm** (n=798 patients)

Surgical Site Infection (SSI)

(ITT Cohort)



Key Secondary Efficacy Endpoint #2

Combined Efficacy Endpoint - overall study population:

A combination of at least one SSI event in the overall study population of subjects with **incision length >7 cm** (n=975 patients), all-cause mortality and re-interventions through the abdominal incision within 30 days post index surgery

Combined Efficacy Endpoint

(Overall Study Population)



Key Secondary Efficacy Endpoint #3

ASEPSIS Score – ITT Cohort:

Number of subjects with ASEPSIS score >20 within 30 days post abdominal (index) surgery. The ASEPSIS score is a clinical tool used to objectively assess surgical wound infections.

ASEPSIS Score >20

(ITT Cohort)



Next Steps

Pre-NDA meeting with the FDA planned by end of 2025

NDA submission planned for early 2026







Q & A