Lipella Pharmaceuticals

A Clinical Stage Biotechnology Company Addressing Serious Diseases with Significant Unmet Need

NASDAQ:LIPO

lipellapharmaceuticals.com

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Mission

Lipella is committed to providing supportive care to cancer survivors.

Our mission is to develop and commercialize treatments for serious diseases resulting from cancer treatments including radiation and chemotherapy.

Business Growth Strategy

Focused on rare and orphan drug indications and leveraging the 505(b)(2) pathway. Lipella anticipates this strategy will lower cost and allow for a faster approval process

Why rare and orphan drugs?

- Lipella can be first to market by pursuing conditions for which there are no current FDA approved treatments.
- Requires smaller and less costly drug trials with greater flexibility from the FDA.
- Orphan drug market exclusivity limits additional market entrants.
  - 7 years in the US, 10 years in the EU and Japan.

Why leverage the 505(b)(2) pathway?

- Bypasses Phase 1 trials by utilizing drugs and mechanisms of action where safety and efficacy have already been established.
- Can immediately initiate Phase 2 clinical trials.
- Potentially mitigates risk from a CMC, safety and clinical development standpoint.
- Greater flexibility from the FDA.

About

Lipella Pharmaceuticals is a clinical-stage biotechnology company developing new drugs by reformulating active agents in existing generic drugs for serious diseases characterized by significant morbidity and mortality, where no approved drug therapy exists.

Market Data

SYMBOL	NASDAQ: LIPO
Price as of 1-05-2024	$1.09
52 Week Range	$0.85 - $6.10
Average Volume	~437K
Market Capitalization	$6.3M
Current Shares Outstanding	5.8M
Insider Ownership	30%

Lipella Pharmaceuticals

NASDAQ:LIPO

Overview of Opportunity

Drug Development

- Lead product candidate, LP - 10, a 505(b)(2) drug candidate for hemorrhagic cystitis.
- LP- 10 granted FDA Orphan Drug Designation; potential candidate for multiple accelerated pathways.
- Successfully completed Phase 2a clinical trial; FDA Type B meeting anticipated in 4Q 2023.
- Peak annual revenue estimates in hemorrhagic cystitis exceed $1 billion.
- Addressable market of approximately 60,000 potential new patients each year.

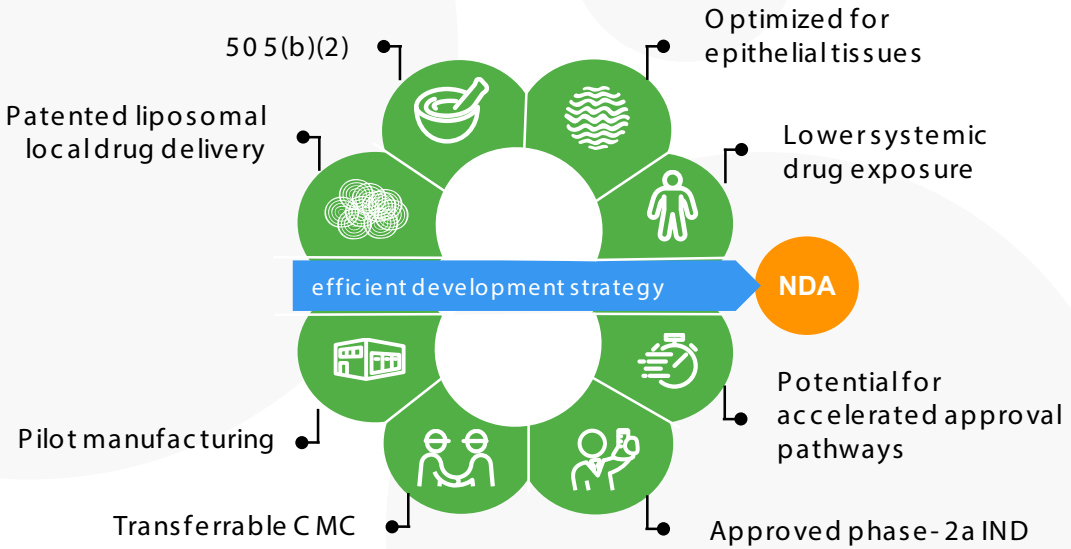
Drug Delivery

- Proprietary drug delivery technology with potential applications in bladder, urethra, oral cavity, esophageal and colonic.
- Designed for use with other lipophilic drugs; potential for technology partnerships, commercial licensing agreements.

Executive Summary

Emerging, clinical - stage, proprietary 505(b)(2) opportunity

Drug - Delivery Focused Biotech



Impressive Revenue Potential

$20,000 annual revenue per patient [7]

$1.2 billion annual revenue potential [8]

Prostate and other pelvic malignancies

Over 3,000,000 survivors in US[4]

Pelvic radiation theraphy

Over 900,000 survivors in US[5]

Radiation - hemorrhagic cystitis

Over 60,000 patients per year [6]

(4) American Cancer Society Cancer Treatment and Survivorship Fact and Figures 2019-2021, (5) based on the Company's 30% estimate (6) 8% estimate, (7) based on the Company's estimate, (8) $20,000 average revenue per each of an estimated 60,000 patients treated per year.

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Cancer Survivorship and Potential Addressable Market

Expected annual revenue per patient is ***$20,000***

Market penetration of 60,000 patients (50%) yields ***$1.2 billion*** *annual revenue in US*

(1) American Cancer Society Cancer Treatment and Survivorship Fact and Figures 2019-2021.
(2) Based on the Company's estimate.

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Asset Pipeline

A growing pipeline with strong patent protection

Product Candidate	Target Indication	Preclinical	Phase 1	Phase 2	Phase 3	Marketing Approval	Next Anticipated Milestone
LP- 10	Hemorrhagic Cystitis						FDA Type-C mtg Completed Nov. 7, 2023
LP- 310	Oral Lichen Planus						Phase-2a IND FDA Clearance Received Oct. 20, 2023
LP- 410	Oral Graft vs. Host Disease						Phase-2a IND FDA Clearance Expected 2Q 2024

- **LP- 10: Liposomal tacrolimus for hemorrhagic cystitis**
  Proprietary liposomal formulation being evaluated as a treatment for hemorrhagic cystitis.
- **LP- 310: Liposomal tacrolimus for oral lichen planus**
  Proprietary liposomal oral rinse formulation of LP- 10 as a potential treatment for oral lichen planus.
- **LP- 410: Liposomal tacrolimus for oral graft vs. host disease**
  Proprietary liposomal oral rinse formulation of LP- 10 as a potential treatment for oral graft vs. host disease.

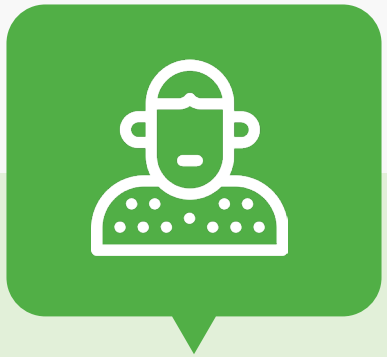
Hemorrhagic Cystitis, Uncontrolled Urinary Blood Loss

Hemorrhagic cystitis is a serious, life - threatening bladder damage from pelvic radiation therapy and/or bladder - toxic chemotherapy.

Millions of patients are diagnosed each year with pelvic malignancies including prostate cancer, and cancers of the uterine corpus, requiring treatment.

20% of these patients receive pelvic radiation therapy during the treatment of their cancer, in addition to surgery and chemotherapy.

An increasing US population is surviving cancer therapies, including pelvic radiation, and chemotherapies that damage DNA.



Years after receiving treatment, many patients acquire hemorrhagic cystitis, uncontrolled bladder blood loss.

Hemorrhagic cystitis is a potentially chronic, highly morbid condition with no approved drug therapy, and a four percent mortality rate.

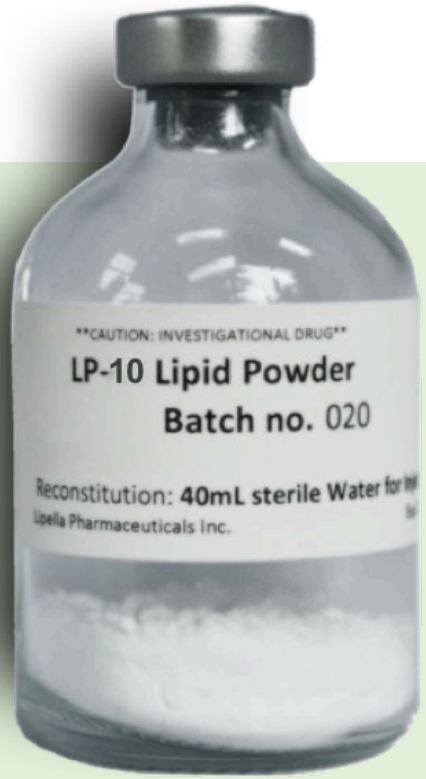
LP- 10 for Hemorrhagic Cystitis

Liposomal tacrolimus treatment for hemorrhagic cystitis

Potent vasoconstrictor; reduces capillary blood flow to the bladder lumen

Potent anti - inflammatory; inhibits cytokine cascade and reduces injury to the bladder tissue

Well known pharmacologic mechanisms increase the probability of efficacy

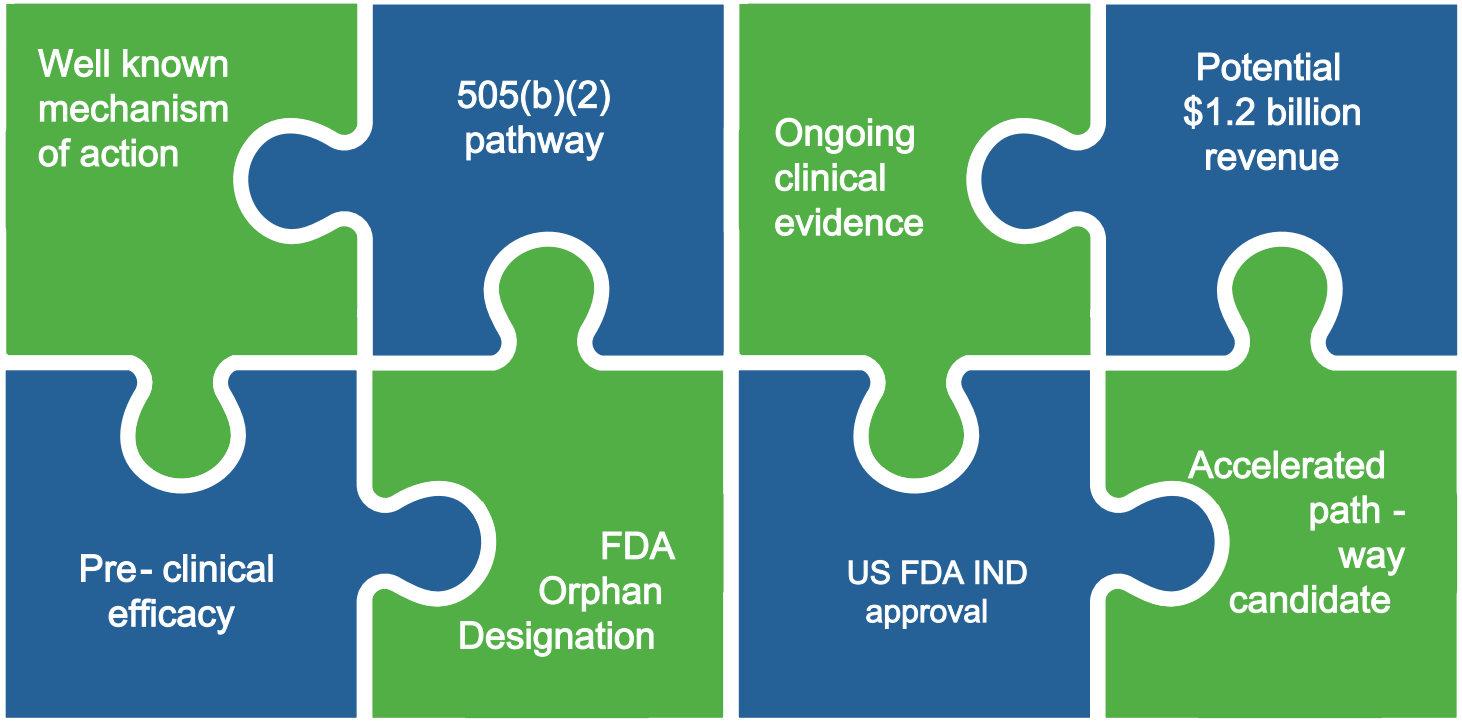


- Sterile powder
- Easy to deliver
- Low COGS
- In- house CMC

LP- 10: an Outstanding Drug Candidate

Multiple reasons increase LP - 10 probability of success

- Well Known mechanism of action
- Pre-clinical efficacy
- 505(b)(2) pathway
- Potential $1.2 billion revenue
- US FDA IND approval
- Accelerated path-way candidate
- Patent protection secured for LP-10 through 2034



LP- 10: Phase 2a Trial

A Phase 2a clinical trial (NCT01393223):

- Multi - center, dose - escalation study
- 13 subjects with moderate to severe refractory hemorrhagic cystitis
- Subjects treated with up to two courses of LP - 10 intravesical bladder instillations.

Top line results

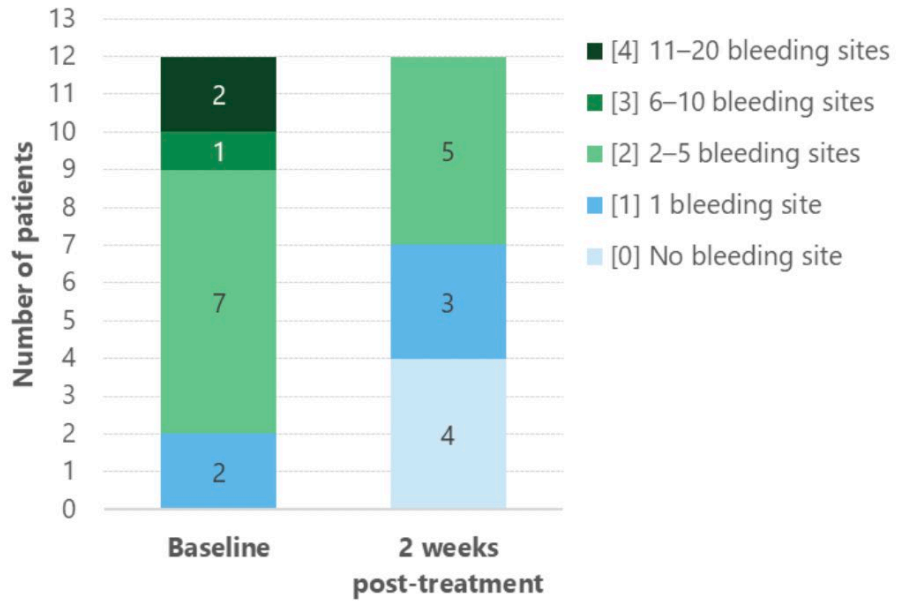
- All subjects tolerated LP - 10 instillations with no serious adverse events (SAE) reported
- LP- 10 demonstrated short duration of systemic uptake
- Decreased cystoscopic bleeding hematuria and improved urinary incontinence
- 58% of patients achieved complete or near complete resolution of bleeding per cystoscopy

Next Steps

- Type - C meeting with the FDA completed Nov. 7, 2023
- FDA approval of phase - 2b clinical trial design anticipated 2Q2024
- Begin recruitment of oral lichen planus phase 2a clinical trial
- Obtain IND approval for oral graft vs. host indication anticipated 2Q2024.

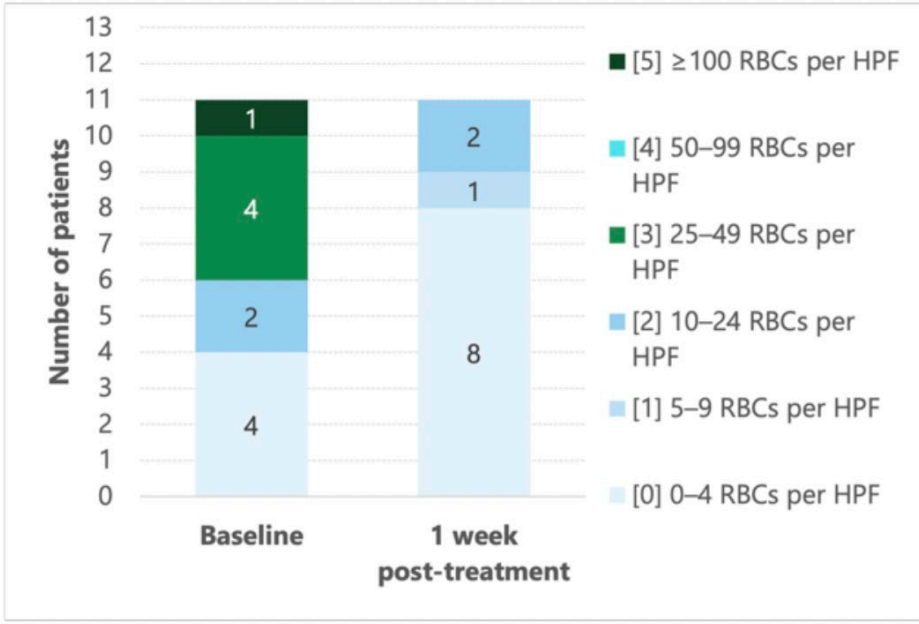
Bleeding: Cystoscopy & Microscopy

A Number of bleeding sites on cystoscopy at baseline and 2 weeks post-treatment (n=12)*



*One patient was unable to undergo post-treatment cystoscopy.

B Red blood cell count per HPF on urine microscopy at baseline and 1 week post-treatment (n=11)*



*For 2 patients, urine for microscopic analysis was not collected.

LP- 10 Phase 2b Trial Design

Key criteria:

- Randomized, double-blind, placebo controlled, multi-center clinical trial of 36 Male and Female hemorrhagic cystitis patients, randomized 1:1:1
- Subjects will be randomized into one of three groups: 2mg LP-10 , 4 mg LP-10 or Placebo

Primary Efficacy Endpoint:

- Change in number of hematuria episodes from baseline to Week 4 on a 7-day voiding diary.

Secondary Efficacy Endpoints:

- Change in number of urinary incontinence episodes from baseline to Week 4 on a 7-day voiding diary.
- Cystoscopic number of bleeding sites
- Urine analysis with microscopy including RBC/hpf at baseline and Week 4

LP- 310 for Oral Lichen Planus

Oral Lichen Planus (OLP) is a chronic inflammatory, T- cell - mediated autoimmune oral mucosal disease

- Painful and comes with the risk of complications including infections, scarring, stress and depression.
- Has malignant potential.
- Most currently available therapies are palliative rather than curative.

LP- 310

Oral Lichen Planus Mouth Rinse

LP- 310

- Oral rinse formulation of LP- 10
- Increased local concentration in oral cavity while minimalizing systemic toxicity
- 505(b)(2) pathway, platform technology expansion
- Low COGS and fast development plan
- Large market size opportunity (6 million US) with no current approved therapy
- Phase 2a IND approval received Q4, 2023
- Initiation of phase 2a clinical trial expected 2Q 2024.

Manufacturing Capabilities

- Lipella maintains a sterile manufacturing facility in Pittsburgh, PA for the production of clinical supplies and research products.
- LP-10 has been produced at high quantities in this facility for Lipella's clinical trials.
- The facility is also used for development of liposomal formulations intended for intravesical delivery.
- Lipella is currently collaborating with Cook Myocyte (a subsidiary of Cook Medical) regarding commercial grade manufacturing.

Experienced Management Team

Lipella is led by an experienced team with complementary skillset and years of experience working together.

Jonathan Kaufman, PhD

Chief Executive Officer

- 23+ Years Experience
- Co-founded Lipella in 2005
- Co-founder of Knopp Biosciences. CFO of Semprus Biosciences. CSO LaunchCyte LLC.
- PhD Penn. MBA Wharton.

Michael Chancellor, MD

Chief Medical Officer

- 30+ Years Experience
- Lipella co-founder. Joined Lipella in 2008
- Co-founder of Cook-Myosite; Professor of Urology, William Beaumont Medical Center.
- MD University of Michigan.

Michele Gruber

Director of Operations

- 12+ Years Experience
- Joined Lipella in 2009
- CMC development, facilities, R&D management.
- BS Carnegie Mellon

Janet Okonski

Director Clinical Operations

- 20+ Years Experience
- Joined Lipella in 2021
- Clinical trial management, safety monitoring
- BS Indiana University of Pennsylvania

Key Takeaways

Drug Development

- Lead product candidate, LP-10, a 505(b)(2) drug candidate for hemorrhagic cystitis.
- LP-10 granted FDA Orphan Drug Designation; potential candidate for multiple accelerated pathways.
- Successfully completed Phase 2a clinical trial; End of Phase 2 meeting with the FDA anticipated.
- Peak annual revenue estimates in hemorrhagic cystitis exceed $1 billion.
- Approximately 60,000 new US patients each year.
- Patent protection secured for LP-10 through 2034.
- Manufacturing capabilities at in-house facility.

Drug Delivery

- Proprietary drug delivery technology with potential applications in bladder, urethra, oral cavity, esophageal and colonic.
- Designed for use with other lipophilic drugs; potential for technology partnerships, commercial licensing agreements.

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LP- 10 Phase 2a Trial Patient Demographics

	Mean	Comment
Age, years	67	Range 25-89
Race		
• White	9	
• Non-White	4	
Radiation induced HC	11	
Chemotherapy induced HC	2	
Cancer		
• Prostate cancer	9	
• Bladder cancer	2	
• Lymphoma	2	
Duration of HC years	4	Range 1-14 years
Prior HC treatment	13	medication, HBO, catheters, surgical procedures

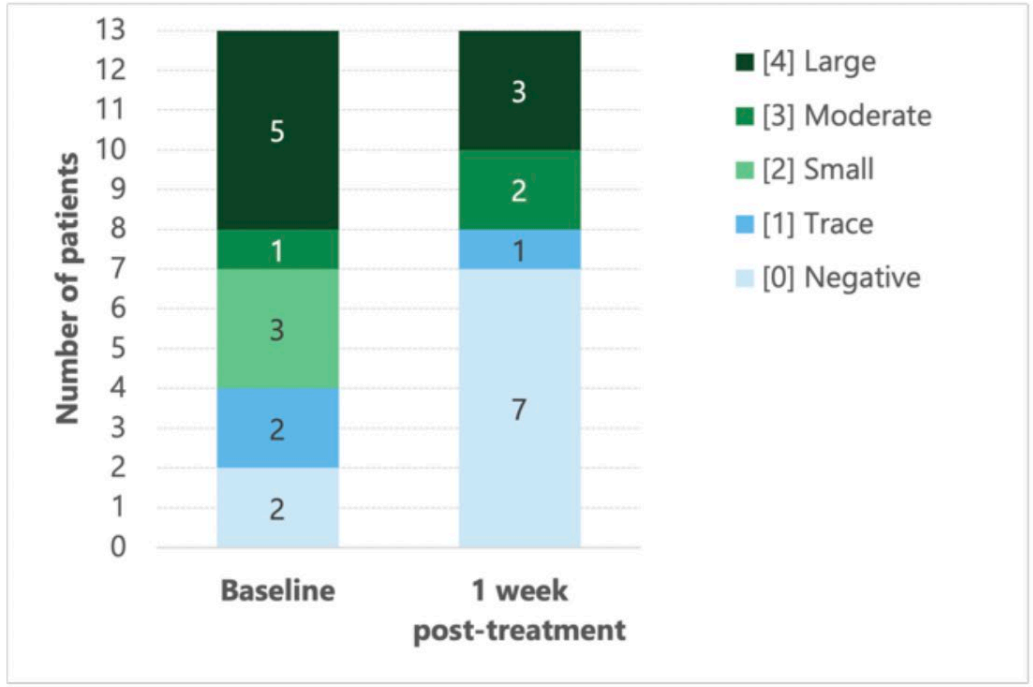
LP- 10 Safety

Adverse events (AE)

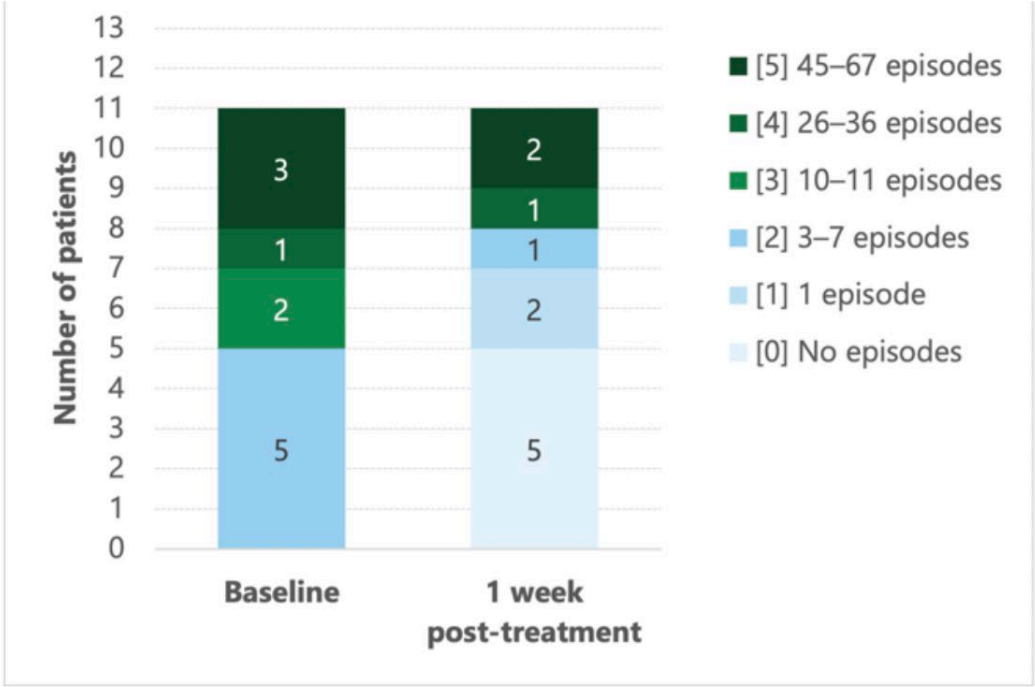
	Number	Comment
Product related significant adverse events	0	
Subject discontinuations	0	
Number of subjects with adverse events	6/13	12 AEs reported in 6 subjects 2 mg: 4 AEsin 3 subjects 4 mg: 2 AEs in 1 subject 8 mg: 6 AEs in 2 subjects
Bladder spasm, urinary urgency, pain and dysuria	4	
Artificial urinary sphincter malfunction	1	
Weakness and dizziness	1	
Low blood pressure	1	
Flank pain	1	
Urinary retention due to bladder blood clot	1	
Headache	1	
Arthralgia	1	
Urinary tract infection	1	

Hematuria & Incontinence

C Hematuria on urine dipstick at baseline and 1 week post-treatment (n=13)



D Number of incontinence episodes at baseline and 1 week post-treatment (n=11)*



*For 2 patients, incontinence was not reported at baseline

Dose Response: Bleeding by Cystoscopy

Change in the number of bleeding sites between baseline and 2 weeks

	Tacrolimus 2 mg (n=3)[a]	Tacrolimus 4 mg (n=4)	Tacrolimus 8 mg (n=5)
Much worse	–	–	–
Worse	–	–	1 (20%)
No change	1 (33%)	1 (25%)	–
Better	2 (67%)	1 (25%)	1 (20%)
Much better	–	2 (50%)	3 (60%)
p value for comparison with 2 mg tacrolimus[c]		0.26	0.20
p value for comparison with 4 mg tacrolimus[c]			0.50

Dose Response: Urinary Urge Incontinence

Change in the severity of incontinence between baseline and 1 weeks post-treatment

	Tacrolimus 2 mg (n=3)	Tacrolimus 4 mg (n=4)	Tacrolimus 8 mg (n=5)
Worse	1 (33%)	–	–
No change	1 (33%)	1 (25%)	–
Better	1 (33%)	3 (75%)	4 (100%)
p value for comparison with 2 mg tacrolimus[c]		0.20	0.11
p value for comparison with 4 mg tacrolimus[c]			0.34