Lipella Pharmaceuticals

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

2025 BIO CEO & Investor Conference
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DIFFERENTIATED TECHNOLOGY PLATFORM:

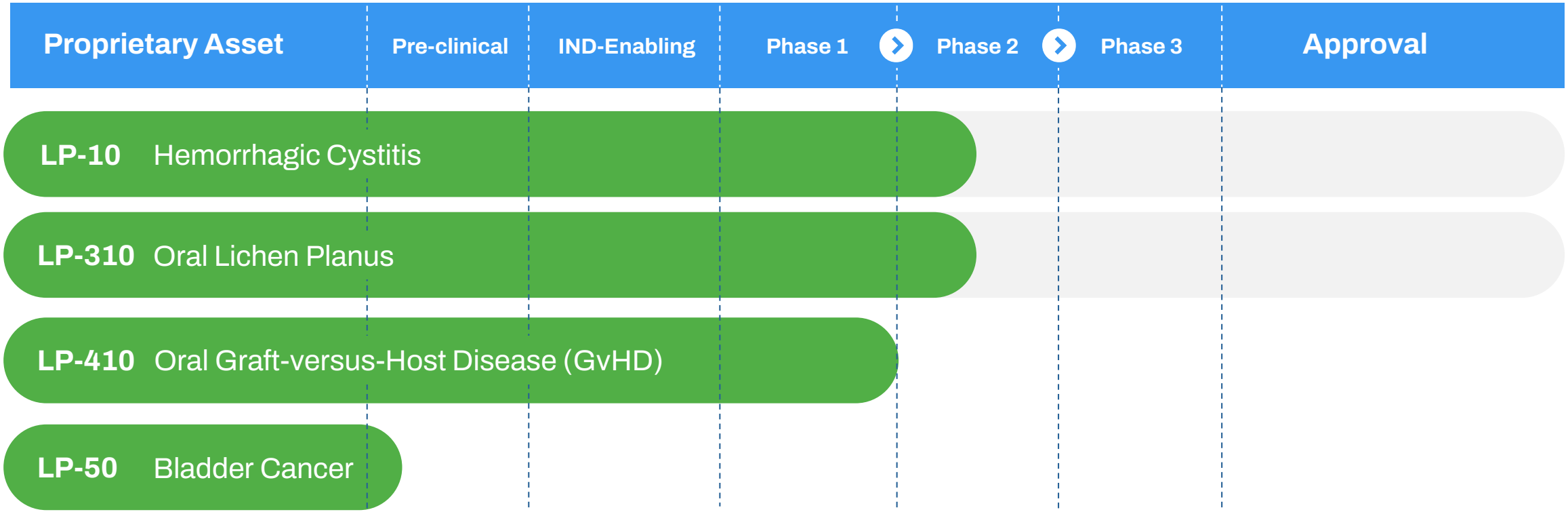
Liposomal Formulation of Tacrolimus

Maximizing Therapeutic Responses with Directed Localized Administration

Optimized Efficacy	By encapsulating tacrolimus in liposomes, our technology ensures a more stable and controlled release, maximizing therapeutic benefits while minimizing systemic exposure.
Reduced Adverse Effects	The liposomal delivery method offers localized treatment, reducing the risk of severe side effects typically associated with systemic administration.
Potential for Broader Applications	Liposomal encapsulation of tacrolimus enables targeted treatment for a broad range of mucosal tissue diseases, including the bladder, urethra, oral cavity, esophagus, and colon.
In House CMC Advantage	Ensures consistent quality from clinical studies to the marketed drug, maintaining high standards throughout development and commercialization

Strong potential for our technology in partnerships and commercial licensing agreements

COMPANY PIPELINE



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DE-RISKED LEAD PROGRAMS WITH ROBUST REVENUE OPPORTUNITY

505(b)(2) drug candidates

Positioned For Market Exclusivity

LP-10

- Liposomal tacrolimus for the treatment of Hemorrhagic cystitis. LP-10 has a well-established mechanism of action and has demonstrated safety and efficacy in Phase 2a studies**. LP-10 is the only therapeutic for HC in development.**

- *Hemorrhagic cystitis affects* ***~60,000 annually***
- *Expected annual revenue per patient:* ***$20,000 per drug intravesical instillation***
- *Market penetration of* ***60,000 patients (45%) yields $1.2B annual revenue***

LP-310

- Oral rinse formulation of LP-10 for the treatment for Oral Lichen Planus (OLP). High safety profile with no systemic toxicity observed. **There are no current topical OLP treatments in development.**

- *Target market of* ***6 million Americans***
- *The global OLP market was valued at* ***USD 980 million in 2028*** *and is projected to grow to* ***USD 2.7 billion by 2034***

Lipella Lead Pipeline Product:

LP-310 for Oral Lichen Planus

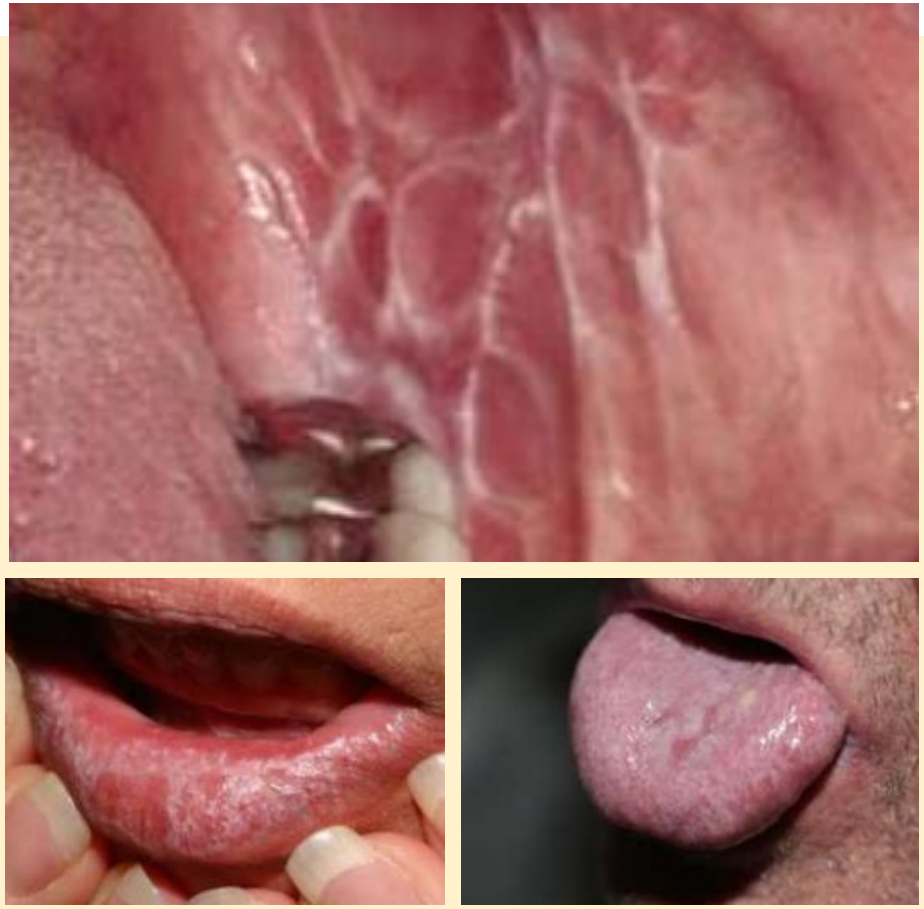
Phase 2a multicenter dose escalation study completion anticipated in 2Q25

- Similar formulation of LP-10 for oral rinse
- Increased local concentration in oral cavity while minimalizing systemic toxicity
- 505b2 pathway expand Lipella's platform expertise
- Low COGS and fast development plan
- Large market size opportunity identified by pharmaceutical industry with no current effective therapy

WHAT IS ORAL LICHEN PLANUS (OLP)?

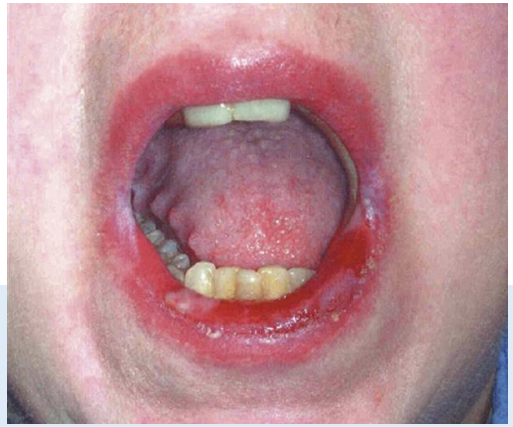
- **Chronic Disease**: OLP is a **T-cell-mediated autoimmune disorder** affecting the oral mucosa.
- **Long-Term Condition**: Unlike cutaneous lichen planus, OLP follows a **chronic course**, with most available therapies being **palliative rather than curative**.
- **Prevalence**: Affects **1-2%** of the population.
- **Who It Affects**: Women are affected more often than men (**2:1 female-to-male ratio**), with onset typically occurring between **ages 30-60**.
- **Malignant Potential:** Malignant transformation (squamous cell carcinoma) between 0.4-5% (annual rate between 0.2-0.5%)

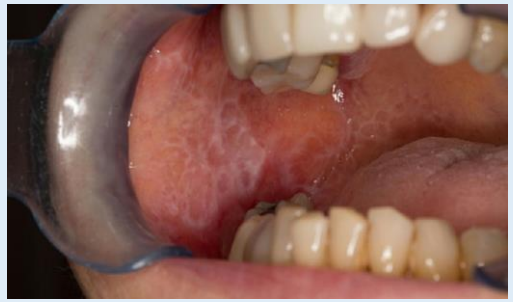
OLP Affects 6 Million Americans. There is no current FDA approved pharmacotherapy for oral lichen planus



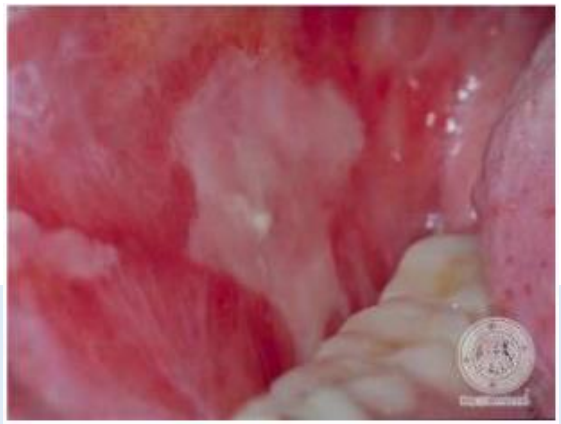
OLP SYMPTOMS, COMPLICATIONS AND IMPACT

- **Appearance**: Lacy, white, raised patches; red, swollen, tender areas; open sores.
- **Location**: Found inside cheeks, gums, tongue, lips, and palate.
- **Symptoms**: Burning pain, sensitivity to spicy foods, gingivitis, discomfort when chewing or swallowing.
- **Complications**: Pain, weight loss, stress, depression, scarring, secondary fungal infections.
- **Malignant Potential**: Risk of squamous cell carcinoma (0.4-5% transformation rate).





Oral erosions on the tongue, lips, and buccal mucosa.



Erosive type lichen planus- ulcerated lesion in the buccal mucosa with erythematous borders

CURRENT TREATMENT OPTIONS FOR ORAL LICHEN PLANUS (OLP)

Category	Examples	Key Advantage	Key Limitation
Topical Steroids	Clobetasol, Betamethasone	Reduces inflammation	Risk of mucosal thinning
Systemic Steroids	Prednisone	Controls severe cases	Significant side effects
Immunomodulators	Tacrolimus	Effective in resistant cases	Local irritation possible
Systemic Immunosuppressants	Cyclosporine, Azathioprine	Useful for refractory cases	Systemic side effects
Adjunctive Therapies	Tetracycline, Analgesics	Symptom relief	Does not treat root cause
Natural Therapies	Aloe vera, Curcumin	Few side effects	Limited clinical evidence
Phototherapy	Laser therapy	Non-invasive	Specialized equipment needed

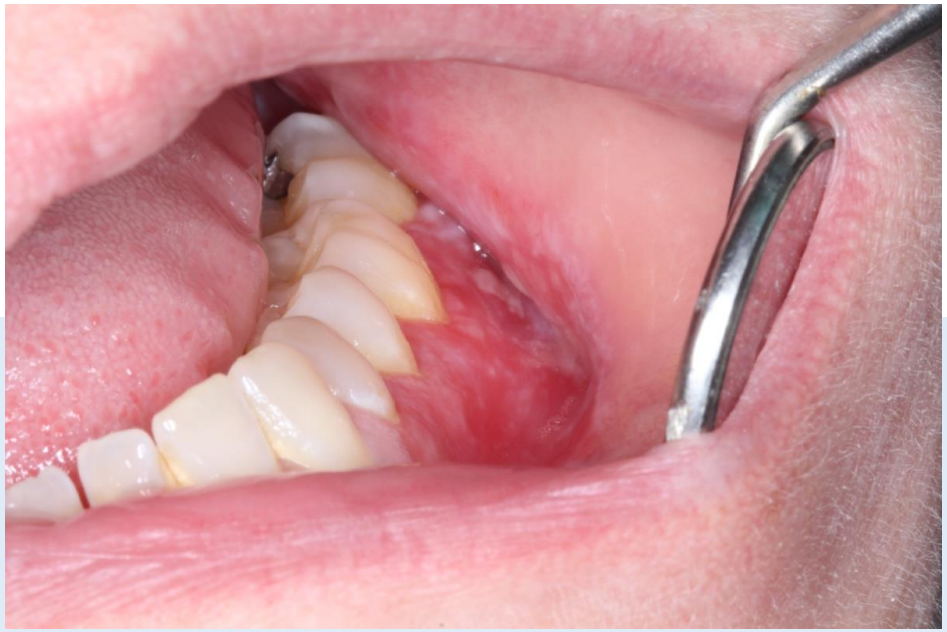
RISKS OF TOPICAL STEROID USE FOR ORAL LICHEN PLANUS (OLP)

Risk/Problem	Description	Clinical Consequence
Fungal Infection	Immunosuppression in the oral cavity	Oral thrush, requires antifungal treatment
Masking Infections	Steroids mask signs of bacterial/viral infections	Delayed diagnosis and treatment
Mucosal Atrophy	Thinning of the oral mucosa with prolonged use	Increased susceptibility to trauma
Burning/Irritation	Local discomfort from potent steroids	Reduced patient compliance
Systemic Absorption	Steroids enter bloodstream	Potential systemic side effects
Steroid Resistance	Reduced efficacy over time	Need for alternative therapies
Rebound Inflammation	Symptoms worsen after stopping steroids	Prolonged therapy, challenges in tapering

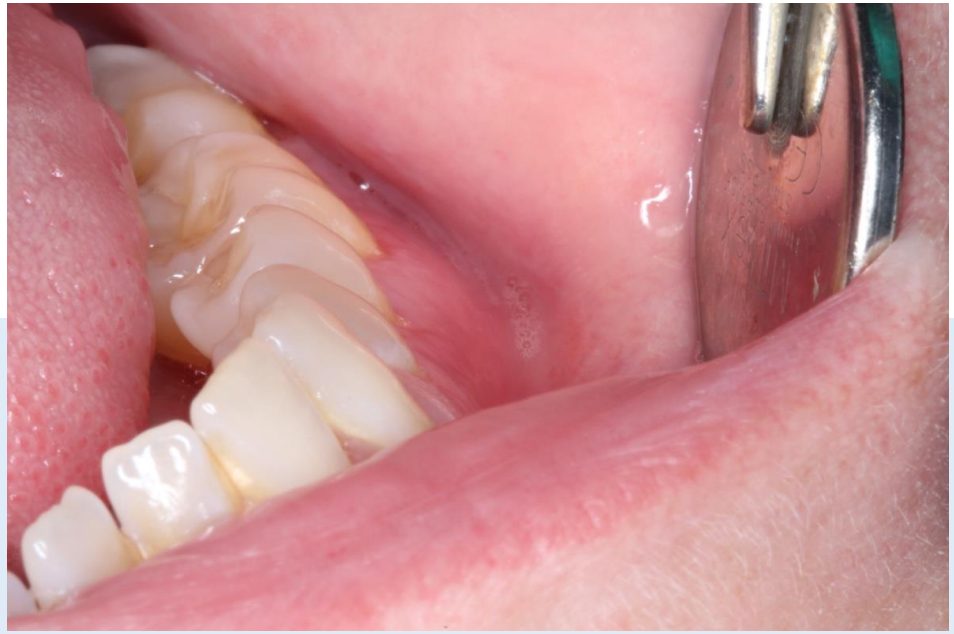
Positive Phase 2a Results for LP-310 in Oral Lichen Planus

LP-310: VISIBLE TREATMENT IMPACT

Day 1 First Oral Rinse- Left mandibular gingiva



Week 4 Last Oral Rinse- Left mandibular gingiva



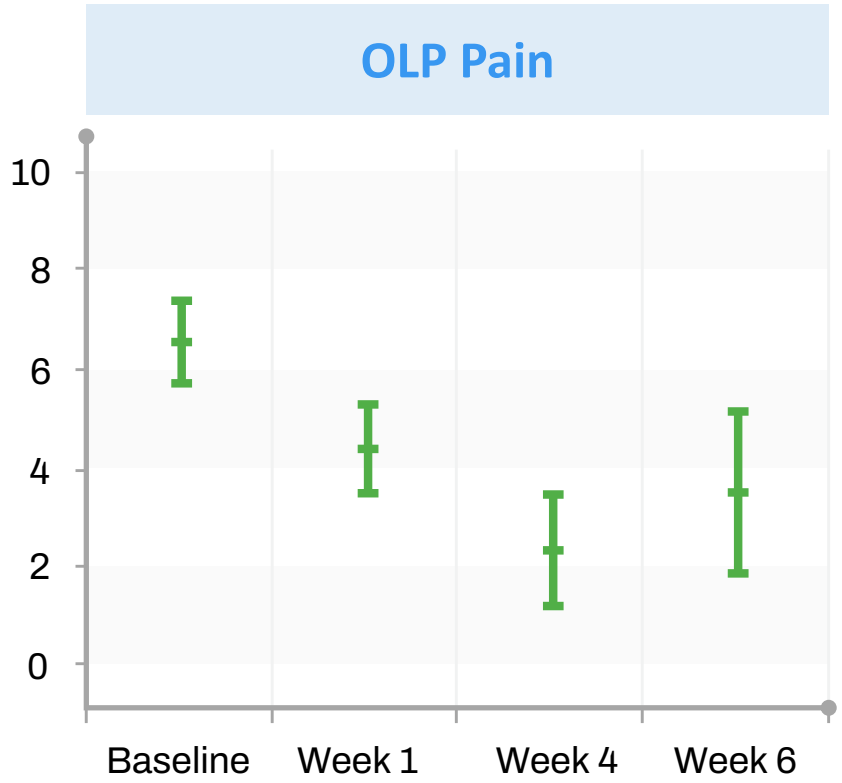
The decrease in inflammation, redness and healing of the white ulcers is remarkable and patients reported significant improvement.

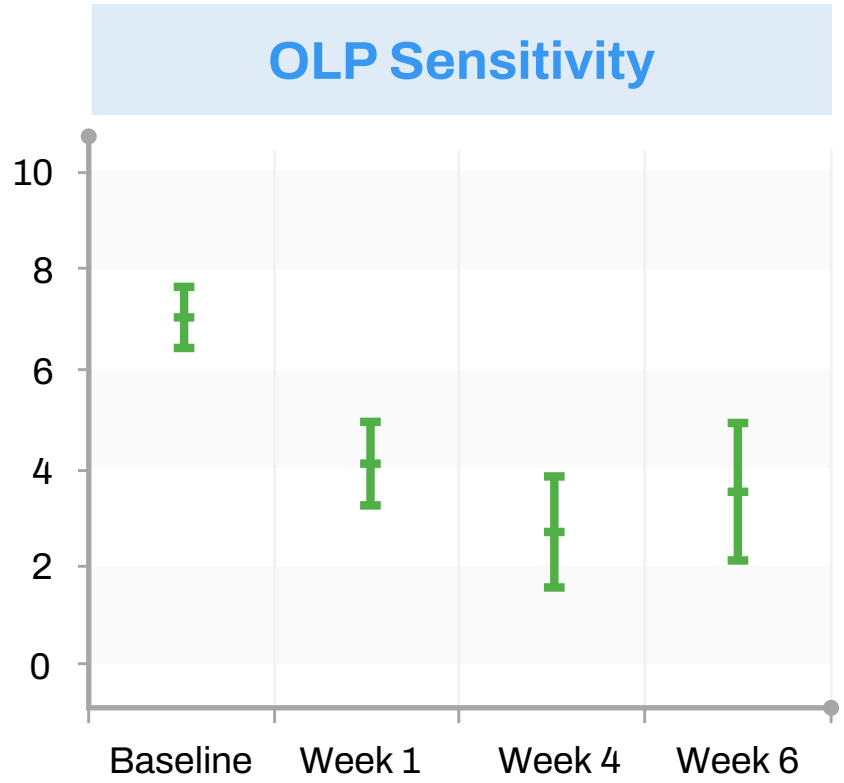
STUDY OVERVIEW

- Multicenter dose-ranging study in adult male and female subjects aged ≥18 years with symptomatic OLP designed to evaluate the safety, tolerability, and preliminary efficacy of LP-10 at dose levels of 0.25 mg, 0.5 mg, and 1.0 mg of tacrolimus.
- Approximately 24 subjects will be enrolled at 7 study sites in the U.S. Enrollment is expected to be completed within 1 year of initiating the study
- LP-10 will be reconstituted for at home oral rinse. Each bottle will contain a 1-week supply.
- The study consists of a Screening Phase, a Treatment Phase, and a Follow-up Phase. Throughout the Treatment Phase, patients will perform a 3-minute oral rinse using 10 mL of LP-10 twice daily for a duration of 4 weeks. The Follow-up Phase consists of one visit 2 weeks after the last dose of LP-10
- Pharmacokinetic (PK) and pharmacodynamic (PD) data regarding LP-10 will be obtained

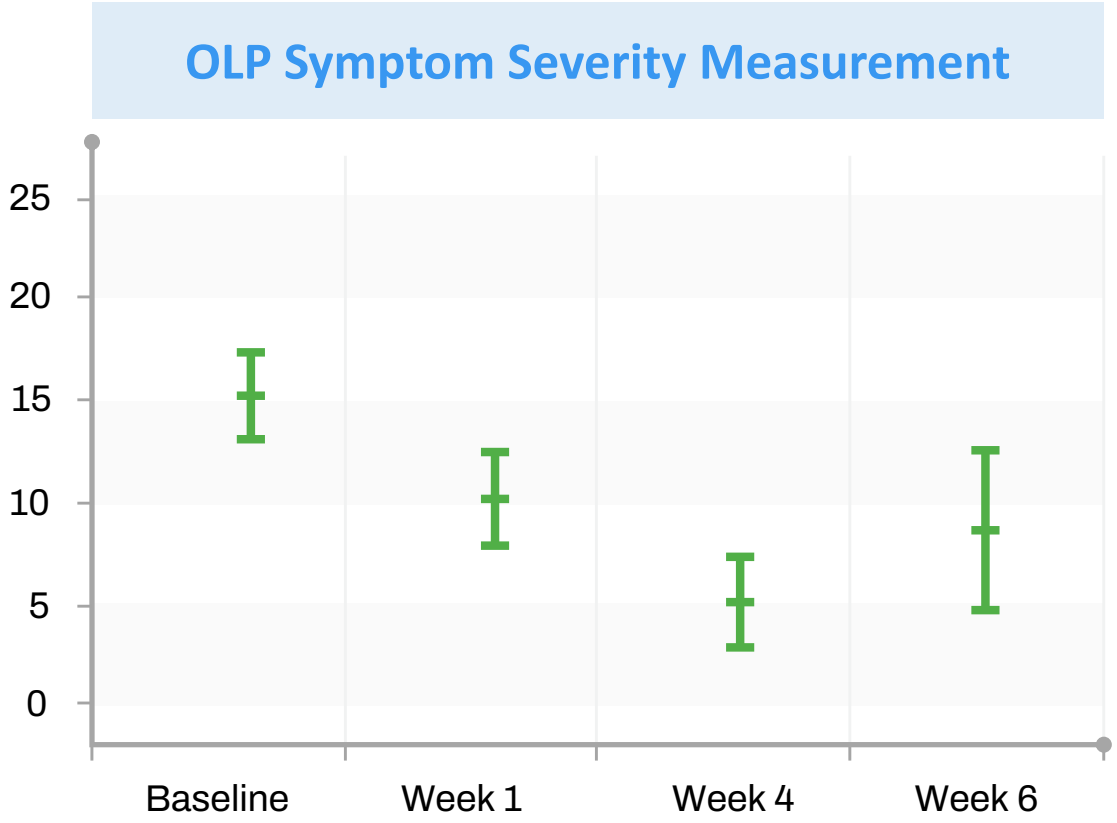
OLP PAIN, SENSITIVITY AND GRA

- **Pain NRS:** Improved from 6.63+0.80 (baseline) to 4.38+0.96 at week 1 (p=0.004), 2.38+1.15 at week 4 (p=0.004), and 3.60+1.63 at week 6 (p=0.031).
- **GRA:** Significant improvement was observed at week 4 (p=0.031).





OLP SYMPTOM SEVERITY MEASUREMENT (OLPSSM)



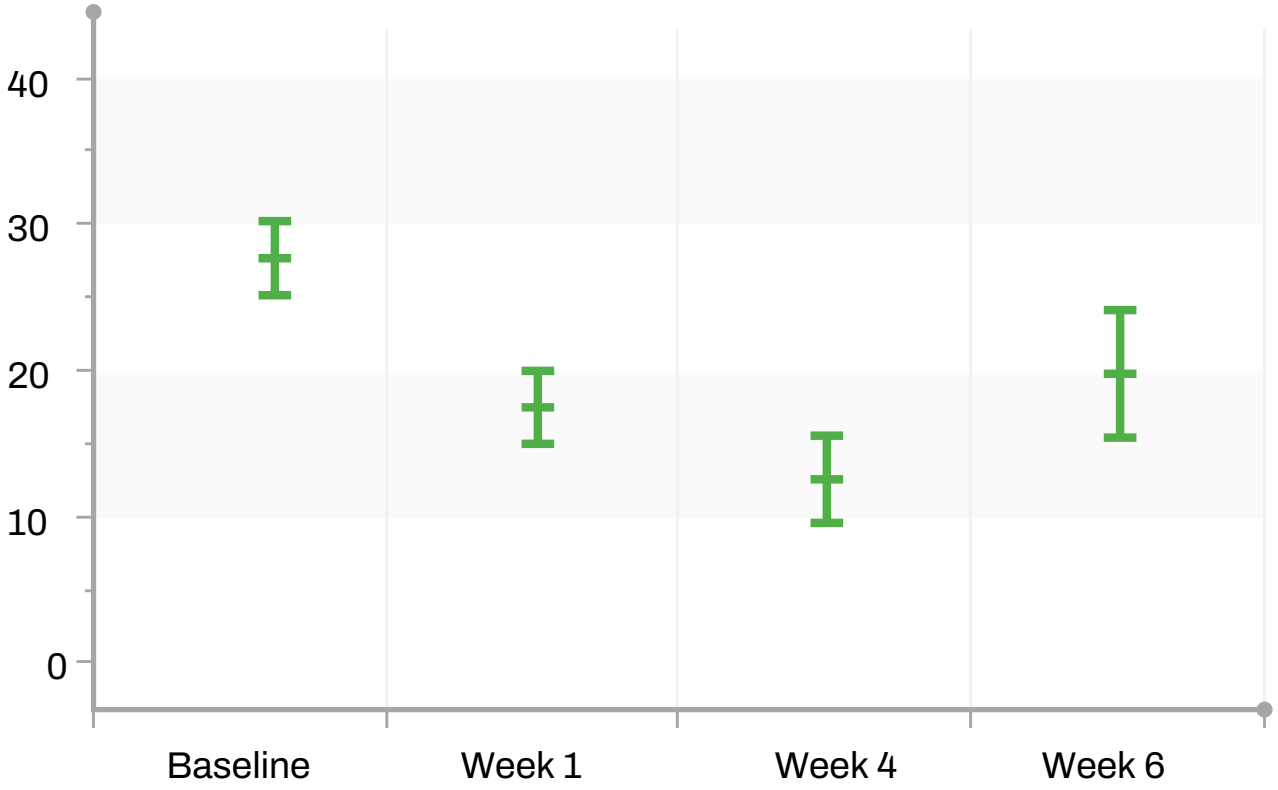
- OLPSSM (0-7): Reduced from 15.38+2.20 (baseline) to 10.13+2.34 at week 1 (p=0.035), 5.00+2.28 at week 4 (p=0.004), and 8.60+4.06 at week 6 (p=0.031).
- Similar improvement seen in OLPSSM 8, 9 and 10

outcome	w1-b	w4-b	w6-b
OLPSSM 8	0.031	0.004	0.031

outcome	w1-b	w4-b	w6-b
OLPSSM 9	0.008	0.035	0.063

Outcome	w1-b	w4-b	w6-b
OLPSSM 10	0.008	0.004	0.031

OLP Reu Scoring System



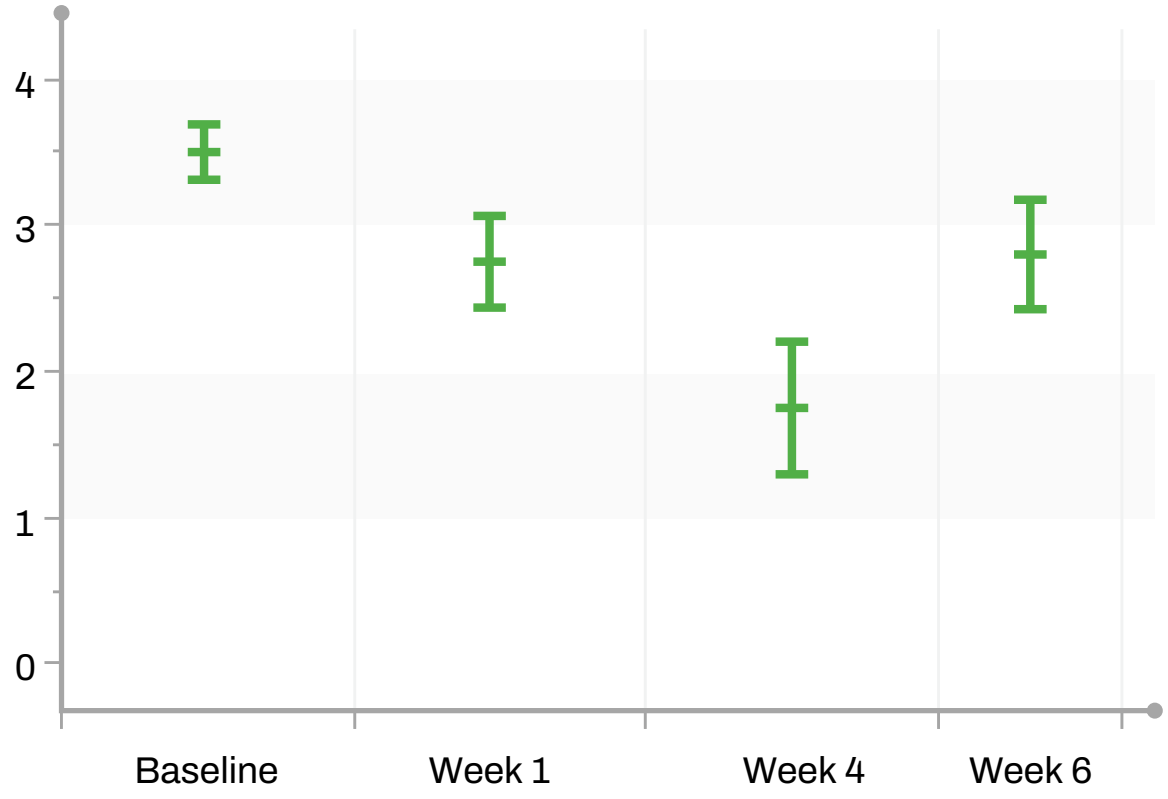
OLP REU SCORING SYSTEM

- REU: Improved from 27.75+2.71 (baseline) to 17.56+2.51 at week 1 (p=0.004), 12.69+3.06 at week 4 (p=0.004), and 19.60+4.31 at week 6 (p=0.031).

OLP INVESTIGATOR GLOBAL ASSESSMENT (IGA)

- IGA: Decreased from 3.50+0.19 (baseline) to 2.75+0.31 at week 1 (p=0.031), 1.75+0.45 at week 4 (p=0.008), and 2.80+0.37 at week 6 (p=0.125).

OLP Investigator Global Assessment



LP-310 PHASE 2A TOPLINE RESULTS SUMMARY

LP-310 data shows safety

- No Product related SAEs
- Twice a day, 3 minute, 10ml rinse well tolerated by all subjects with no dropout

LP-310 pharmacokinetic analysis demonstrated nondetectable or minimal duration of systemic uptake

Statistically significant improvement of efficacy

- Investigator measurement of oral ulceration score
- Patient reported symptom outcome
- Patient reported pain scale
- Patient report global response assessment

Next Step

- Successful completion of Phase 2a multicenter clinical trial in 2Q25
- Submit final report to FDA and Phase 2b clinical trial IND 2H2025
- Submit Breakthrough Designation request 2H25

LP-310 FOR ORAL LICHEN PLANUS BLUEPRINT FOR SUCCESS

A Parallel to Restasis: Developed by Allergan for dry eye disease, addressing an unmet need with no FDA-approved therapies.

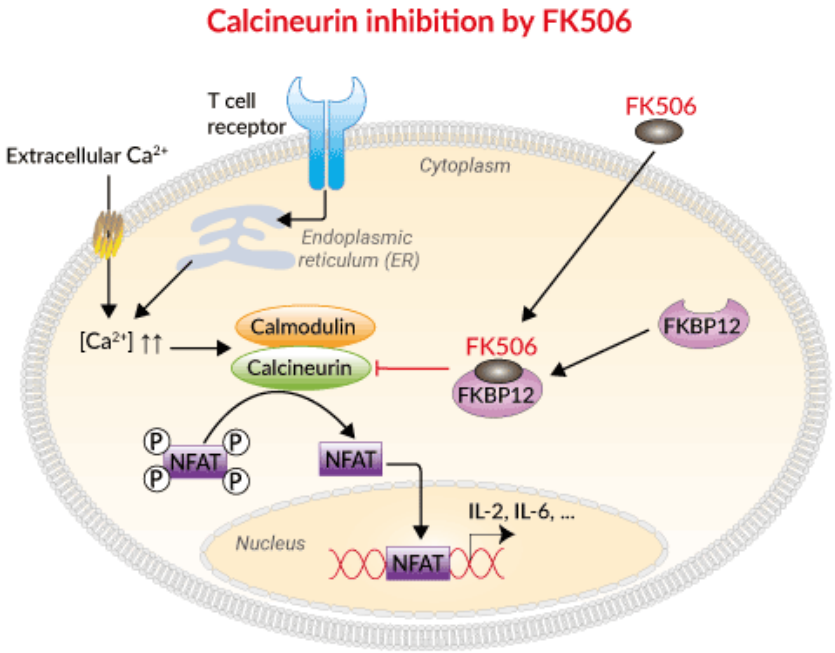
- **Market Impact**: Despite early skepticism, its targeted, non-steroidal approach drove annual sales **beyond $1B**, becoming Allergan's second-largest asset after Botox.
- **Pricing Power**: Restasis costs **$771.30/month**, demonstrating strong market support for premium therapies in underserved conditions.
- **Unmet Need**: Oral Lichen Planus affects ~6 million Americans with no FDA-approved treatments.
- **Steroid Limitations**: Prolonged steroid use in the mouth, like the eyes, is not viable for long-term care.
- **Innovative Therapy**: LP-310 offers a targeted, localized treatment minimizing systemic exposure while delivering efficacy.
- **Market Opportunity:** Like Restasis, LP-310 has the potential to provide an effective alternative to steroids and unlock significant market value in a large patient population.

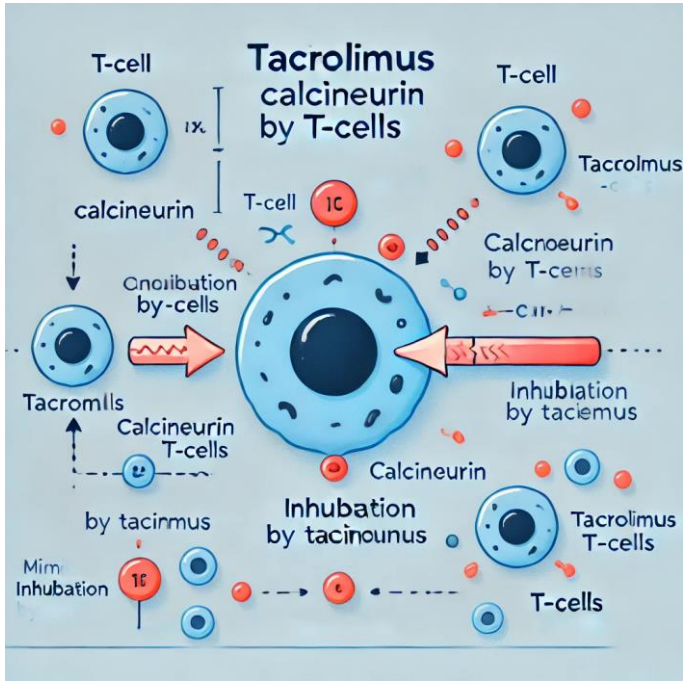
ORAL LICHEN PLANUS MARKET SNAPSHOT

Target market: 6 to 7 million Americans
Population of Severe Cases: 1.5 million
Projected Annual Revenue per customer: $8,000

LP-310 MECHANISM OF ACTION

- Tacrolimus inhibits calcineurin, blocking T-cell activation and reducing inflammatory cytokines that are central to OLP pathology.
- **Advantages over steroid:** Reduced risk of mucosal atrophy, suitability for patients unresponsive to steroids and lower systemic absorption





Meta-Analysis Supports Tacrolimus in Oral Lichen Planus Treatment: A Pathway for LP-310's Success

Clinical Meta-Analysis Highlights Tacrolimus' Role in Oral Lichen Planus: LP-310's Pathway to Innovation

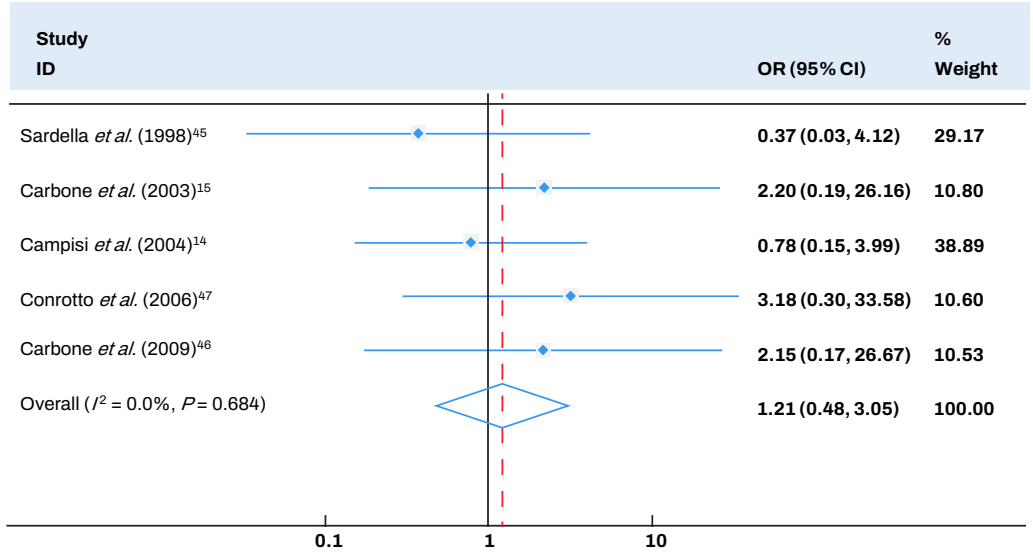


Figure 2 Overall odds ratios (ORs) of recovery in patients with oral lichen planus treated with clobetasol in a fixed model (numerical scale). 95% confidence interval (CI)

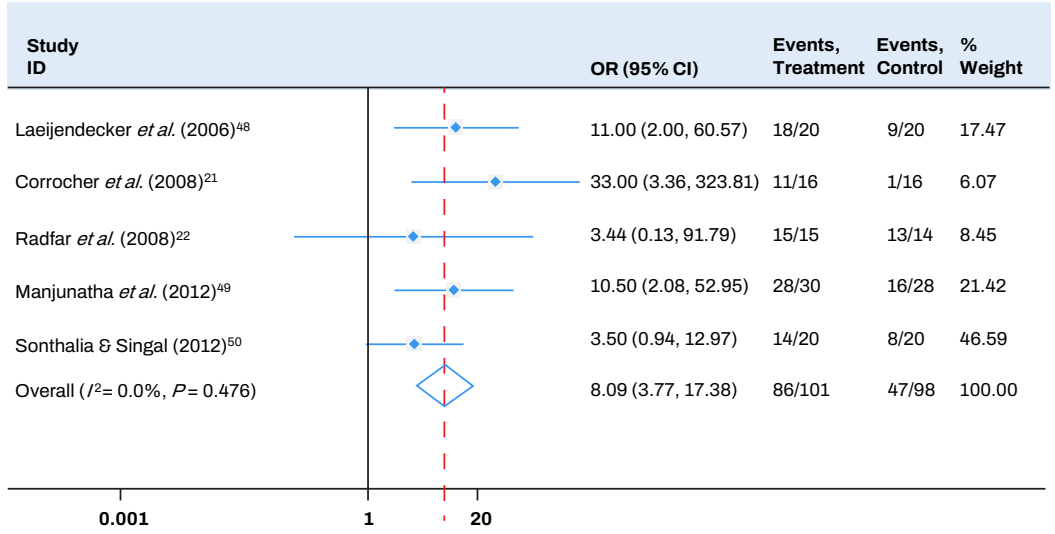


Figure 3 Overall odds ratios (ORs) of recovery in patients with oral lichen planus treated with tacrolimus in a fixed model (numerical scale). 95% CI

- Systematic review and meta-analysis: 10 randomized clinical trials, 5 evaluating clobetasol and 5 tacrolimus. 3 of the 5 clobetasol studies reported positive clinical outcomes while all 5 of tacrolimus studies did (Chamani et al., 2015).
- Overall odds ratios (ORs) of recovery in patients with OLP treated with clobetasol = 1.21 (95% CI; 0.48 – 3.05). Overall ORs of recovery in patients with oral lichen planus treated with tacrolimus = 8.09 (95% CI; 3.77 – 17.38). 6 of the 10 studies reported no serious adverse events.

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Clinical Pipeline to Treat Rare and Serious Diseases with Unmet Medical Need

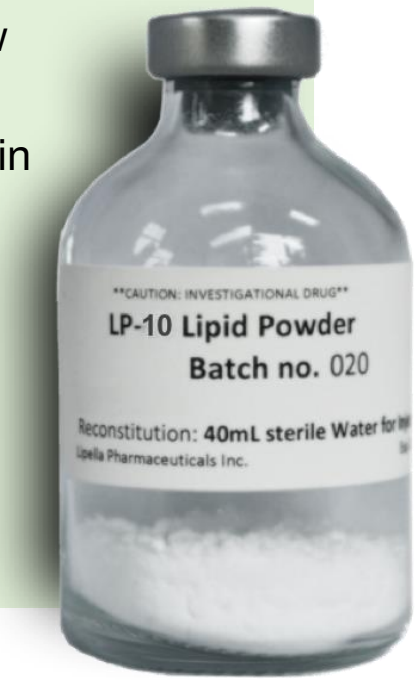
LP-10 FOR HEMORRHAGIC CYSTITIS (HC)

Liposomal tacrolimus treatment for hemorrhagic cystitis

Urgent Need For Effective HC Treatment Options

- HC is challenging to treat due to poor blood flow in affected tissue
- Existing therapies, including steroids and vitamin E, are largely ineffective.
- Adjusting radiation fields and limiting bladder dose offers limited success.
- Current approach can compromise radiation treatment effectiveness.

Patent protection secured for LP-10 through 2034



- **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-410 FOR ORAL GRAFT-VERSUS-HOST DISEASE

Oral Graft-Versus-Host Disease (GVHD) is a clinical syndrome where donor-derived immunocompetent T cells react against patient tissues directly or through exaggerated inflammatory responses following HCT.

- GVHD is a major cause of morbidity and mortality with chronic GVHD being the leading cause of nonmalignant fatality post Hematopoietic Cell transplantation (HCT).
- Oral GVHD is one of the most debilitation manifestation of GVHD and has a prevalence of approximately 30,000 in the US.
- Malignant transformation may occur with oral chronic GVHD

LP-410

Oral Graft-Versus-Host Disease Mouth Rinse

LP-410

- Alternative oral rinse formulation of LP-10 for the indication of oral GVHD
- 505(b)(2) pathway, platform technology expansion
- Lipella received FDA Orphan Disease Designation on LP-410 for the treatment of GVHD.
- Received IND approval in Q1, 2024 for Phase 2a clinical trial, expects to initiate human clinical trials in 2H 2025.

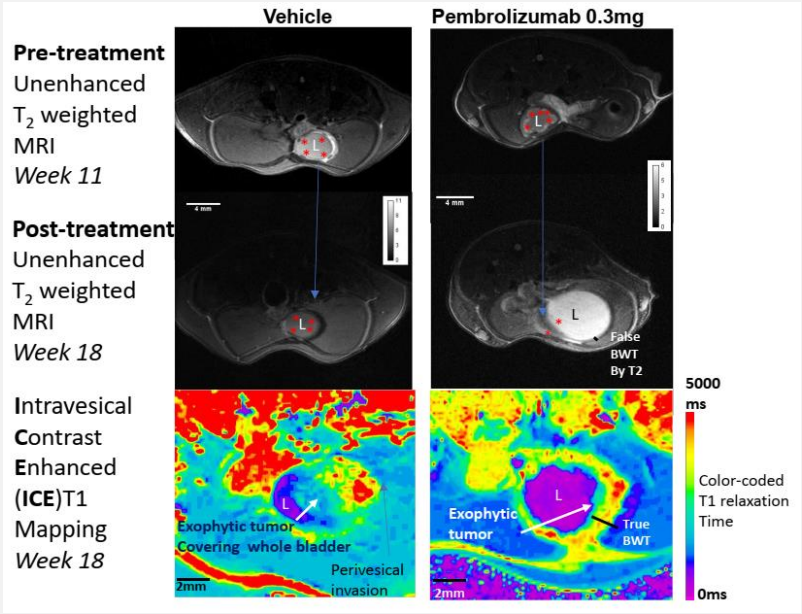
LP-50 FOR BLADDER CANCER

Novel liposomal formulation of checkpoint inhibitors

- Intravesical formulation for local, intravesical PD-1 (i.e. checkpoint) inhibition, intended for the treatment of non-muscle invasive bladder cancer (NMIBC).
- Intravesical immunotherapy presents a promising avenue for bladder cancer treatment, offering the potential for increasing efficacy while minimizing systemic toxicity.

LP-50

- LP-50 is an intravesical liposomal formulation of checkpoint Inhibitor for the treatment of bladder cancer.
- Preclinical study has been accepted for abstract publication at ASCO
- Preclinical work continuing with journal article publication and advisory board.

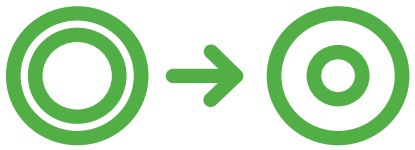


LP-50

Intravesical Liposomal Delivery of Checkpoint Inhibitor

Lipella Pharmaceuticals

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



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Presentation Appendix I: LP-310 Clinical Design

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LP-310 CLINICAL SNAPSHOT

Design : Randomized, prospective multicenter dose escalation study with 24 patients.

Efficacy : Anticipate a statistically significant decrease in oral lichen planus lesion score within 1 week of administration, maintained for at least 4 weeks.

Quality of Life : Expect a clinically relevant improvement in quality-of-life measures.

Safety : No systemic or renal function toxicity projected.

Dosage and Administration

- **Regimen**: Twice daily oral rinse of 10 ml of LP-310 (27 mg sphingomyelin and 0.25 mg, 0.5 mg and 1 mg tacrolimus, respectively) for 3 minutes for four weeks.
- **Monitoring**: Whole blood tacrolimus levels checked after one week.

Mechanism of Action

- **Active Ingredient**: Tacrolimus, a calcineurin inhibitor.
- **Function**: Serves as a potent immunosuppressant that improves barrier function of the skin and mucosa.
- **Impact**: Disrupts inflammatory signaling events mediated by calcineurin and suppresses inflammation associated with oral lichen planus.

Safety Profile

- **Anticipated Adverse Events**:
  - Oral cavity infection (~2%)
  - Mouth burning (~5%)
- **Toxicity**: No systemic or renal function toxicity associated with LP-310.

TRIAL DESIGN SUMMARY

Recruitment sites and subject disposition

Patient Disposition	Number	Comments
Screened, n	12	2 male, 10 female
Enrolled, n	8	2 male, 6 female
Number of instillations	448	Tolerated in all participants
Discontinued, %	0	
Withdrew consent, %	0	
Lack of compliance, %	0	
Lost to follow-up, %	0	

Patient Demographics	Mean	Comment
Age, years	61	Range 38-72
Race		
White	5	
Black	1	
Asian	1	
Indian	1	
Mean duration of OLP (years)	8	Range 2-20 years
Prior OLP treatment		Dexamethasone, clobetasol, fluocinonide, gabapentin, plaquenil, mycophenolate mofetil, vitamin D

INCLUSIONS AND EXCLUSIONS

Key Inclusion Criteria:

- Moderate OLP based on an OLP Investigator Global Assessment (IGA) score of ≥ 3
- OLP Pain or Sensitivity Numerical Rating Scale (NRS) score of ≥ 3
- Oral biopsy performed within the last 10 years before the Screening Visit demonstrating OLP and/or oral lichenoid mucositis in the absence of cancer or dysplasia
- Patients taking prescription oral steroid or rinse treatment(s) at the time of the Screening Visit agree to stop treatment for the duration of the trial and to undergo a 4-week washout period

Key Exclusion Criteria:

- History of oral cavity or oropharyngeal cancers
- Patients who failed tacrolimus treatment for OLP in the past
- Patient is currently or has previously participated in another oral cavity therapeutic or device study within 3 months of screening and has not returned to baseline
- Known allergy to liposomes and/or egg yolk and/or tacrolimus

KEY TAKEAWAYS LP-310

- Phase 2a multicenter trial on tract for completion in 2Q25
- **Tolerability:** First in human Phase 2a LP-310 well tolerated with no drop out
- **Safety:** Minimal systemic absorption, low systemic side effects. Mild local irritation
- **Pharmacokinetic:** Undetectable or minimal system tacrolimus PK
- **Efficacy:** Statistically significant ($p < 0.05$) and clinically meaningful improvement across all efficacy outcome parameters.
- Targeting Large patient population with unmet needs including:
  - 6 million patients living with OLP.
  - Affects women 3x more often than men
  - No current approved FDA drug treatment
  - Rate of malignant transformation is 1.5%
- Patent protection secured through 2034.
- In-house facility manufacturing capabilities.
- LP-310 offers an alternative for relapsing OLP cases, addresses steroid-induced limitations, and expands therapeutic options.

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Presentation Appendix II: LP-10 Market Data

Lipella Pharmaceuticals Inc.
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Pittsburgh, PA 15208

412-894-1853

NASDAQ:LIPO

lipellapharmaceuticals.com

CANCER SURVIVORSHIP & HEMORRHAGIC CYSTITIS

- Expected annual revenue per patient is $20,000
- Market penetration of 60,000 patients (45%) yields $1.2 billion annual revenue
- The current phase-2a is focused on radiation cystitis.
- LP-10 is also expected to address chemo cystitis.

Prostate Cancer

700,000
Pelvic Radiation Survivors

42,000
Severe HC Survivors

Uterine Corpus Cancers

200,000
Pelvic Radiation Survivors

12,000
Severe HC Survivors

Rectal & Other Pelvic

300,000
Pelvic Radiation Survivors

18,000
Severe HC Survivors

Breast Cancer

360,000
x-DNA Chemotherapy Survivors

36,000
Severe HC Survivors

Lukemia & Lymphoma

180,000
x-DNA Chemotherapy Survivors

18,000
Severe HC Survivors

Other Tumors

60,000
x-DNA Chemotherapy Survivors

6,000
Severe HC Survivors

LP-10 Addresses a potential $1.2 Billion Market

Expected annual reimbursement is $20,000 per patient
Market penetration of 60,000 patients yields $1.2 billion in recurring revenue

Cancer Survivor Original Malignancy	Survivors of Pelvic Radiation Therapy	Severe HC
Prostate Cancer	700,000	42,000
Cancers of the Uterine Corpus	200,000	12,000
Rectal Cancer	200,000	12,000
Other Pelvic Malignancy	100,000	6,000
Total	**1,200,000**	**72,000**

*Penetration 45,000 patients

Original Cancer	Incidence Chemo	Prevalence Chemo	Prevalence HC
Breast Cancer	120,000	360,000	36,000
Lukemia & Lymphoma	60,000	180,000	18,000
Other	20,000	60,000	6,000
Total	**200,000**	**600,000**	**60,000**

*Penetration 15,000 patients

2025 BIO CEO & Investor Conference
Feb 11, 2025, New York, NY

Presentation Appendix III: Several LP-310 Endpoint Descriptions

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INVESTIGATOR REPORTED

OLP Investigator Global Assessment (IGA)

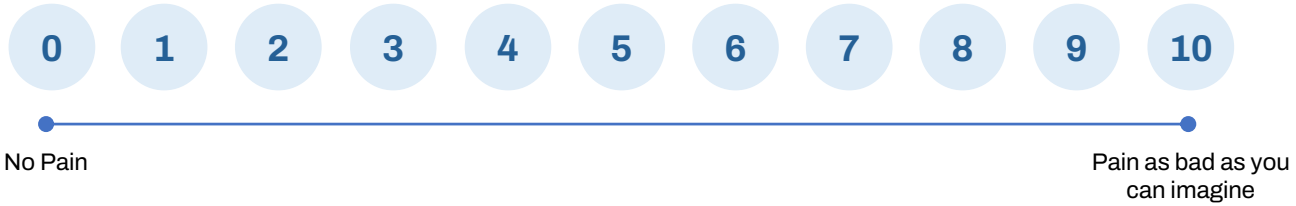
Score	Grade	Definition version				Definition version		
		Ulcer		Ery thema		Ulcer		Erythema
0	Clear	No ucler	and	None		None	and	None
1	Almost clear	A single ulcer <2 mm	and/or	Minor		Barely perceptible	and/or	Light red
2	Mild	Single ulcer 2-4.9mm, and/or multiple ulcer <2mm	and/or	Marked		Single small or multiple barely perceptible	and/or	Bright red
3	Moderate	Single ulcer 5-9.9mm, and/or multiple ulcers with at least 2 uclers ≥2mm	and	None to marked		Single moderate or multiple small	and	None to bright red
4	Severe	Single ulcer ≥10mm, and/or multiple ulcers with at least 2 uclers ≥5mm	and	None to marked		Single large or multiple moderate	and	None to bright red

PATIENT REPORTED

OLP Pain and Sensitivity Rating Scale (NRS)

Oral Cavity Pain

Please circle the number that best describes the Oral Lichen Planus pain that you have experienced over the last 24 hours.



Oral Cavity Sensitivity

Please circle the number that best describes the Oral Lichen Planus sensitivity that you have experienced over the last 24 hours.

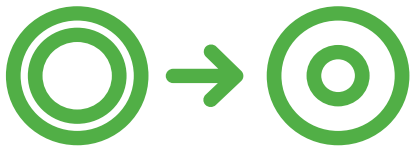
Patient Global Response Assessment (GRA)

As compared to when you started the study, how would you rate your overall quality of life now?

- Markedly worse
- Moderately worse
- Slightly worse
- No change
- Slightly improved
- Moderately improved
- Markedly improved

Lipella Pharmaceuticals

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



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