

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): July 14, 2026

PALVELLA THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Nevada
(State or other jurisdiction
of incorporation)

353 W. Lancaster Ave, Suite 200
Wayne, Pennsylvania
(Address of principal executive offices)

001-37471
(Commission File Number)

30-0784346
(IRS Employer
Identification No.)

19087
(Zip Code)

Registrant's telephone number, including area code: (484) 253-1461

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- ☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- ☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- ☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- ☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common stock, \$0.001 par value per share	PVLA	The Nasdaq Global Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 8.01 Other Events.

On July 14, 2026, Palvella Therapeutics, Inc. (the “Company”) posted a corporate presentation to its website, which representatives of the Company will use in various meetings with investors from time to time. A copy of the presentation is filed herewith as Exhibit 99.1, and incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Corporate Presentation of Palvella Therapeutics, Inc., dated July 14, 2026*
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

* Filed herewith

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

PALVELLA THERAPEUTICS, INC.

Date: July 14, 2026

By: /s/ Matthew Korenberg
Matthew Korenberg
Chief Financial Officer



First-in-disease therapies for patients
with rare diseases

Corporate Presentation
July 2026



Forward Looking Statements

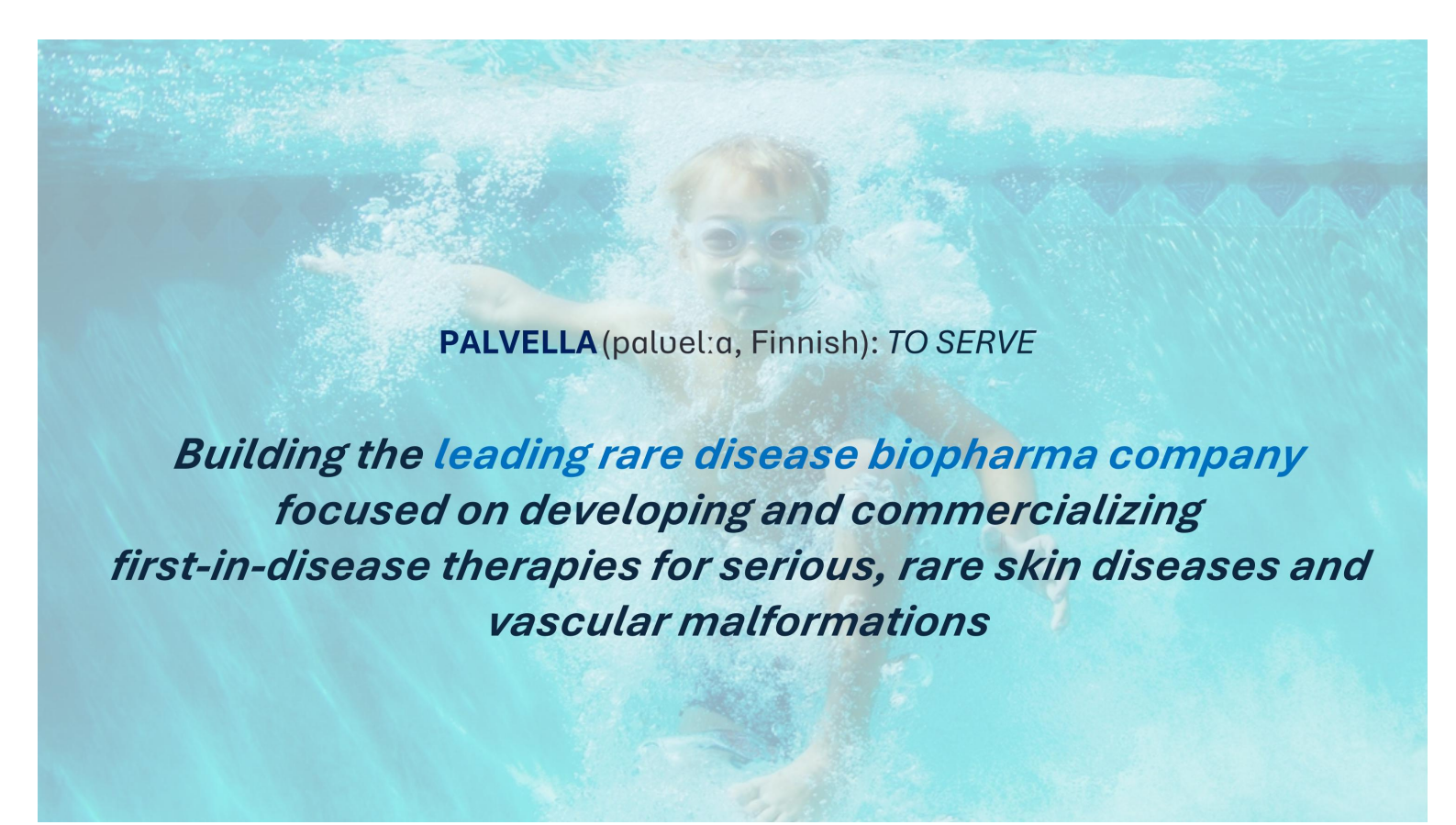
This presentation contains forward-looking statements of Palvella Therapeutics, Inc. ("the Company") within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements include all statements that are not historical facts, and in some cases, can be identified by terms such as "may," "might," "will," "could," "would," "should," "expect," "intend," "plan," "objective," "anticipate," "believe," "estimate," "predict," "potential," "continue," "ongoing," or the negative of these terms, or other comparable terminology intended to identify statements about the future. Forward-looking statements contained in this presentation include, but are not limited to, statements regarding the Company's future financial or business performance, conditions, plans, prospects, trends or strategies and other financial and business matters, the Company's current and prospective product candidates and any additional indications or platform candidates, the Company's planned research and development activities, the Company's planned clinical trials, including timing of receipt of data from the same, the Company's expectations regarding the timing of completion of the New Drug Application ("NDA"), the planned regulatory framework for the Company's product candidates, the Company's ability and the ability of third-party manufacturers the Company engages to optimize and scale manufacturing, the strength of the Company's intellectual property portfolio, and projections of the Company's future financial results and other metrics. Such forward-looking statements are subject to risks, uncertainties, and other factors which could cause actual results to differ materially from those expressed or implied by such forward looking statements.

These forward-looking statements are based upon current estimates and assumptions of the Company and its management and are subject to a number of risks, uncertainties and important factors that may cause actual events or results to differ materially from those expressed or implied by any forward-looking statements contained in this presentation. Factors that may cause actual results to differ materially from current expectations include, but are not limited to: competition, the ability of the Company to grow and manage growth, maintain relationships with suppliers and retain its management and key employees; the success, cost and timing of the Company's product development activities, studies and clinical trials; changes in applicable laws or regulations; the possibility that the Company may be adversely affected by other economic, business or competitive factors; the Company's estimates of expenses and profitability; the evolution of the markets in which the Company competes; the ability of the Company to implement its strategic initiatives and continue to innovate its existing products; and the ability of the Company to defend its intellectual property.

Nothing in this Presentation should be regarded as a representation by any person that the forward-looking statements set forth herein will be achieved or that any of the contemplated results of such forward-looking statements will be achieved. You should not place undue reliance on forward-looking statements, which speak only as of the date they are made. The Company undertakes no duty to update these forward-looking statements.

Industry and Market Data: The Company may from time to time provide estimates, projections and other information concerning its industry, the general business environment, and the markets for certain conditions, including estimates regarding the potential size of those markets and the estimated incidence and prevalence of certain medical conditions. Information that is based on estimates, forecasts, projections, market research or similar methodologies is inherently subject to uncertainties, and actual events, circumstances or numbers, including actual disease prevalence rates and market size, may differ materially from the information reflected in this presentation. Unless otherwise expressly stated, we obtained this industry, business information, market data, prevalence information and other data from reports, research surveys, studies and similar data prepared by market research firms and other third parties, industry, medical and general publications, government data, and similar sources, in some cases applying our own assumptions and analysis that may, in the future, prove not to have been accurate.

Trademarks: This Presentation may contain trademarks, service marks, trade names and copyrights of other companies, which are the property of their respective owners. Solely for convenience, some of the trademarks, service marks, trade names and copyrights referred to in this Presentation may be listed without the TM, SM ® or ® symbols, but the Company will assert, to the fullest extent under applicable law, the rights of the applicable owners, if any, to these trademarks, service marks, trade names and copyrights.



PALVELLA (paluel:ɑ, Finnish): *TO SERVE*

***Building the **leading rare disease biopharma company**
focused on developing and commercializing
first-in-disease therapies for serious, rare skin diseases and
vascular malformations***

What Makes Palvella Stand Apart

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Repeatably
unlocking multi-
billion dollar market
opportunities in
previously untreated
orphan diseases



1 First-in-Disease Focus

+

2 Rare Diseases with Clear Disease Biology

+

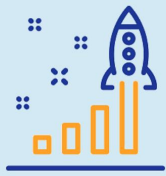
3 Leveraging Existing Human Proof-of-Concept
and Safety Data

+

4 Innovative QTORIN™ Platform: Durable IP
Generation

Veteran team executing rare disease model designed to reduce time and capital to FDA approval

What's New at Palvella – Q3 2026



U.S. launch planning is accelerating for microcystic LMs (first indication)

- Multi-billion dollar uncontested TAM with estimated U.S. peak sales >\$1 billion
- Sales force planned at ~40 reps, the upper end of prior ~20-40 rep range, to strengthen launch execution, field coverage, physician education, and patient access from day one
- 1H 2026 commercial talent recruited: Matt Pauls, Board Director (*Savara, Soleno, Insmad*), Jen McDonough, SVP Market Access (*prev. Krystal Biotech*); Kent Taylor, SVP Sales (*prev. Arcutis*)
- Well-capitalized after \$230mm oversubscribed Q1 2026 financing



NDA submission underway with potential 1H 2027 FDA approval in microcystic LMs

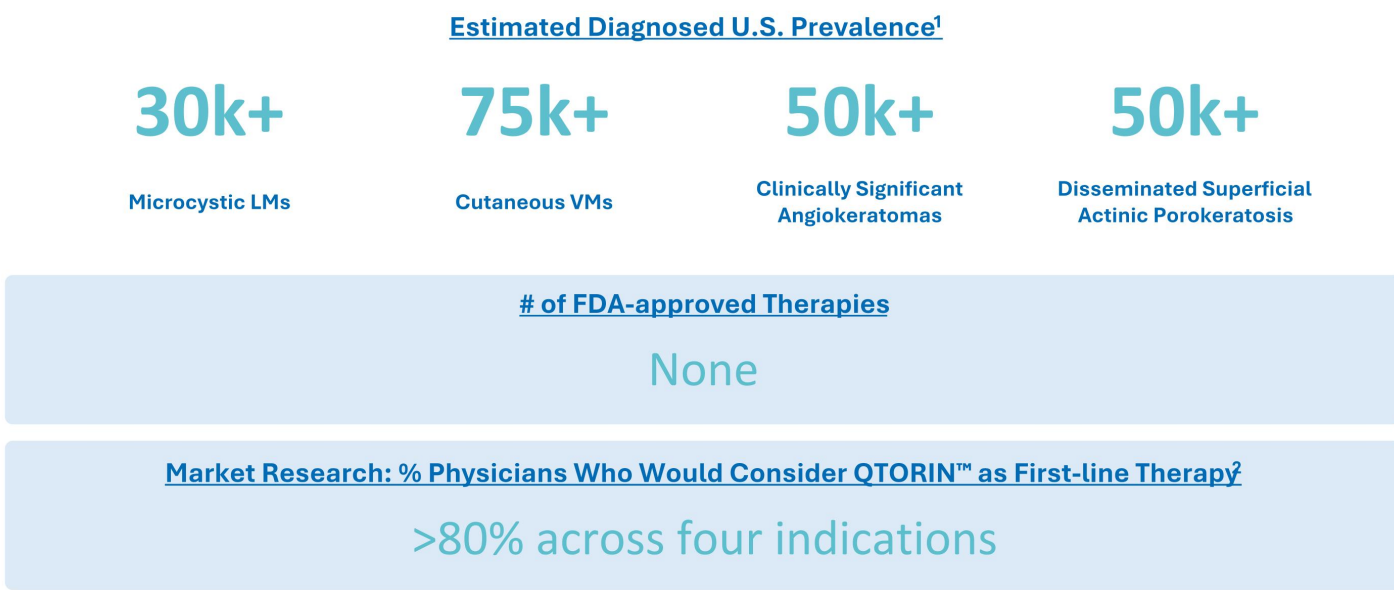
- Completed Pre-NDA meeting with FDA, granted rolling review, first module of NDA submitted



Leveraging QTORIN™ to expand into additional first-in-disease opportunities in orphan indications that are commercially underappreciated (*see next slide*)

- Deep rare disease pipeline with three QTORIN™ programs across six rare diseases anticipated by year end 2026

Palvella: Driving the Next Wave of Innovation in Under-appreciated Rare Skin Diseases and Vascular Malformations



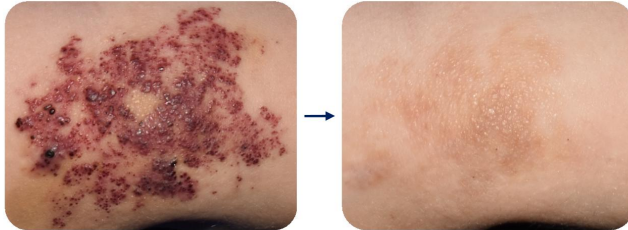
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1. Clarity Pharma, Trinity Life Sciences, MedaCorp, and ZS Associates. 2. MedaCorp market research.

Microcystic Lymphatic Malformations: Complete NDA Submission on Track for 2H 2026 with Anticipated U.S. Commercialization in 1H 2027

1

Microcystic Lymphatic Malformations

- ✓ Positive Phase 3 SELVA data
- ✓ Completed pre-NDA meeting (June 2026)
- ✓ Rolling review granted by FDA
- ✓ Findings presented at ISSVA World Congress, May 2026
- First module of rolling NDA submitted in Q2 2026; completed NDA submission on track for 2H 2026



**Potential FDA
approval and
U.S. launch
1H 2027**

Multiple High-Impact Pipeline Milestones in 2026: Density of Catalyst Creation Driven by QTORIN™

2

Cutaneous Venous Malformations

✓

Positive Phase 2 data

•

P3 initiation expected Q4 2026

•

EOP2 meeting planned with FDA to discuss trial design



3

Clinically Significant Angiokeratomas

✓

Fast Track Designated

✓

Phase 2 initiated April 2026, ahead of schedule

•

Phase 2 data expected 2H 2027



4

Disseminated Superficial Actinic Porokeratosis

✓

QTORIN™ pitavastatin formulation developed, IP filed

•

Phase 2 initiation expected 2H 2026



5

QTORIN™ Third Program

•

Announcement expected 2H 2026

•

Potential pipeline-in-a-product



DAVID OSBORNE, PhD
Chief Innovation Officer

6

QTORIN™ Rapamycin Fourth Indication

•

QTORIN™ rapamycin fourth indication announcement expected 2H 2026





OUR LEAD PRODUCT CANDIDATE

QTORIN™ 3.9%
RAPAMYCIN ANHYDROUS
GEL

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QTORIN™: Reproducible Platform for Generating Novel, Topical Product Candidates in a Capital Efficient Manner



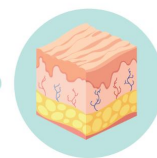
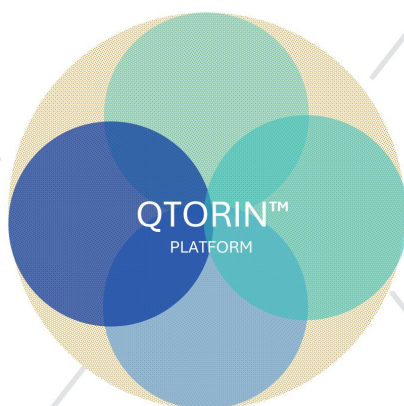
HIGH DRUG LOADING CAPACITY

High solubility → high concentrations → potential for rapid onset and large magnitude treatment effect



TOLERABILITY

Retaining active drug in the skin while minimizing systemic absorption



DERMAL ENGAGEMENT

Delivery to deeper layers of skin, often the site of disease pathophysiology



IP

Each QTORIN™ product candidate eligible for composition IP on formulation

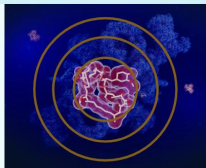
Our Breakthrough Innovation: QTORIN™ 3.9% Rapamycin Anhydrous Gel

Oral rapamycin is not a viable therapeutic option in skin diseases:

Systemic toxicities & low biodistribution to the skin

OPTIMIZED CONCENTRATION

QTORIN™ synergistic solubility results in 3.9% concentration



DERMAL ENGAGEMENT

Rapamycin concentration in dermis exceeds IC90 for mTOR inhibition¹



TOLERABILITY

No traditional penetration enhancers; limited systemic absorption²



Intended for once daily at-home self-administration

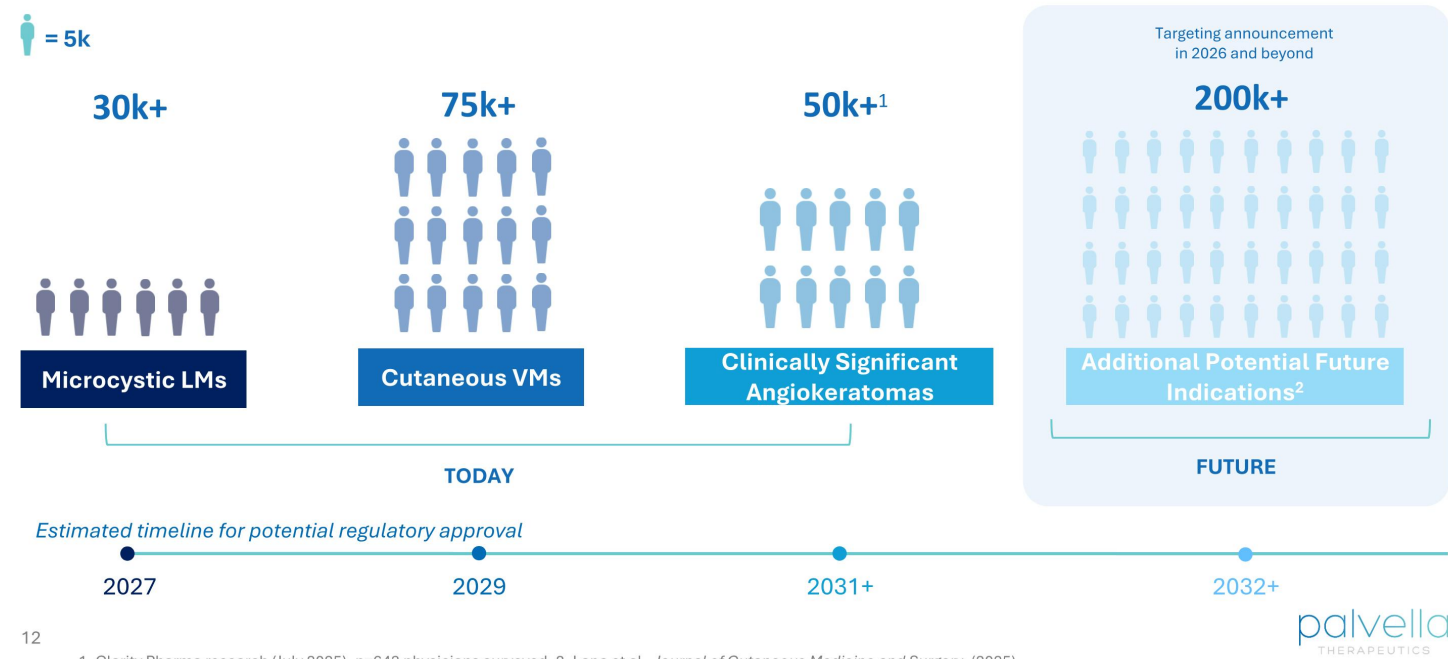
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QTORIN™ 3.9% rapamycin anhydrous gel is for investigational use only and has not been approved or cleared by the FDA or by any other regulatory agency. The safety or efficacy has not been established for any use.

1. Data on file. 2. Clinical Study Report PALV-0609.

QTORIN™ Rapamycin: Fourth Indication Announcement in 2H 2026

Pipeline-in-a-product strategy expands addressable U.S. patient pool by 10x beyond initial indication





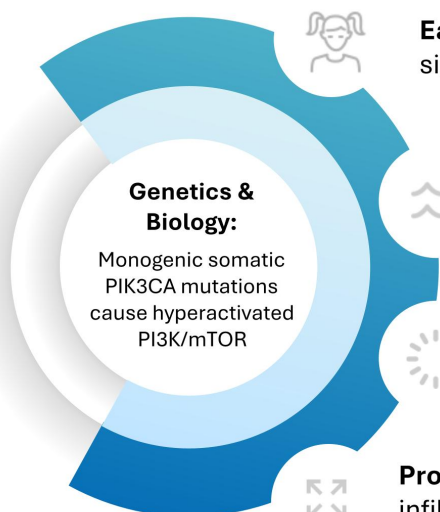
QTORIN™ 3.9% RAPAMYCIN

FOR

Microcystic Lymphatic Malformations

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Microcystic Lymphatic Malformations: *Serious, Debilitating, and Lifelong*



Early onset: Present at birth and significant impact to adolescents

Lymphorrhea: Persistent discharge of lymphatic fluid through skin layers

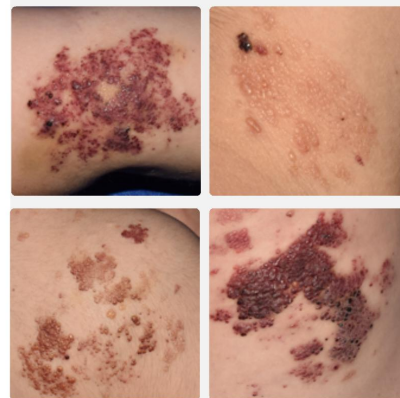
Deep infections: Recurrent cellulitis and serious soft tissue infections, resulting in hospitalizations

Proliferative, progressive disease with infiltrative lesions and no spontaneous regression

> 30k patients

ESTIMATED DIAGNOSED IN THE U.S.¹

No FDA-approved therapies



Breakthrough
Therapy
Designation

Fast
Track
Designation

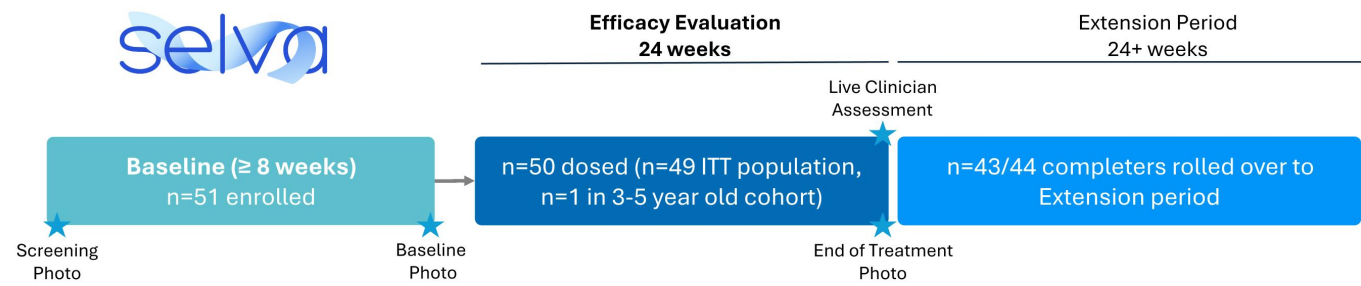
Orphan
Drug
Designation

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14 1. Incidence, prevalence, and care for patients with lymphatic malformations (LMs) in the U.S.: A claims-based analysis, Society of Investigative Dermatology, (2025) and Gallagher et al, *Orphanet Journal of Rare Diseases*, (2022). Includes microcystic LM and mixed LM (patients with both microcystic and macrocystic disease).

Phase 3 SELVA Trial Design

Single-arm, baseline-controlled, QD dose



Primary Endpoint: mLM-IGA (Investigator Global Assessment)

Key Secondary Endpoint: Blinded mLM Multi-Component Static Scale (mLM-MCSS): independent, blinded review of randomized Baseline and Week 24 photos evaluating three key signs of disease: Vesicle Appearance, Height, Leaking/Bleeding

Secondary Endpoints: Live mLM-MCSS, Patient Global Impression of Change (PGI-C), Clinician and Patient Global Impression of Severity (CGI-S, PGI-S), and Incidence and Severity of Adverse Events

Supported by FDA Orphan Products Grant:

Two tranches of non-dilutive funding received (most recent in Oct '25)

15 Note: Of the 51 participants enrolled, 50 initiated treatment, including 49 aged ≥6 years (ITT population). During the 24-week efficacy evaluation period, six participants discontinued treatment: four participants discontinued for reasons unrelated to adverse events, one participant discontinued due to an adverse event not related to study drug, and one participant discontinued due to an adverse event possibly related to study drug.

selva: A Clear Path Forward for Patients

**QTORIN™ Rapamycin
at Week 24:**

**Highly statistically
significant across
primary, key
secondary, and all four
secondary endpoints
(all $p < 0.001$)**

+2.13

Mean improvement on mLM-IGA primary
endpoint ($p < 0.001$)

**Participants aged ≥ 6 who completed the efficacy
evaluation period:**

95%

Improved on mLM-IGA

86%

“Much Improved” (+2) or “Very Much
Improved” (+3) on mLM-IGA

**Potential to be first and only FDA-approved therapy for
>30,000 diagnosed U.S. patients**

SELVA: Primary and Key Secondary Endpoints Achieved

	Mean Change at Week 24 (95% CI)	p-value
Primary Endpoint: Microcystic Lymphatic Malformation Investigator Global Assessment (mLM-IGA)*	+2.13 (1.88, 2.38)	p<0.001
Key Secondary Endpoint: Blinded Microcystic Lymphatic Malformation Multi-Component Static Scale**	-3.36 (-4.34, -2.38)	p<0.001

*Dynamic change scales (7-point scales ranging from "Very Much Worse" (-3) to "Very Much Improved" (+3); positive values indicate improvements from baseline)
**mLM-MCSS (Sum of three static severity scales: Height, Leaking/Bleeding, Vesicle Appearance: Each scale rated "Clear or Almost Clear" (1) to "Very Severe" (5); total score 3-15. Test baseline to Week 24 change; negative values indicate improvements from baseline)

Highly statistically significant across primary, key secondary, and all four secondary endpoints (all p<0.001)

Phase 3 Results: Well-Tolerated and Favorable Safety Profile

	Number of Participants (%)
Any Treatment-Emergent Adverse Event	35 (70%)
Severe (not related to study drug)	1 (2%)
Serious (not related to study drug)	4 (8%)
Any Treatment-Related ¹ Adverse Event	17 (34%)
Severe	0 (0%)
Serious	0 (0%)
Treatment-Related ¹ AEs with ≥ 5% Incidence	
Application site acne	3 (6%)
Application site discoloration	3 (6%)
Application site pruritus	3 (6%)
Possibly Treatment-Related AE Leading to Discontinuation	1 (2%)

Rapamycin levels were below 2 ng/mL in systemic circulation on for all participants at all timepoints in the study

Note: n=50 participants in efficacy evaluation evaluated for safety. 1. Denotes related or possibly related. 2. Validated assay of lower limit of quantification (100 pg/mL).

Phase 3 Results: Age 10, Male, mLM-IGA: +2 “Much Improved”

Baseline



Week 24



Prior Interventions: Multiple sclerotherapy procedures, antibiotics due to infection

Phase 3 Results: Age 7, Female, mLM-IGA: +3 “Very Much Improved”



Prior Interventions: Laser therapy, compounded topical rapamycin (discontinued due to skin irritation)

20 Note: Selective photos.

Regulatory: NDA Submission On Track for 2H 2026

Breakthrough, Fast Track, and Orphan Designations granted

**Completed Pre-
NDA Meeting with
FDA**

**Rolling Review
Granted**

**First NDA Module
Submitted**



- 1 Phase 3 SELVA and Phase 2 studies highly statistically significant and clinically meaningful; real-world studies from off-label rapamycin use as supportive evidence
- 2 Granted Breakthrough, Fast Track, and Orphan Designations, and FDA Orphan Drug Grant; intend to seek 6-month priority review
- 3 505(b)(2) submission: leveraging FDA's prior findings for rapamycin to streamline review process
- 4 Seeking traditional approval (not accelerated) based on clinical endpoints; intent to seek broad label age 3 and above

Strong Barriers Through Multi-Layered Exclusivity Strategy

IP portfolio, trade secrets, and regulatory exclusivities through at least 2038

Granted U.S. Patents

6 issued U.S. patents with claims through at least 2038

Including protection against 0.1% to 20% anhydrous gel compositions of rapamycin and other mTOR inhibitors

Trade Secrets

Multiple trade secrets related to proprietary formulation processes and manufacturing know-how

Regulatory

Orphan drug designation and 7-year data exclusivity from anticipated FDA approval

Pending patents could extend U.S. IP into mid-2040s



DAVID OSBORNE, PhD
Chief Innovation Officer



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U.S. Commercial Launch Planning

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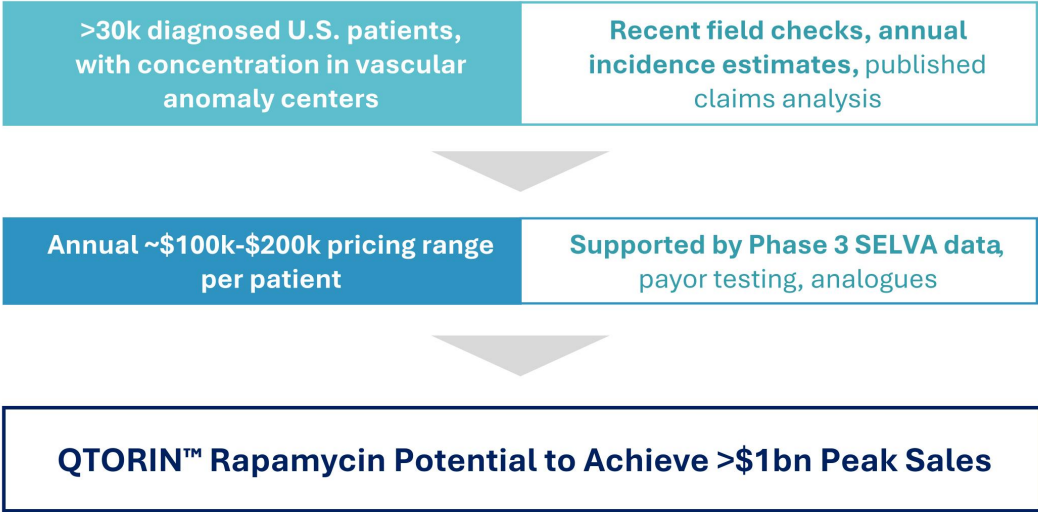
Microcystic LMs: Multi-billion Dollar, Uncontested U.S. Market Opportunity with Commercial Build-Out Underway

- 1 **Large orphan market:** Claims analysis presented at 2025 Society for Investigative Dermatology (SID) Meeting verified > 30k estimated diagnosed U.S. patients, with >1,500 incident patients annually
- 2 Positioned to be **first and only FDA-approved therapy**, market research indicates **strong intent to prescribe, including in pediatric population**
- 3 Payor testing and orphan analogues validate **expected orphan pricing corridor above \$100k per patient per year**
- 4 **Concentrated prescriber base** in vascular anomaly centers (VACs) & other clinics

QTORIN™ Rapamycin: >\$1bn U.S. Peak Sales Potential in Microcystic LMs

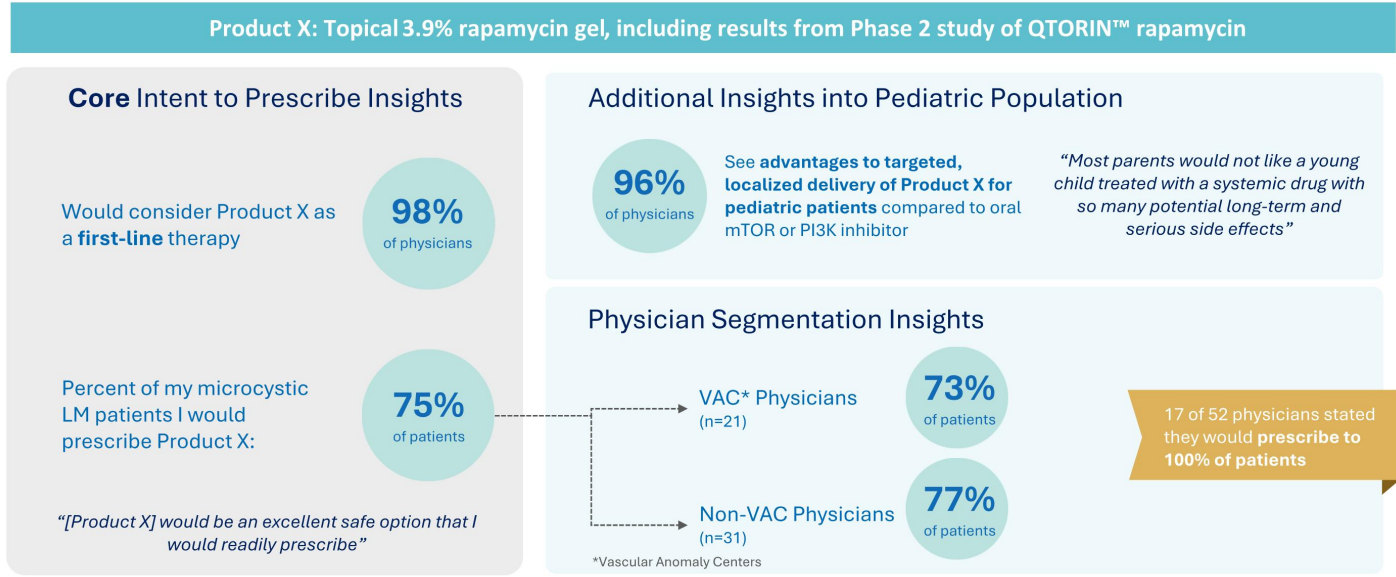


Microcystic Lymphatic Malformations

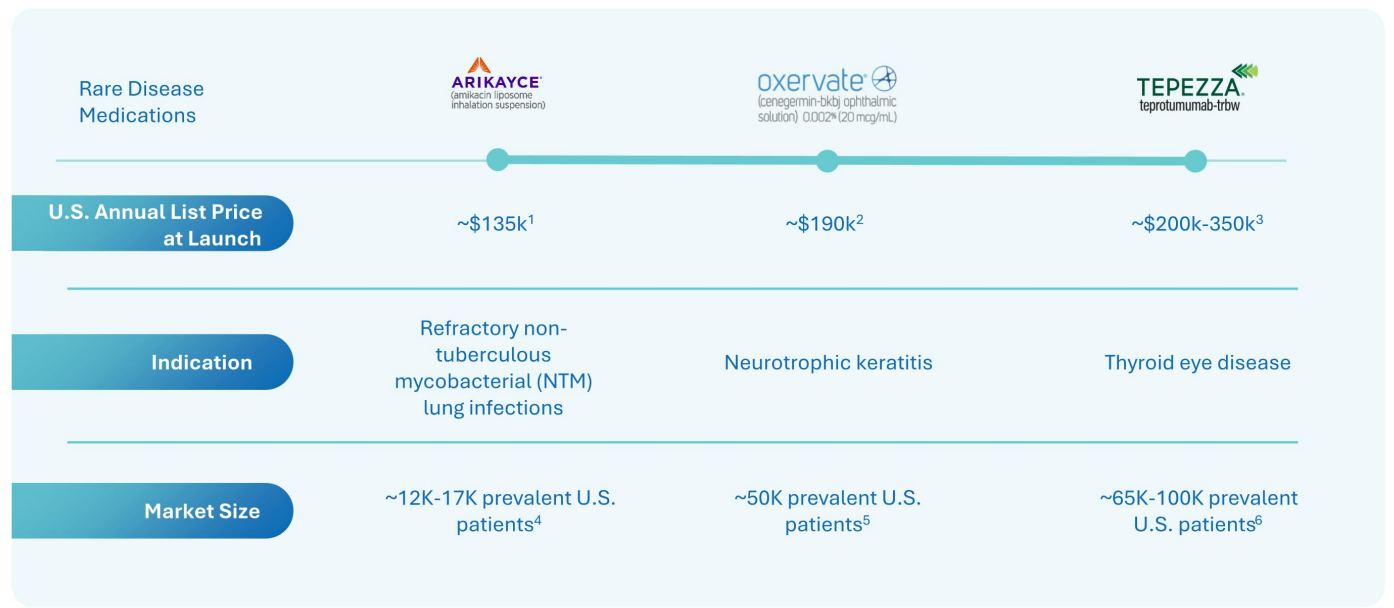


QTORIN™ Rapamycin Physician Market Research:

Potential to be First Line, Standard of Care Therapy for Microcystic LMs



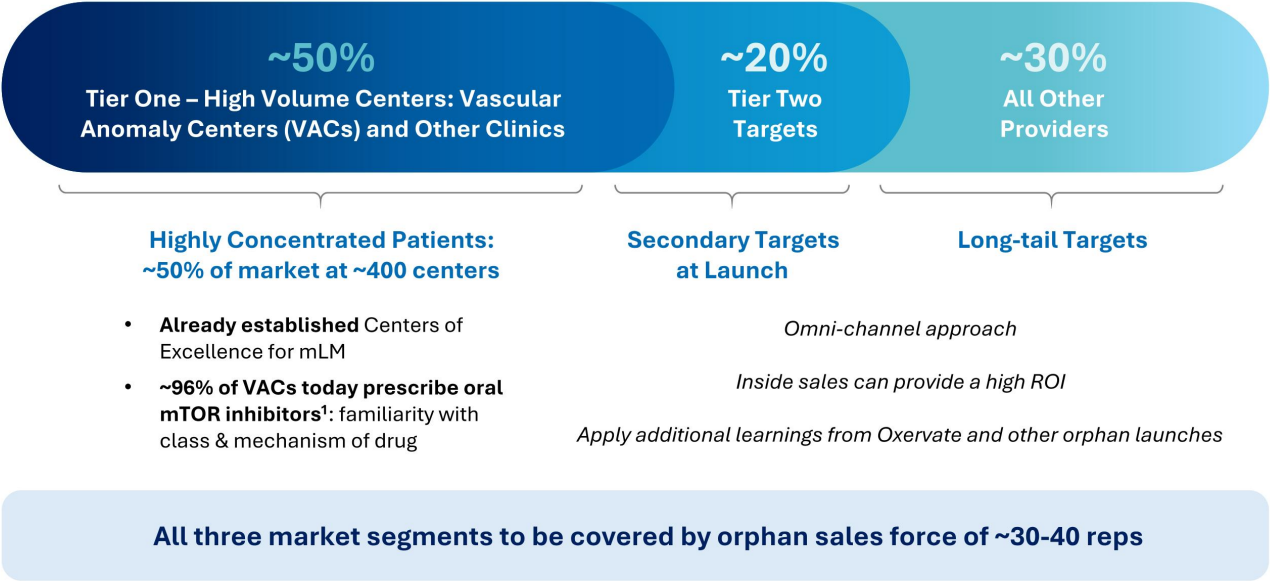
QTORIN™ Rapamycin Pricing: Prior First-in-Disease Launches and Recent Topical Orphan Launches Support Potential Orphan Drug Pricing



1. Medscape Medical News interview with Mandy Fahey, Insmid Director of Corporate Communications (2018). 2. Assumes one course of 8-week therapy for both eyes. 3. Horizon Therapeutics Management guidance and Wall Street research. Price dependent on weight-based dosing. 4. Insmid corporate presentation (2025). 5. Sacchetti et al., *Clin Ophth* (2014). 6. Stan et al., *Clin Endocrinol (Oxf)* (2024), Horizon Therapeutics investor presentation (2023).

Highly Concentrated Patient Population: ~400 Established High Volume Centers for Treating Vascular Malformations Comprise ~50% of Market

CLAIMS ANALYSIS SUPPORTS THREE SEGMENTS





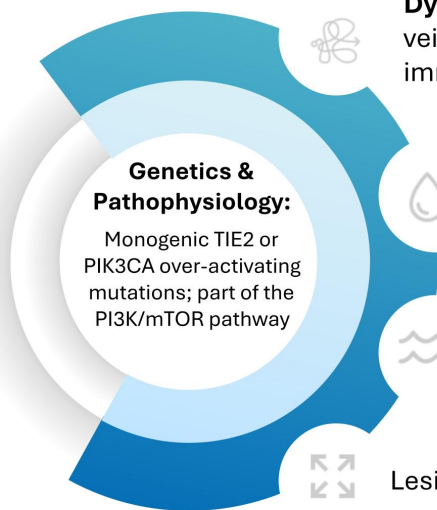
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Cutaneous Venous Malformations

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Cutaneous Venous Malformations: Serious, High Unmet Need



Dysregulated growth of malformed veins and **hyperproliferation** of immature venous endothelial cells

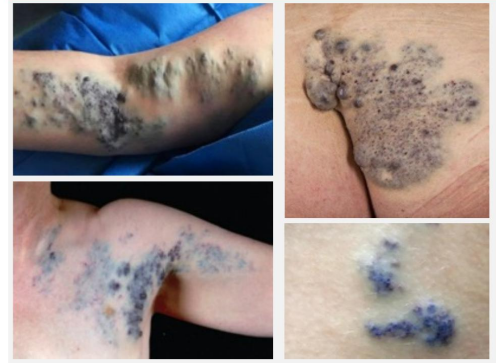
Dysfunctional venous architecture leads to bleeding, thrombosis, ulceration

Skin involvement in ~50-80% of venous malformations patients²

Lesions do not resolve spontaneously³

> 75k patients

ESTIMATED DIAGNOSED IN THE U.S.¹



Leads to physical & functional impairment, psychological distress, with no FDA-approved therapies

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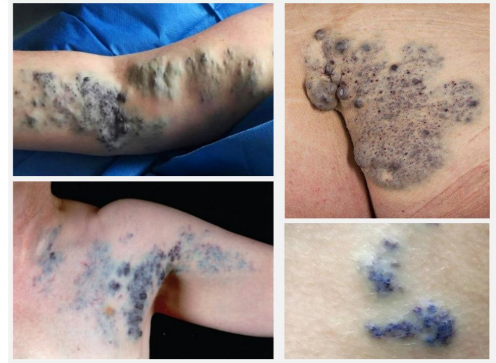
Cutaneous Venous Malformations: Near-term Phase 3 Pivotal Study Planned

POSITIVE PHASE 2 DATA ANNOUNCED DEC 2025

- **Most common vascular malformation with significant treater overlap with microcystic lymphatic malformations**
- **New 24-week data presented at ISSVA World Congress May 2026 by Dr. Jim Treat (CHOP)**
- **Recent publication highlights off-label sirolimus as the most utilized medical therapy for VMs (Coulie et al, July 2026)**
- **Clinical development plan:**
 - On track for Phase 3 trial initiation in Q4 2026
 - Planning for EOP2 meeting with FDA to discuss Phase 3 trial design
 - Breakthrough Therapy resubmission planned, incorporating TOIVA patient interviews and new 24-week data, following FDA's recent decision (July 2026) to not grant the designation at this time

> 75k patients

ESTIMATED DIAGNOSED IN THE U.S.



No FDA-approved therapies

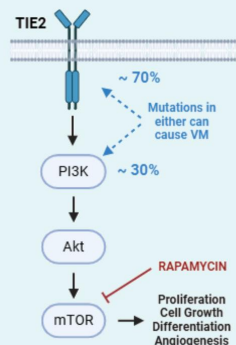
Fast Track Designation Granted

**Pipeline-in-a-product:
sNDA planned**

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Venous Malformations: Progress Towards the Potential First Targeted Therapy for Unaddressed Cutaneous Disease

Known Genetics / Clear Biology



Plausible mechanism

Limaye et al (2009, 2015)

Real-world Evidence

LYMPHATIC RESEARCH AND BIOLOGY
Volume 00, Number 00, 2025
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DOI: 10.1177/15377662251377562

Sirolimus for Venous Malformations: A Systematic Review of Efficacy and Safety

Joyce Teng, MD, PhD,¹ Jeff Martini, PhD,² Michael Kelly, MD, PhD,³ Megha Tollefson, MD,⁴ and Alexander Greer⁵

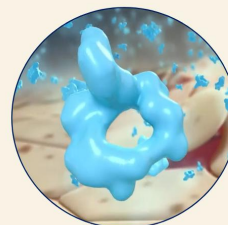
Real-world evidence supports rapamycin's off-label use in primarily internal manifestations of VMs...

...however, poor patient outcomes persist in cutaneous disease

Teng et al (2025)

On Target, In Tissue

QTORIN™
RAPAMYCIN

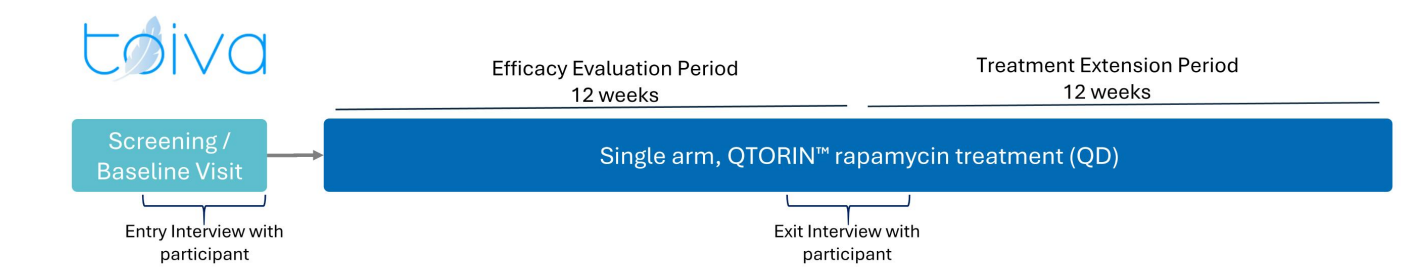


3.9% concentration
Dermal penetration
Extensive CMC package

Phase 2 TOIVA Data (2025)

Phase 2 TOIVA Study in cVMs: 24-Week Study

Single-arm, baseline-controlled, QD dose, age 6+



Safety and Tolerability

Efficacy (no pre-specified primary endpoint): cVM-IGA (7-point clinician change scale), cutaneous VM multi-component static scale (cVM-MCSS), other clinician- and patient-reported outcomes

Statistics: Intent-to-Treat (ITT) population, based on available data at each time point and analyzed per statistical analysis plan

Key Entry Criteria: Enriched for patients with cutaneous disease and confirmed by third party eligibility consult team; genetics not required

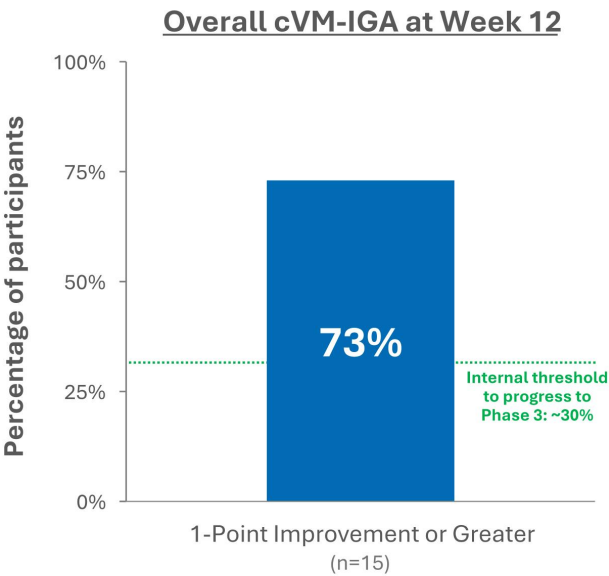
Enrollment: 16 participants enrolled and dosed

Sites: MAYO CLINIC, Cleveland Clinic, Children's Hospital of Philadelphia, Stanford MEDICINE, UCI, Children's Hospital Colorado, Children's Healthcare of Atlanta, JOHNS HOPKINS, U HEALTH UNIVERSITY OF UTAH, UNC HEALTH, MINNESOTA CLINICAL STUDY CENTER

33 Note: Statistical significance ($p < 0.05$) is nominal as there was no adjustment for multiplicity amongst efficacy endpoints. Data analyzed per statistical analysis plan; ITT analyzed with no imputation of values for missing data.

Overall cVM-IGA: 73% of Participants Demonstrated Improvement at Week 12

Single-arm, baseline-controlled, QD dose, age 6+



- **Overall cVM-IGA:** 7-point clinician-assessed dynamic change scale ranging from “Very Much Worse” (-3) to “Very Much Improved” (+3)
 - Mean effect size at week 12: **+1.5 (p<0.001)**
 - Median effect size at week 12: **+2.0**
- **73%** of participants (11/15 participants) demonstrated at least a 1-point improvement on the Overall cVM-IGA at Week 12
- **67%** of participants (10/15 participants) were rated as either “Much Improved” (+2) or “Very Much Improved” (+3) on the Overall cVM-IGA at Week 12

34 Note: Statistical significance (p<0.05) is nominal as there was no adjustment for multiplicity amongst efficacy endpoints. Data analyzed per statistical analysis plan; ITT analyzed with no imputation of values for missing data.

1. Genetic testing was not required as part of the protocol; Palvella is continuing efforts to collect genetic data on trial participants.

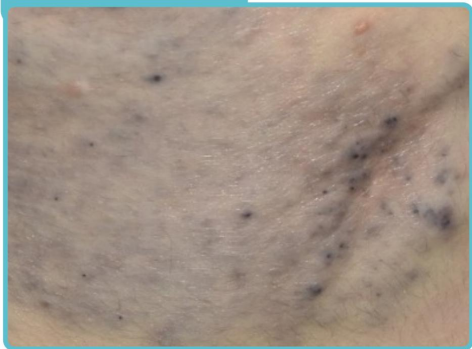
Phase 2 Results: Meaningful Improvement in Patient QoL



Site: CHOP
Investigator: Dr. Denise Adams

Participant Age: 17
Mutation: TEK
cVM-IGA at Week 12:
Very Much Improved (+3)

Baseline



Week 12

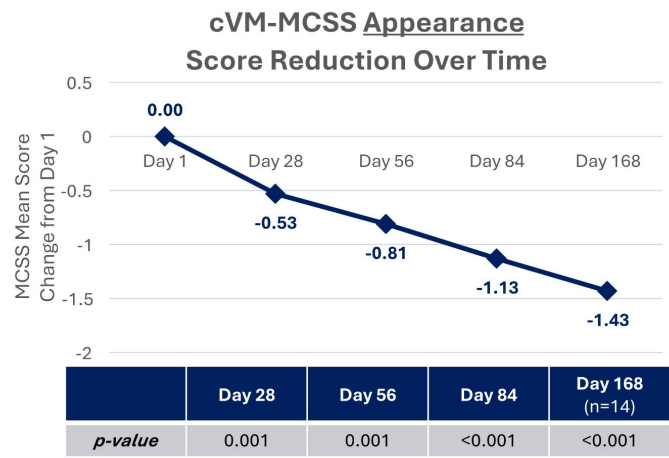
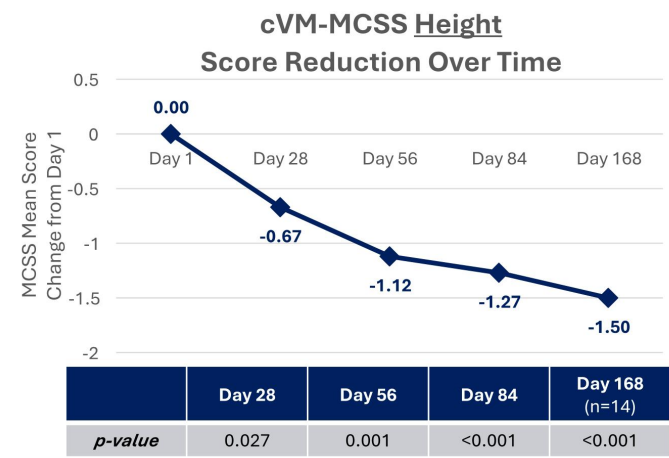


Participant Qualitative Interview: “I’ve definitely noticed some improvements...it’s definitely had a positive effect...It’s more comfortable to wear a bra now...I’ve had less pain in that specific area”

cVM Clinical Signs: Height/Engorgement and Appearance Results Through 24 Weeks

New 24-week data on two of the key clinical signs measured in the TOIVA trial: height/engorgement and appearance

- Data on bleeding, another key clinical sign in cutaneous venous malformations, were recently presented at the 83rd Annual Meeting of the Society for Investigative Dermatology



cVM-MCSS (cutaneous VM multi-component static scale) Height and Appearance are rated on 5-point scales ranging from 1 to 5; negative values indicate improvements from Day 1



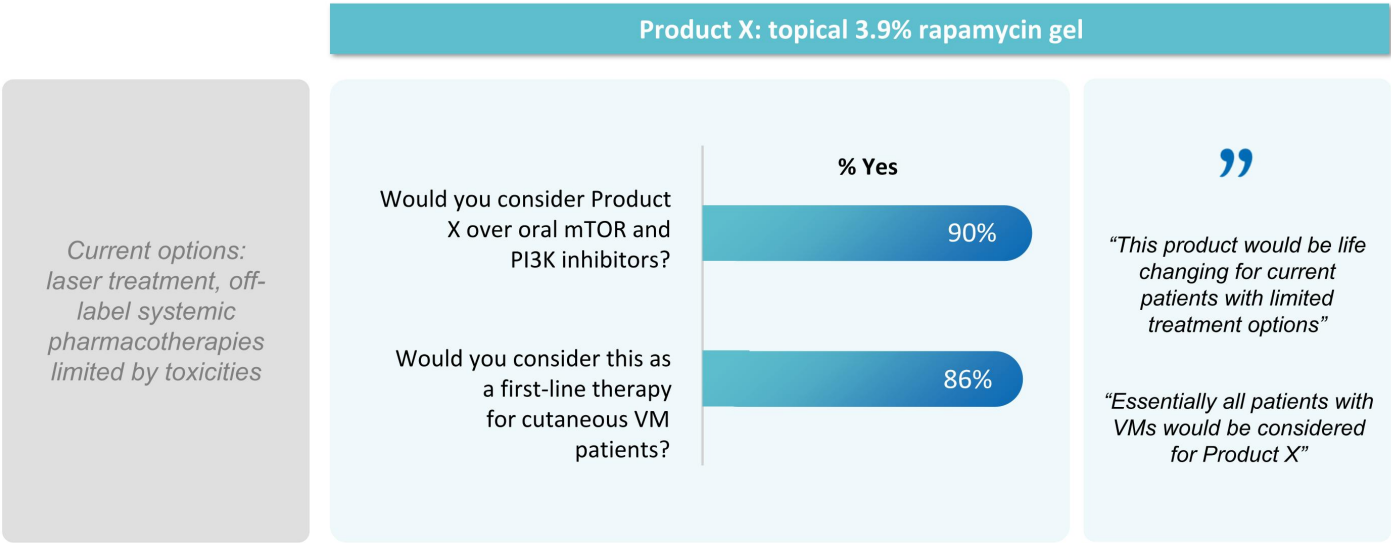
Phase 2 Results: Safety and Tolerability

- QTORIN™ rapamycin was generally well-tolerated, similar to previous clinical trials
- Most common Treatment-Emergent Adverse Events were application site reactions (erythema, 25%)
- All Treatment-Related Adverse Events were moderate or mild (no severe events)
 - Majority of AEs were mild
 - No SAEs related to study drug
 - No unexpected AEs

Rapamycin levels were below the lower limit of quantification (2 ng/mL) in systemic circulation on a standard lab assay for all participants at all timepoints in the study

Significantly below 5 ng/mL which is the lower boundary where rapamycin begins to exert immunosuppressive effects

Market Research in Cutaneous VMs (Sept 2024): Strongly Indicates QTORIN™ Rapamycin’s Potential as First Line Therapy



Survey of 50 high-volume dermatologists and hematologists with an average of 10.6 cutaneous VM patients seen per month



QTORIN™ 3.9% RAPAMYCIN

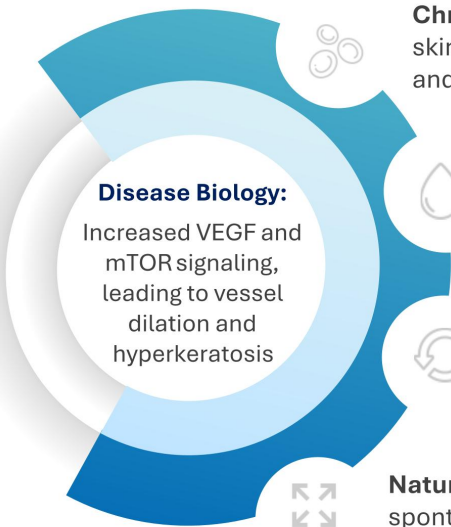
FOR

Clinically Significant Angiokeratomas

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Clinically Significant Angiokeratomas: Superficial Lymphatic Malformations

Palvella’s focus to include Fordyce, Solitary, Mibelli, and Circumscriptum subtypes



Wang et al., *Journal of Cutaneous Pathology*, (2014); Trindade et al., *Am J Dermatopathol*, (2014); Prindaville et al., *Pediatric Dermatology*, (2017); Singh et al, *Indian Journal of Dermatology*, (2023); Caraffa et al, *International Journal of Infection*, (2025); Molla, *Clinical, Cosmetic and Investigative Dermatology*, (2024). Ivy H, Julian CA. Angiokeratoma Circumscriptum. Treasure Island (FL): StatPearls Publishing; 2025 Jan; Lapa et al., *Journal of Cutaneous Medicine and Surgery*, (2025).
1. Clarity Pharma research (July 2025), n=643 physicians surveyed.

> 50k patients

ESTIMATED DIAGNOSED IN THE U.S.¹



No FDA-approved therapies

*Pipeline-in-a-product:
sNDA planned*

**Phase 2 trial initiated April 2026
ahead of schedule**

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QTORIN™ PITAVASTATIN

FOR

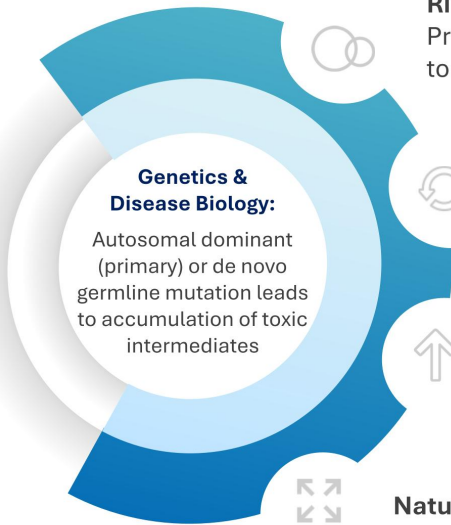
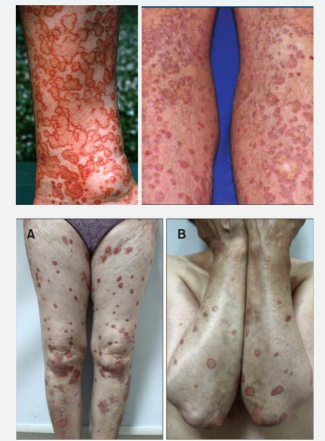
Disseminated Superficial Actinic Porokeratosis

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Disseminated Superficial Actinic Porokeratosis (DSAP): Chronic, Pre-Cancerous, and Progressive

> 50k patients

ESTIMATED DIAGNOSED IN THE U.S.¹



Risk of malignant transformation:

Premalignant disease with transformation to non-melanoma skin cancers²

Significant impact to quality of life:

clinical signs include skin disfigurement, burning, and persistent itch

Persistent and extensive:

Clonal proliferation of abnormal keratinocytes leads to increased number and size of lesions

Natural history: Spontaneous regression is extremely rare²

No FDA-approved therapies

Phase 2 trial initiation expected
2H 2026

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Unmet Need for First FDA-approved Topical Mevalonate Pathway Inhibitor for DSAP

Oral statins are not a viable therapeutic option in DSAP:

High first pass metabolism and/or sub-therapeutic biodistribution to the skin

Topical cholesterol/lovastatin for the treatment of porokeratosis: A pathogenesis-directed therapy

Lili Atzmony, MD,^{a,b,c} Young H. Lim, BS,^{a,b,d} Claire Hamilton, MD, PhD,^a Jonathan S. Leventhal, MD,^a Annette Wagner, MD,^{e,f} Amy S. Paller, MD,^{e,f} and Keith A. Choate, MD, PhD^{a,b,h,d}
New Haven, Connecticut; Tel Aviv, Israel; and Chicago, Illinois

Proof-of-concept study, demonstrating a plausible mechanistic approach

Recently published systematic review in *Clinical and Experimental Dermatology* (Martini et al, 2026) included **24 case studies** of off-label use of topical statin therapy in porokeratosis...

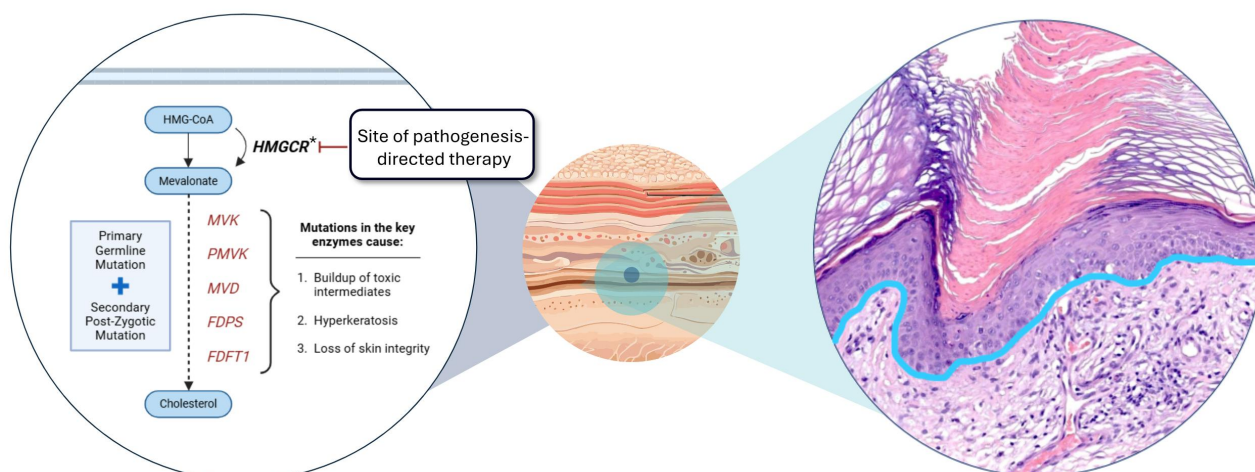
...however, today **poor patient outcomes persist** due to lack of access and known variability in unapproved formulations which can limit safety, efficacy, and quality

Significant need for an FDA-approved topical mevalonate pathway inhibitor

Clear Biology: Targeting the Causal Mevalonate Pathway

Target: Mevalonate Pathway

Tissue: Epidermis & Dermis

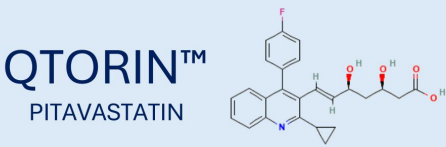


An on-target, in-tissue approach could result in significant clinical improvement

QTORIN™ Pitavastatin: On Target, In Tissue

Using QTORIN™, we considered and tested a wide range of mevalonate pathway inhibitors

Molecule	Potency	Optimal Skin PK	Stability
Pitavastatin	✓	✓	✓
Mev. Inhibitor 2	Did not meet some or all pre-defined target product attributes		
Mev. Inhibitor 3			
Mev. Inhibitor 4			
Mev. Inhibitor 5			
Mev. Inhibitor 6			
Mev. Inhibitor 7			



- **Pitavastatin is an FDA-approved next-generation oral statin** for patients with primary hyperlipidemia and mixed dyslipidemia
- **Superior inhibition of the mevalonate pathway compared to all molecules evaluated**
- **Key characteristics:**
 - Payload: > 2% concentration achieved
 - Dermal penetration: *in vitro* penetration test confirms > IC90
 - Low systemic absorption
 - Encouraging preliminary drug stability
 - IP: Filed formulation & method of use IP and licensed Yale IP



QTORIN™

Platform

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QTORIN™: New Product Development Engine



DAVID OSBORNE, PhD
Chief Innovation Officer

- **VALIDATION OF QTORIN™ PLATFORM**

Two positive clinical study readouts (Phase 3 SELVA trial and Phase 2 TOIVA trial results)

- **SCALING OF PIPELINE WITH NEW QTORIN™ PROGRAMS**

Rapidly advancing and testing multiple molecules through QTORIN™ platform in capital- and time-efficient manner

- **PLANNING TO PURSUE PLATFORM DESIGNATION**

We expect to apply for FDA's Platform Technology Designation Program following QTORIN™ rapamycin's targeted approval in 2027

We plan to announce one new QTORIN™ program and one new QTORIN™ rapamycin indication later this year

Finance

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Well-Capitalized with High-Quality Investor Participation in \$230mm Oversubscribed Feb. 2026 Financing Following Positive SELVA Data

\$262 million

3/31/26 cash

Potential to Fund Through:

- NDA filing, FDA approval, and, if approved, U.S. launch for QTORIN™ rapamycin in microcystic LMs
- NDA filing for QTORIN™ rapamycin in cutaneous VMs
- Multiple Phase 2 data readouts from pipeline programs

QTORIN™ + 505(b)(2) + rare disease focus offers potential for attractive ROI

What Sets Palvella Apart: Building The Leader in Rare Skin Diseases and Vascular Malformations

Positive Phase 3 data in microcystic lymphatic malformations, focused on NDA rolling submission and potential U.S. commercial launch

QTORIN™ rapamycin: potential to be first approved therapy and SOC in U.S. for microcystic LMs, cutaneous VMs, and angiokeratomas

U.S. commercial opportunity: multi-billion dollar TAM in mLMs, with potential to expand addressable pool of patients by 10x

Deep pipeline of rare disease therapies: six diseases anticipated by year end 2026

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**Striving to be
first for rare
disease patients**

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Thank You

Striving to be first for rare disease patients

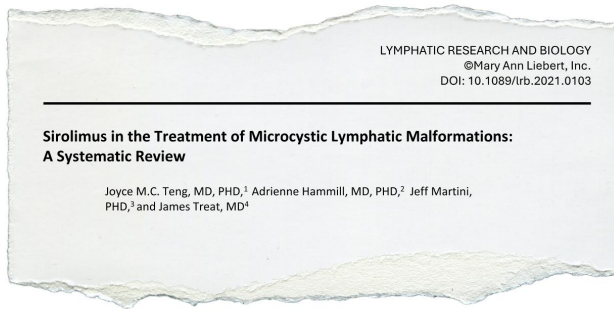
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52

A 34-year, 28-subject study confirmed no spontaneous regression

Types	Microcystic
Subtotal	28
Sex (F:M)	14:14
Age (y), mean $\pm$ SD	0.89 $\pm$ 1.4
Maximum diameter (cm), mean $\pm$ SD	—
Spontaneous regression	
Positive	0
Negative	28

Regulatory: Real-world Evidence to Support NDA Submission

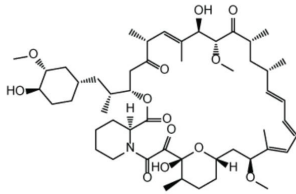


"Micro LMs represent therapeutically challenging congenital vascular lesions. There is no universally accepted gold standard of care and there are no FDA approved therapies...this review examines clinical data over the last 10 years on the role of sirolimus [rapamycin]...a total of 16 studies were identified...clinically meaningful, long-term improvement (up to 3 years) was noted...however, developing a commercial topical sirolimus formulation faces important challenges."



"Sirolimus [rapamycin] is the disease-modifying treatment of choice. It should be started early in life (early childhood) to prevent the increase in volume of the LM."

54



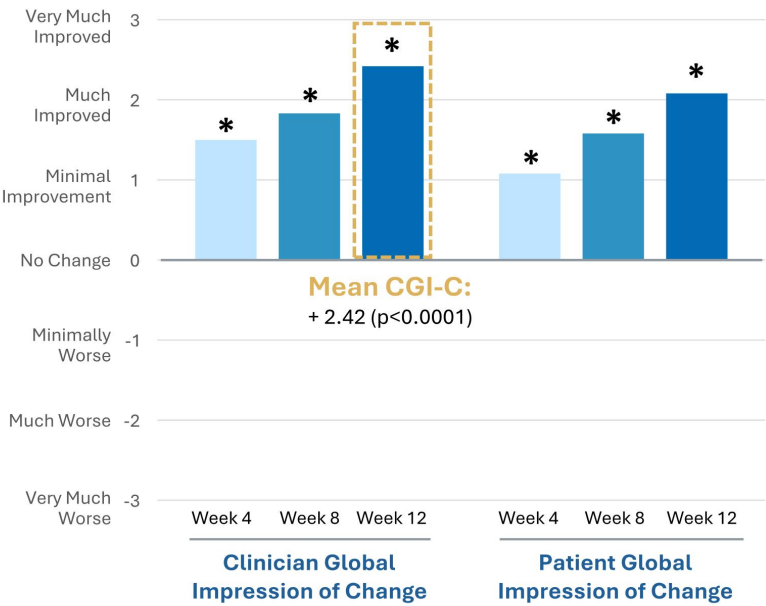
3.9% concentration enabled through synergistic multi-excipient anhydrous solubilization system

Elevated thermodynamic activity drives rapamycin vehicle release and skin bioavailability

Adherence-optimized vehicle designed for chronic dosing in pediatric and adult populations

Phase 2: Clinically Meaningful, Statistically Significant Improvements

n=12; QD dose



Statistically significant across key clinician-assessed individual signs of microcystic LM at week 12

- Height (p<0.0001)
- Leaking (p<0.005)
- Bleeding (p<0.05)
- Erythema (p<0.005)
- Hyperkeratosis (p<0.005)

- 100% of participants were either “Much Improved” or “Very Much Improved” on CGI-C after 12 weeks of treatment
- Palvella was subsequently granted FDA Breakthrough Therapy Designation based on this data

selva: QTORIN™ Rapamycin Exceeded Upside Case Profile

Upside Target Clinical Profile	SELVA Outcome
Statistically significant primary endpoint with mean mLM-IGA of $\geq +1.5$ at Week 24	 Highly statistically significant with mean mLM-IGA of +2.13 at Week 24 ($p < 0.001$)
Statistical significance on independent, blinded key secondary endpoint	 Highly statistically significant ($p < 0.001$), including on all three clinical signs: vesicle appearance, height, leaking/bleeding
Rollover into extension period in line with best-in-class drugs for rare diseases	 98% of Week 24 completers (43/44) rolled over to Extension period
Safety profile: well-tolerated and similar to previous clinical trials	 Well-tolerated across both adult and pediatric patients, supporting chronic administration

Note: Data analyzed per statistical analysis plan; non-completer data handled via multiple imputation per statistical analysis plan; endpoints tested sequentially according to pre-specified hierarchical testing; statistical significance ($p < 0.05$). Week 24 completers included 43 participants ≥ 6 years old and 1 participant 3-5 years old.

Phase 3 SELVA: Baseline Characteristics

	ITT Population (n=49) ¹
Age, Mean [Range]	19.4 [6-57]
Sex M:F	24:25
Prior Medical Interventions for mLM ²	34 (69%)
Laser	17 (35%)
Sclerotherapy	14 (29%)
Surgery	13 (27%)
Topical Sirolimus [Rapamycin]	13 (27%)
Oral Sirolimus [Rapamycin]	2 (4%)

57 1. 51 participants entered Baseline period; 50 dosed with QTORIN™ rapamycin (49 participants ≥6 years old = ITT population; 1 participant 3-5 years old included in safety database). 2. Percentages may not sum to 100% due to some patients having more than one intervention.

SELVA: All Additional Secondary Endpoints Achieved

	Mean Change at Week 24 (95% CI)	p-value
Patient Global Impression of Change*	+1.9 (1.66, 2.16)	p<0.001
Live mLM-MCSS**	-4.6 (-5.20, -3.92)	p<0.001
Clinician Global Impression of Severity***	-1.7 (-1.91, -1.39)	p<0.001
Patient Global Impression of Severity***	-1.0 (-1.26, -0.74)	p<0.001

*Dynamic change scales (7-point scales ranging from "Very Much Worse" (-3) to "Very Much Improved" (+3); positive values indicate improvements from baseline)
**mLM-MCSS (Sum of three static severity scales: Height, Leaking/Bleeding, Vesicle Appearance: Each scale rated "Clear or Almost Clear" (1) to "Very Severe" (5); total score 3-15. Test baseline to Week 24 change; negative values indicate improvements from baseline)
***Static severity scales (5-point scales ranging from 1 to 5; negative values indicate improvements from baseline)

Multiple Studies Indicate At Least Half of Venous Malformation Cases Have Cutaneous Involvement

Percentage of venous malformation cases with cutaneous involvement

Evaluation of pain incidence due to venous malformation based on data from 85 institutions in Japan

Naoaki Rikihiisa, MD, PhD;^a Sadanori Akita, MD, PhD;^b Keigo Osuga, MD, PhD;^c Hidefumi Mimura, MD, PhD;^d Shunsuke Yuzuriha, MD, PhD;^e and Satoru Sasaki, MD, PhD.^f Ichihara, Fukuoka, Suita, Kawasaki, Matsumoto, and Sapporo, Japan

~47% of 2,075 cases

STUDY

Glomuvenous Malformation (Glomangioma) and Venous Malformation

Distinct Clinicopathologic and Genetic Entities

Laurence M. Boon, MD, PhD; John B. Mulliken, MD; Odile Enjolras, MD; Miikka Viskula, MD, PhD

~80% of 1,517 cases

STUDY

Coagulation Disorders in Patients With Venous Malformation of the Limbs and Trunk

A Case Series of 118 Patients

Elisabeth Macoyer, MD; Odile Enjolras, MD; Annouk Bischoff, MD; Jerome Perdu, MD; Michel Wassef, MD; Ludovic Drouot, MD

~65% of 118 cases

Commercial Opportunity for Clinically Significant Angiokeratomas

Estimated Diagnosed U.S. Prevalence

>50k clinically significant angiokeratomas in the U.S. based on nationally representative, blinded, real-world observational study conducted July 2025 (n=643 physicians)¹

Pricing

Anticipate drug pricing similar to QTORIN™ rapamycin for Microcystic LMs and Cutaneous VMs based on disease severity and lack of FDA-approved therapies

Market Research² (n=50 physicians)

96% would incorporate Product X (topical 3.9% rapamycin gel) into their practice

85% believe there is unmet need for a novel treatment across all subtypes

“A topical application that was basically asymptomatic in terms of its application...would be ideal for these intractable cases”

Attractive U.S. Commercial Opportunity for DSAP

>50k

diagnosed DSAP patients in the U.S. based on two sources (Clarity Pharma, n=277 physicians; Zagoras et al, 2023) and confirmed by KOL calls

Orphan
Pricing

anticipated based on disease severity and lack of FDA-approved therapies

100%

96%

Market research (n=55 physicians)¹:
of physicians would incorporate Product X (topical mevalonate pathway inhibitor) into their practice

of physicians would consider Product X as a first line therapy for DSAP patients