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First-in-disease therapies for patients with rare genetic skin diseases

Corporate Presentation
December 2024

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Building the leading therapeutics company focused on rare genetic skin diseases

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What Sets Palvella Apart

First-in-Disease Therapies

- Exclusively focused on developing transformational therapies for rare diseases with no FDA approved treatments

Rare Disease Expertise

- Team with expertise in rare disease drug development, including regulatory and patient interactions
- Proven track record building successful rare disease companies, including Insmed

Capital Efficiency

- Disciplined approach to operating business with our investors' capital top of mind

Late-stage Pipeline and Platform

- Lead product candidate, QTORIN rapamycin, in two ongoing studies: Phase 3 (microcystic LMs) and Phase 2 (cutaneous VMs)
- Versatile QTORIN platform with potential across rare diseases

Our Mission is to Serve Patients with Rare Diseases

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QTORIN™ Rapamycin: Landmark Phase 3 Study Sets Stage for Potential U.S. Launch

Highly statistically significant Phase 2 results in Microcystic LMs
100% of patients (n=12) “much” or “very much” improved with QTORIN™ rapamycin on Clinician Global Impression of Change ($p<0.0001$)

Phase 3 designed for success & expedited regulatory pathway
Single arm Phase 3 study coupled with FDA’s Breakthrough Designation; recently awarded FDA Orphan Product Grant up to $2.6mm to support Phase 3 study

U.S. peak sales potential > $1bn in two uncontested indications
Microcystic LMs (estimated > 30k U.S. diagnosed patients) & Cutaneous Venous Malformations (estimated > 75k U.S. diagnosed patients)

QTORIN™ platform is reproducible with broad applicability
To estimated 600 rare skin diseases, most of which have no approved therapies

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Striving to be first for rare disease patients

Sources: Primary prospective research conducted by Clarity Pharma and Sentero Pharma, claims data, Gallagher et. al. (2022).

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Recent listing on NASDAQ with funding from syndicate of leading healthcare-dedicated investors

Building leading company focused on rare genetic skin diseases

July 2024

Palvella Therapeutics announces reverse merger with Pieris Pharmaceuticals and $78.9 million PIPE

December 2024

Merger closes and Palvella debuts as publicly listed company (NASDAQ:PVLA)

Company has approximately $80.0 million of cash at close

Private Investors

BVF PARTNERS L.P.

CAMCapital CAXTON ALTERNATIVE MANAGEMENT

Ligand

Petrichor Healthcare Capital Management

SAMSARA BIOCAPITAL

Select New PIPE Investors

FRAZIER LIFE SCIENCES

ADAR1 Capital Management

BLUE OWL

DAFNA Capital Management, LLC

NANTAHALA CAPITAL MANAGEMENT, LLC

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OUR LEAD INNOVATION

QTORIN™ 3.9% RAPAMYCIN ANHYDROUS GEL

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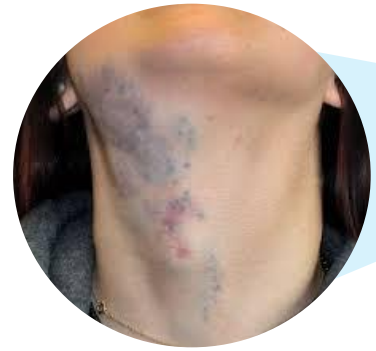
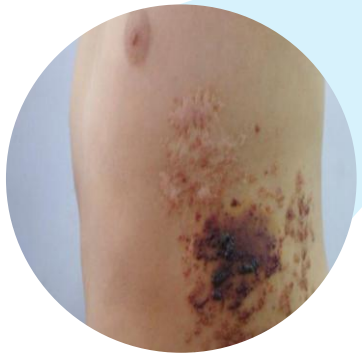
Broad Potential for mTOR Inhibition in Rare Skin Diseases

mTOR is a key driver for genetic skin diseases

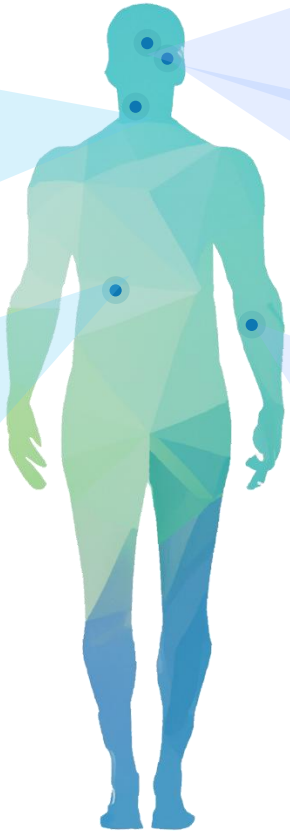
Lead Indications

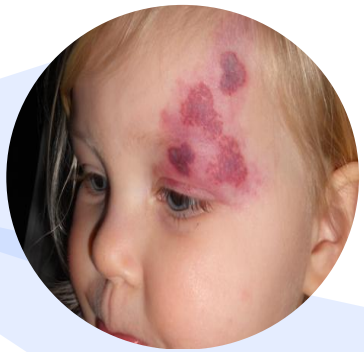


Venous Malformations[1]

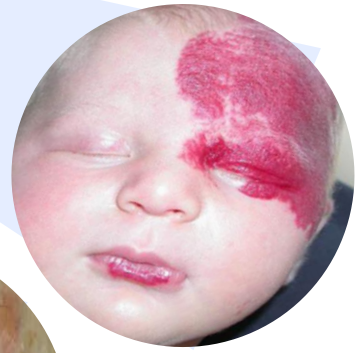


Microcystic LMs[2]

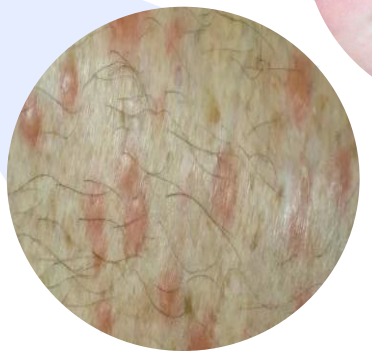




Refractory Vascular Tumors[3]



Capillary Malformations[4]



Cutaneous Sarcoidosis[5]

Subsequent Additional Potential Indications

1. Seront et. al., JCI Insight. (2023). 2. Adams et. al., Pediatrics. (2016). 3. Greenberger et. al., J Invest Dermatol. (2011). 4. Marqués et. al., J Am Acad Dermatol. (2015). 5. Redl et. al., Lancet Rheumatol. (2024).

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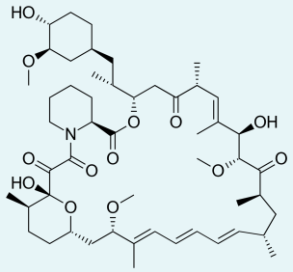
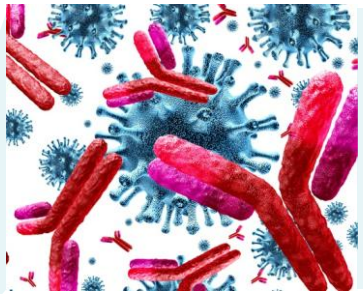
Systemic Rapamycin Limitations Restrict Use in Genetic Skin Diseases

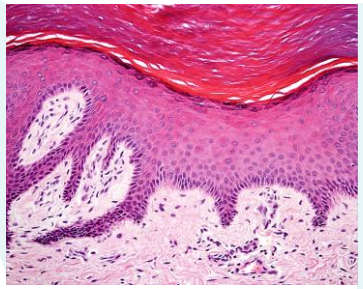
Systemic Rapamycin





Strong immunosuppressive activity
poses significant risks to patients with localized cutaneous disease[1]

Systemic toxicities
including stomatitis, hypertriglyceridemia, hypercholesterolemia, GI distress, peripheral edema, anemia, urinary tract infection[1]



Poor biodistribution to and within the skin[2]

1. Rapamune package insert. 2. Data on file; Kitayama et al., Journal of Derm. Science (2019)

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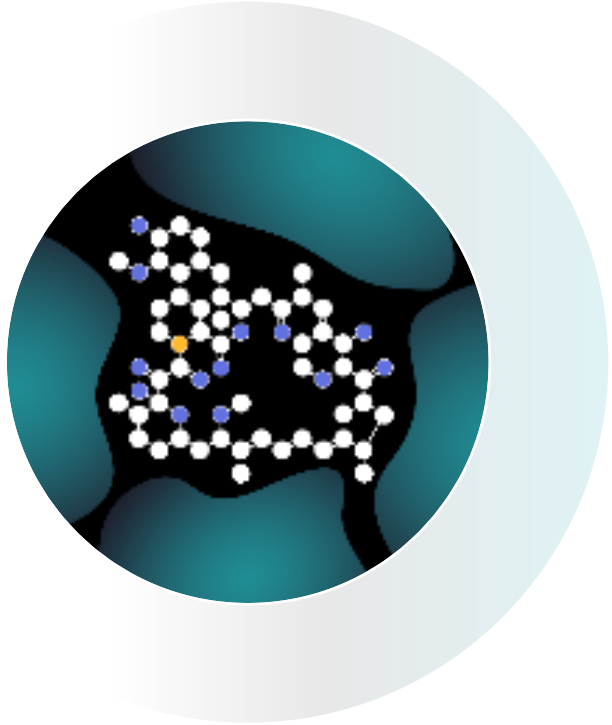
Our Innovation: QTORIN™ Platform

Reproducible platform for generation of novel topical product candidates for rare diseases



High payload capacity optimizes potential for therapeutic activity: Accommodates high API concentrations, i.e., 3.9% rapamycin

Delivery to dermis with limited systemic absorption: Delivers large molecular weight molecules to dermis while overcoming 500 Dalton Rule

Favorable patient tolerability: Precisely selected composition of inactive excipients enables chronic dosing for lifelong genetic diseases

Scalable cGMP process: Physical and chemical stability at room temperature providing for long-term shelf life

QTORIN™ product candidates eligible for composition IP on formulation

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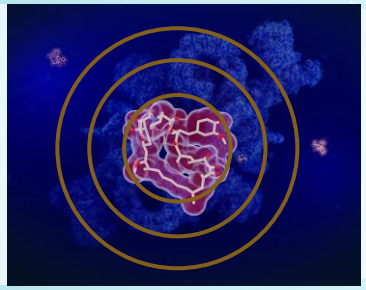
QTORIN™ 3.9% Rapamycin Anhydrous Gel

RAPAMYCIN

Direct mechanistic engagement of causal mTOR pathway

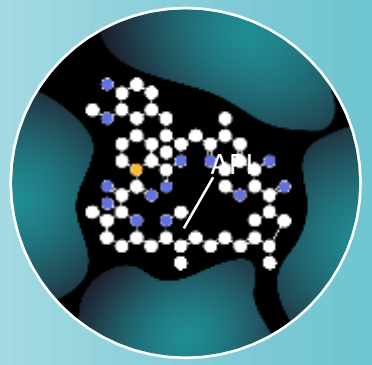


QTORIN™

1000x higher rapamycin levels at site of disease vs. systemic rapamycin[1]

TOPICAL

Limited-to-undetectable systemic absorption[2]



Granted U.S. patents through at least 2038

Stable at room temperature for > 2 years

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™ 3.9% RAPAMYCIN

FOR

Microcystic Lymphatic Malformations and Cutaneous Venous Malformations

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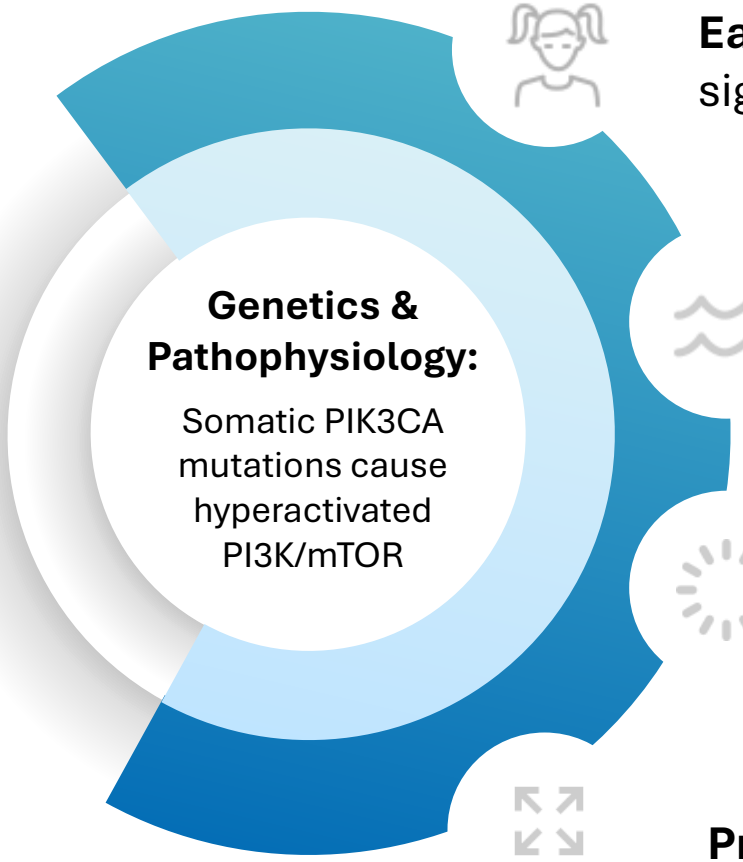
Microcystic Lymphatic Malformations: *Serious, Debilitating, and Lifelong*



Early onset: Present at birth and significant impact to adolescents

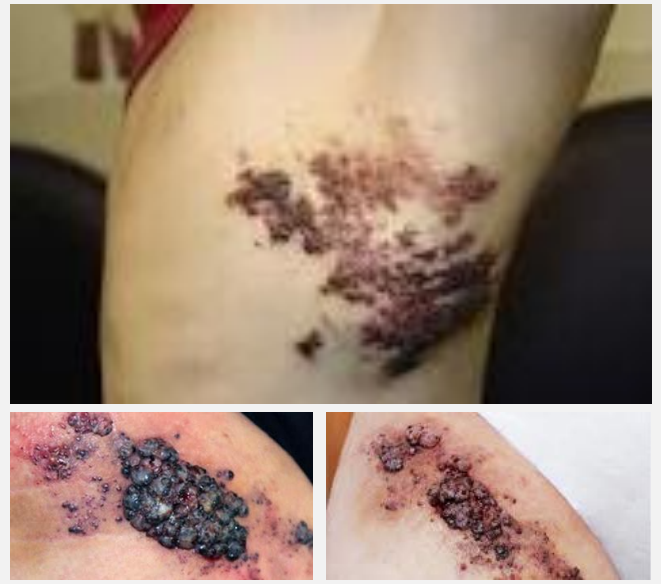
Lymphorrhea: Persistent discharge of lymphatic fluid through skin layers

Deep infections: Cellulitis and other serious infections

Proliferation of infiltrative lesions over time with no spontaneous resolution

> 30k patients

ESTIMATED DIAGNOSED IN THE US[1]



Leads to serious impact to quality of life and hospitalizations, with no FDA approved therapies

Current options: repeated surgeries, off label systemic pharmacotherapies limited by toxicities

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1. Gallagher et. al. (2022).

No Spontaneous Regression Well-Established in Microcystic LMs

OPEN

PRS GLOBAL OPEN ORIGINAL ARTICLE
Reconstructive

Spontaneous Regression of Lymphangiomas in a Single Center Over 34 Years

Motoi Kato, MD*
Shoji Watanabe, MD, PhD*
Reiko Kato, MD†
Hiroshi Kawashima, MD, PhD†
Takuya Iida, MD, PhD‡
Azusa Watanabe, MD, PhD*

Background: A lymphangioma, also called a lymphatic malformation, is a congenital condition that frequently occurs in young children. It is classified into 3 groups depending on the size of the cysts (macrocystic, microcystic, and mixed). Spontaneous regression occurs in some cases; however, the characteristics of patients who show regression have not been studied previously. Furthermore, the types and the timing of the initial treatment are still controversial. Therefore, we statistically analyzed the occurrence of short-term spontaneous regression, patient age at original occurrence, cyst types, cyst sizes, and cyst locations in patients diagnosed with peripheral localized lymphangiomas in a single children center over 34 years.
Methods: We retrospectively collected the data of 153 patients and reviewed the medical charts.
Results: Spontaneous regression occurred only in macrocystic or mixed type; regression was most frequent in patients who, at the time of onset, were more than 2 years old.
Conclusions: We concluded that elderly patients with macrocystic or mixed type lymphangioma may have to wait for treatment for over 3 months from the initial onset. Conversely, microcystic type could not be expected to show regression in a short period, and prompt initiation of the treatments may be required. The difference of the regression or not may depend on the characteristics of the lymph flow. *(Plast Reconstr Surg Glob Open 2017;5:e1501; doi: 10.1097/GOX.0000000000001501; Published online 25 September 2017.)*

MATERIALS AND METHODS

We retrospectively reviewed the medical charts of 501 patients who were diagnosed with lymphangiomas or lymphatic malformations in our hospital over 34 years (April 1983 to December 2016). Lymphangioma cases that showed peripheral localization and were observed for more than 3 months without medical or surgical intervention were included. The diagnosis was reconfirmed on the basis of radiological findings and the clinical course according to the vascular anomalies classification of the International Society for the Study of Vascular Anomalies.[1]

Patients diagnosed with lymphangiomatosis, Gorham disease, combined vascular anomalies (Klippel–Trenaunay syndrome, Proteus syndrome, and Maffucci syndrome), intraabdominal lesions, and/or intrathoracic lymphangiomas were excluded from this study. Additionally, patients who were misdiagnosed, those who did not undergo radiological assessments (ultrasound, computed tomography, or magnetic resonance imaging), those who were not followed for 6 months after onset, and those who were administered treatments for the lesions (medication, aspiration, sclerotherapy, and/or surgery) within 3 months after the original onset were excluded (Table 1; Fig. 1). Patients who were prescribed acetaminophen and/or antibiotics for pain and/or infection and those with peripheral lesions that connected to the intrapleural region were included.

Spontaneous regression was considered as an over 20% decrease in the lesion size over 3 months when compared with the size at the original onset. We analyzed the patient age at the original onset, original lesion size, and lesion location retrospectively. Congenital lesions were considered as having an onset at 0 years of age, even when diagnosed prenatally.

Statistical analyses involved the 2-sided *t* test for normally distributed data and the F-test for assessment of less than 5 patients. A receiver operating characteristic (ROC) curve was drawn using the SPSS software (IBM Corp., Ar-

*From the *Department of Plastic and Reconstructive Surgery, Lymph Clinic, Saitama Children's Medical Center, Saitma, Japan; †Department of Pediatric Surgery, Saitama Children's Medical Center, Saitma, Japan; and ‡Department of Plastic and Reconstructive Surgery, The University of Tokyo, Tokyo, Japan.*
Received for publication March 29, 2017; accepted July 26, 2017.

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Disclosure: *The authors have no financial interest to declare in relation to the content of this article. The Article Processing Charge was paid for by the authors.*

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

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

** Consistent with well-established history of PI3K Related Overgrowth Spectrum, which includes microcystic LM*
***Kato M et al., Plast Reconstr Surg Glob Open. 2017 Sep 25;5(9):e1501.*

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QTORIN™ Rapamycin: Phase 2 Study in Microcystic LMs

n=12; QD dose

James Treat, M.D.

Children's Hospital of Philadelphia

Joyce Teng, M.D., Ph.D.

Stanford MEDICINE

Steve Kempers, M.D.

Associated Skin Care Specialists
BOARD CERTIFIED DERMATOLOGISTS

Milton Waner, M.D.

vascular birthmark institute

Alison Small, M.D.

OHSU School of MEDICINE

Baseline
(4 weeks)

→

Single arm, QTORIN™ rapamycin treatment (QD)
(12 weeks)

Study Objectives: Safety and efficacy

Results

- Clinically & statistically significant on pre-specified global and individual endpoints
- Patient exit interviews and photographs align with clinical data

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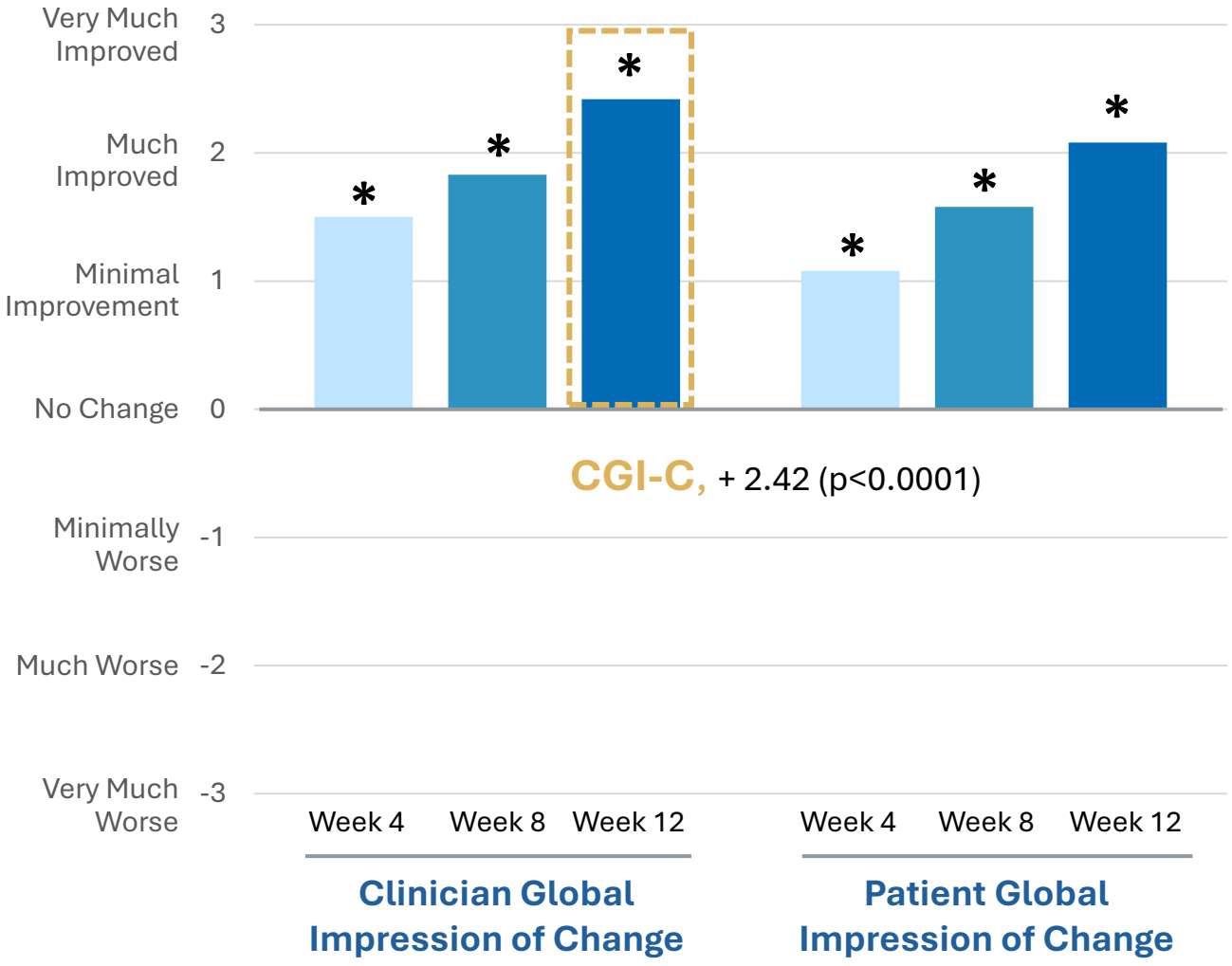
Phase 2: Clinically Meaningful, Statistically Significant Improvements



Individual Clinical Signs: Rapid Onset and Time Dependent Improvements

Statistically significant across key 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)

* = p-value <0.0001

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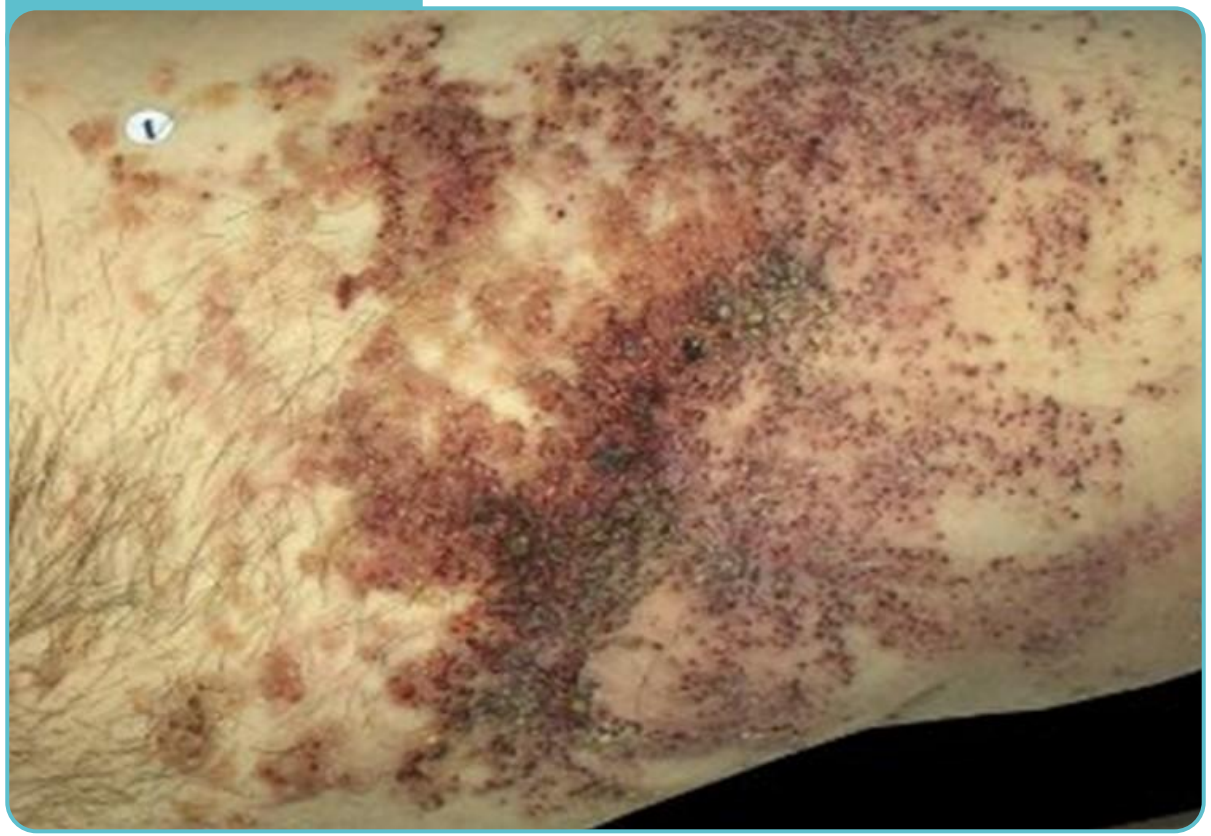
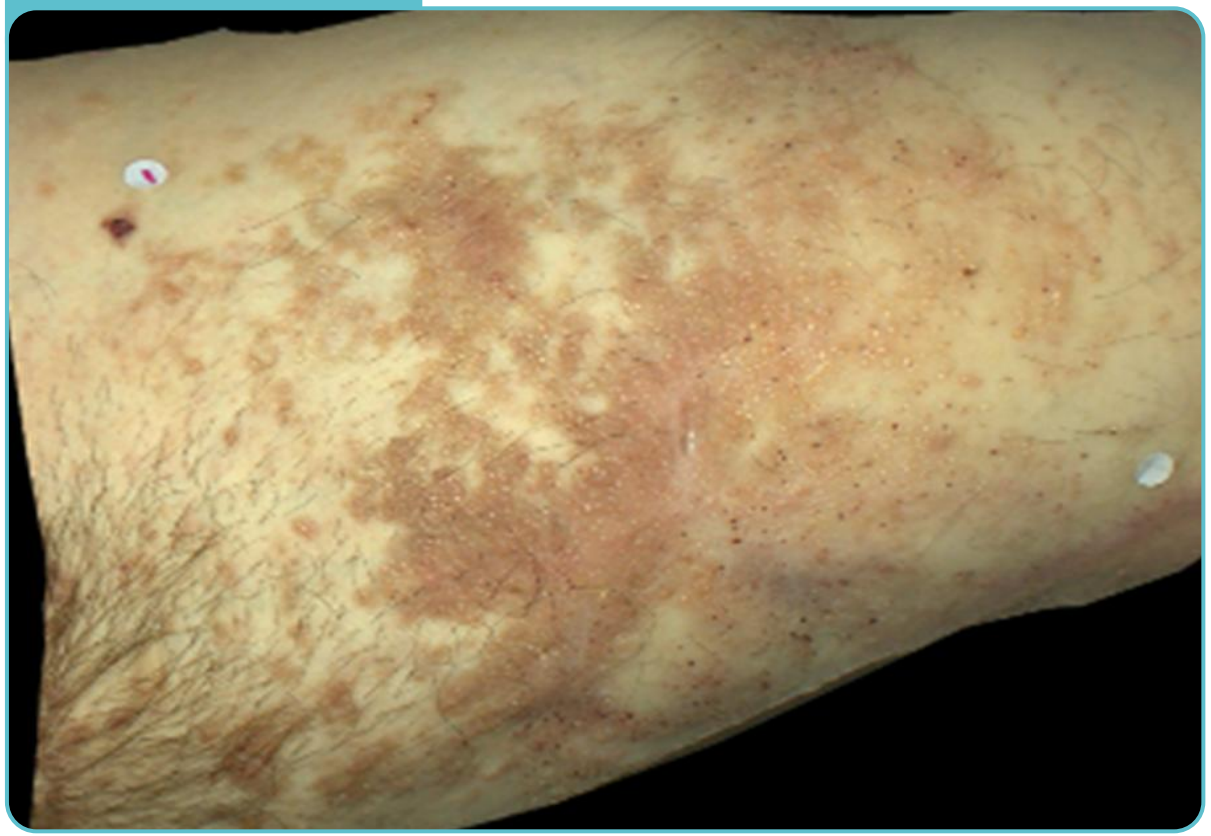
Phase 2 Results: Visible Improvement

Baseline



Week 12



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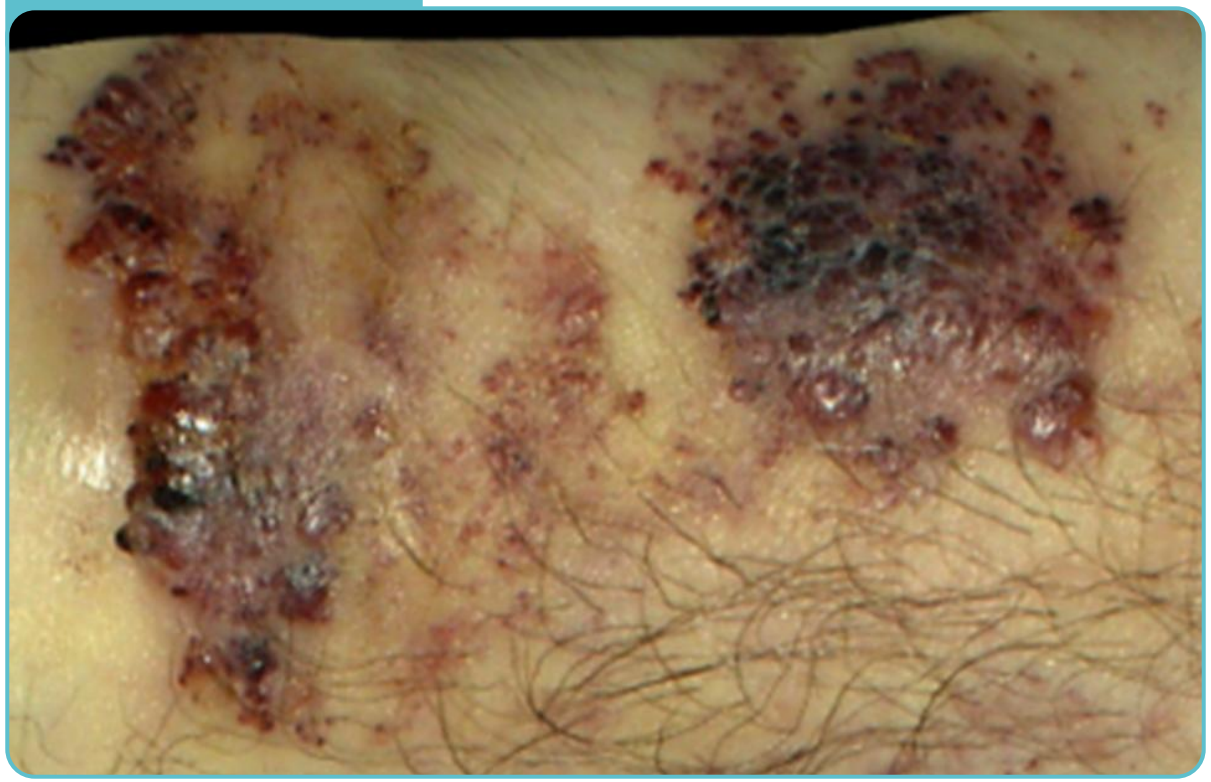
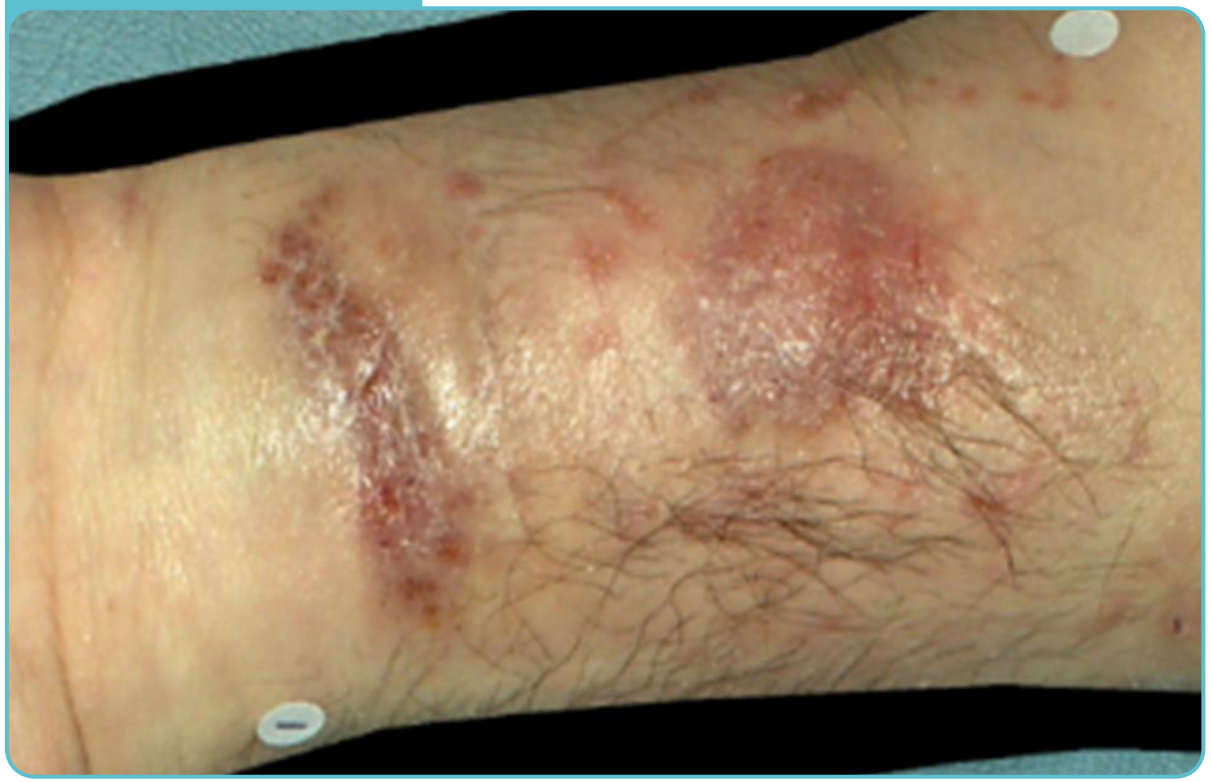
Phase 2 Results: Visible Improvement

Baseline



Week 12



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Microcystic Lymphatic Malformation: Phase 2 All Treatment-Related Adverse Events

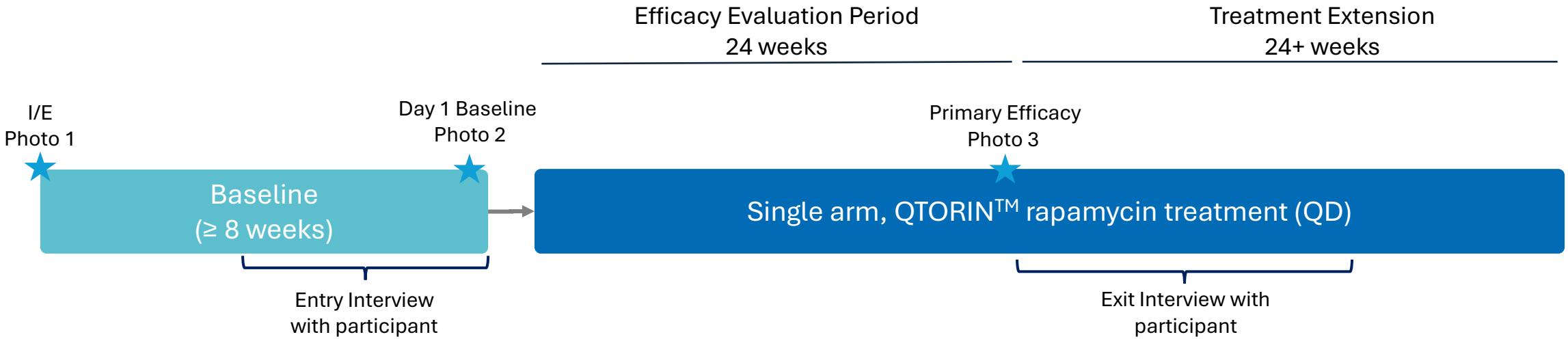
Low blood levels of rapamycin detected in some patients: 120.98 pg/mL (mean)

TREATMENT RELATED AES	RELATED ANY GRADE EVENTS (%, N=12)
Application site pain	3 (25)
Application site pruritus	3 (25)
Application site discharge	1 (8.3)
Application site erythema	1 (8.3)
Application site paraesthesia	1 (8.3)
Nodule	1 (8.3)
Eczema	1 (8.3)
Skin exfoliation	1 (8.3)
Diarrhea	1 (8.3)
Headache	1 (8.3)

- QTORIN™ rapamycin had favorable safety profile and was well tolerated
- All Treatment Related Adverse Events were moderate or mild (no severe events)
- No discontinuations due to AEs
- No unexpected AEs

SELVA Phase 3 Study: Single-Arm, Baseline-Controlled

n=40; QD dose



Primary Efficacy

- mLM-IGA, a 7-point clinician change scale

Key Secondary

- Blinded mLM Multi-Component Static Scale (mLM- MCSS)

Data anticipated Q1 2026

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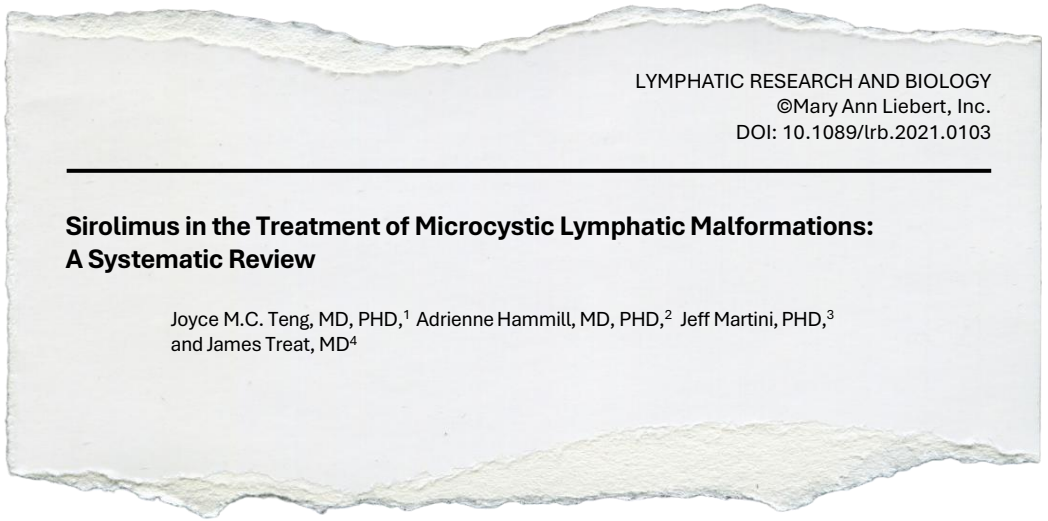
Real World Evidence and OUS Treatment Guidelines



LYMPHATIC RESEARCH AND BIOLOGY
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DOI: 10.1089/lrb.2021.0103

Sirolimus in the Treatment of Microcystic Lymphatic Malformations: A Systematic Review

Joyce M.C. Teng, MD, PHD,[1] Adrienne Hammill, MD, PHD,[2] Jeff Martini, PHD,[3] and James Treat, MD[4]

"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."

Leboulanger *et al.*
Orphanet Journal of Rare Diseases (2023) 18:10
https://doi.org/10.1186/s13023-022-02608-y

French national diagnosis and care protocol (PNDS, protocole national de diagnostic et de soins): cystic lymphatic malformations

Nicolas Leboulanger[1,2*], Annouk Bisdorff[3], Olivia Boccara[4], Anne Dompmartin[5], Laurent Guibaud[6], Christine Labreze[7], Jacques Lagier[8], Bénédicte Lebrun-Vignes[9], Denis Herbreteau[10], Aline Joly[11], Julie Malloizel-Delaunay[12], Arnaud Martel[8], Stéphane Munck[13], Frédérique Saint-Aubin[14] and Annabel Maruani[15,16]

"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."

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Regulatory Overview: NDA Submission Planned for 2026[1]

Phase 3 study in microcystic LMs ongoing; data expected in Q1 2026

Seeking **full FDA approval** based on clinical endpoints utilized in prospective Phase 2 and Phase 3 studies

505(b)(2) pathway leveraging **prior FDA approvals of rapamycin**

Rolling NDA submission with potential for six-month priority review planned for 2026

- Breakthrough Therapy Designation
- Fast Track Designation
- Orphan Drug Designation

1. NDA submission planned if Phase 3 study is successful.

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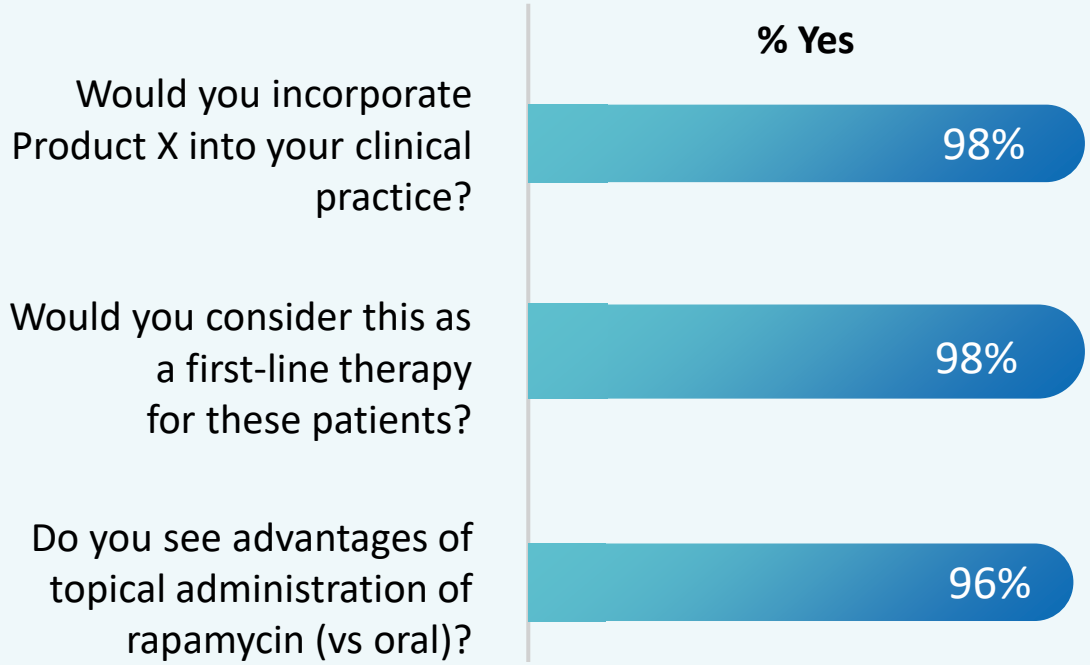
Market Research (May 2024): Strong Uptake in U.S. Anticipated

Product X: topical 3.9% rapamycin gel

Percent of my microcystic LM patients I would prescribe Product X:

75%



”

“It would be a first choice medical therapy”

“I believe patient acceptance would be great”

Survey of 52 high-volume dermatologists and hematologists (average of 11.7 cutaneous microcystic lymphatic malformation patients)

Source: May 2024, Medacorp.

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Favorable Market Dynamics Enable Potential for Self-Commercialization

1

First and only market position in a serious disease with no FDA-approved therapies

2

Relatively small number of US vascular anomaly centers (n=142), mostly within academic medical centers, streamline our commercial and medical affairs efforts

3

Well-defined disease with clear diagnostic parameters, including alignment from the International Society for the Study of Vascular Anomalies (ISSVA) on classification

4

Convenient at-home administration for patients and shelf-stable product not requiring cold chain distribution

5

Second indication (cutaneous VMs) has many synergies with Microcystic LMs

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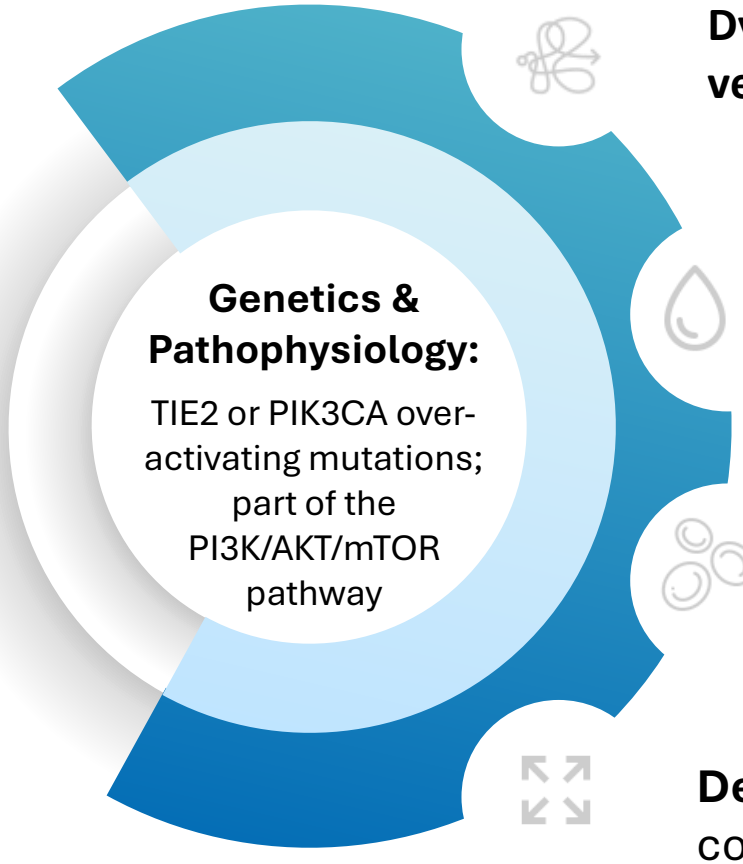
Cutaneous Venous Malformations: *Serious, High Unmet Need*



Dysregulated growth of malformed veins impacting the skin

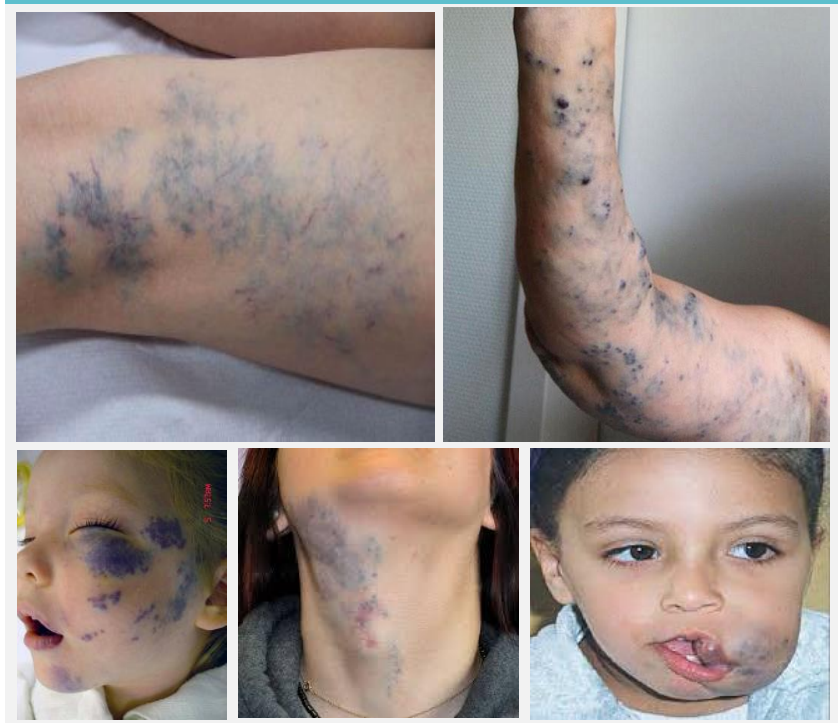
Hemorrhaging

Functional impairment

Deformity as lesions continue to grow

> 75k patients

ESTIMATED DIAGNOSED IN THE US[1]



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

Current options: laser treatment, off label systemic pharmacotherapies limited by toxicities

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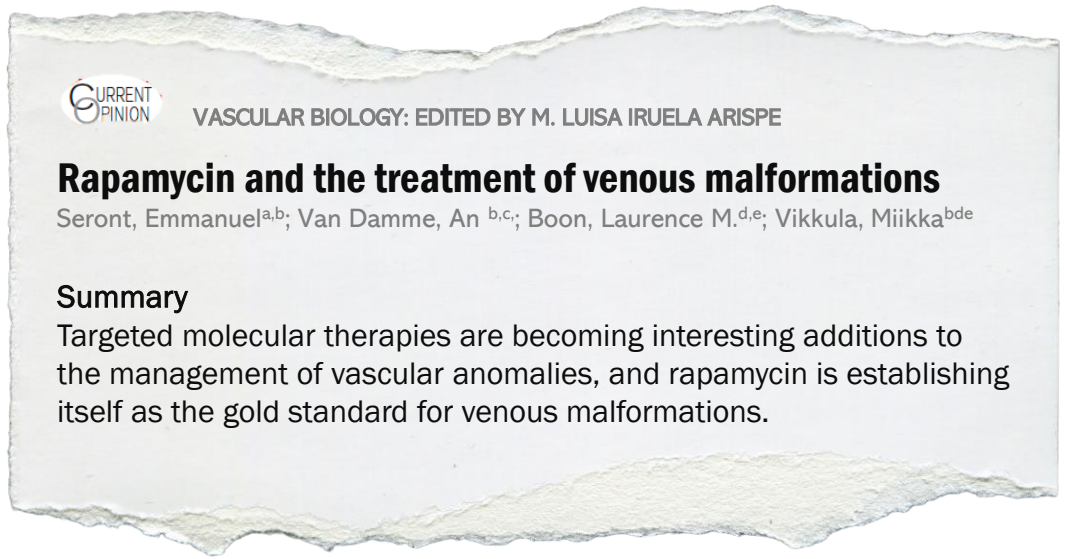
1. Primary prospective research conducted by Clarity Pharma.

Substantial Body of Research Supporting Rapamycin's Potential in VM Led to FDA Fast Track Designation for QTORIN™ Rapamycin



CURRENT OPINION

VASCULAR BIOLOGY: EDITED BY M. LUISA IRUELA ARISPE

Rapamycin and the treatment of venous malformations

Seront, Emmanuel[a,b]; Van Damme, An [b,c]; Boon, Laurence M.[d,e]; Vikkula, Miikka[bde]

Summary

Targeted molecular therapies are becoming interesting additions to the management of vascular anomalies, and rapamycin is establishing itself as the gold standard for venous malformations.

Summary Takeaways

1 **High potential of rapamycin**

"Rapamycin is the first targeted therapy that improves considerably the QoL of these patients"

2 **Need for topical therapies**

"Topical agents…could abolish the need for systemic treatments that have wider toxicity"

Current unmet need for targeted, localized therapy for Cutaneous Venous Malformations

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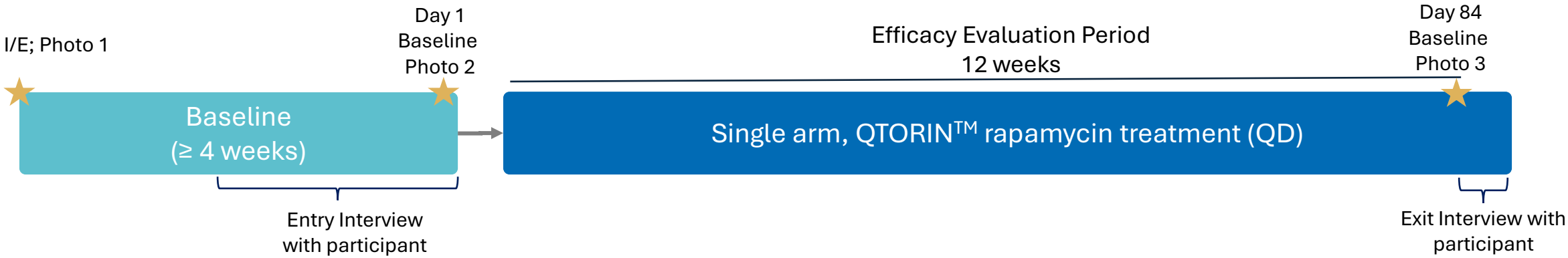
Cutaneous Venous Malformations Phase 2 Study

n=~15; QD dose



Safety

- Safety and tolerability

Efficacy

- Cutaneous venous malformation – investigators' global assessment (7-point clinician change scale)
- Cutaneous venous malformation - multicomponent static scale
- Other clinician and patient-reported outcomes

Data anticipated Q4 2025

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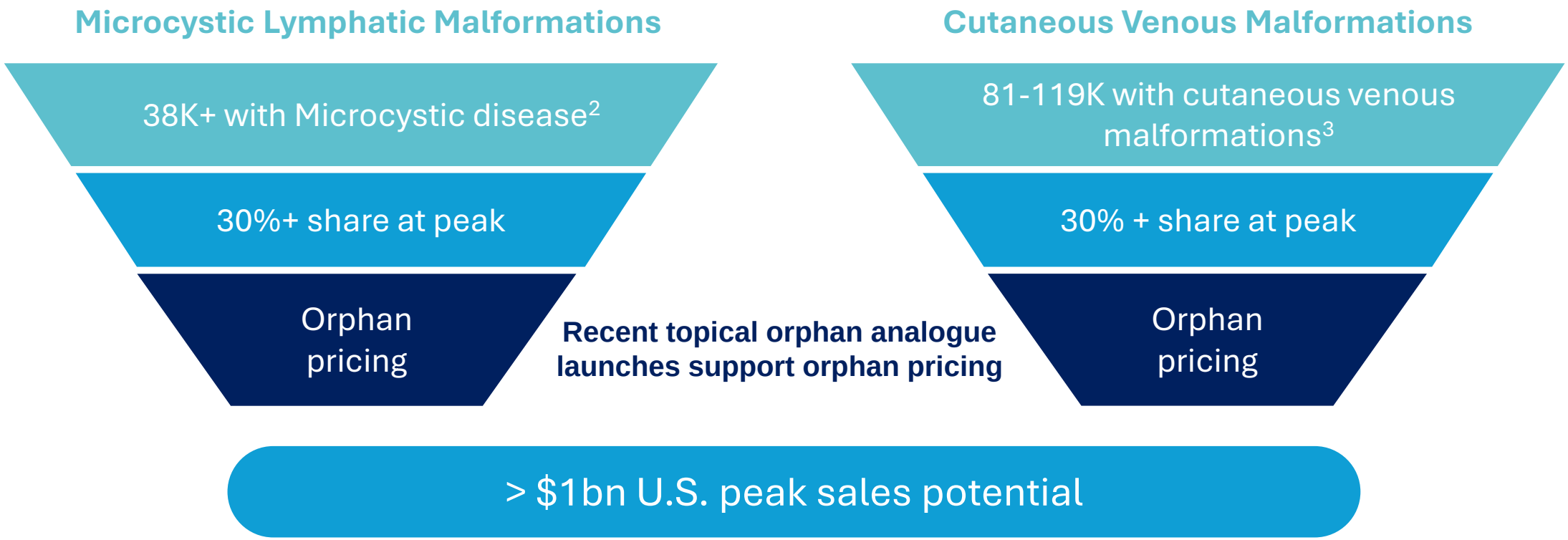
QTORIN™ Rapamycin: > $1B Peak Sales Potential in Five Years[1]

- **Recent (June 2024) claims data analysis confirms significant commercial opportunity in both diseases**



1. Primary prospective research conducted by Clarity Pharma and Sentero Pharma, claims analysis conducted by Trinity Research (June 2024).
2. Includes microcystic LM and mixed LM (patients with both microcystic and macrocystic disease).
3. Includes cutaneous only and mixed venous malformations.

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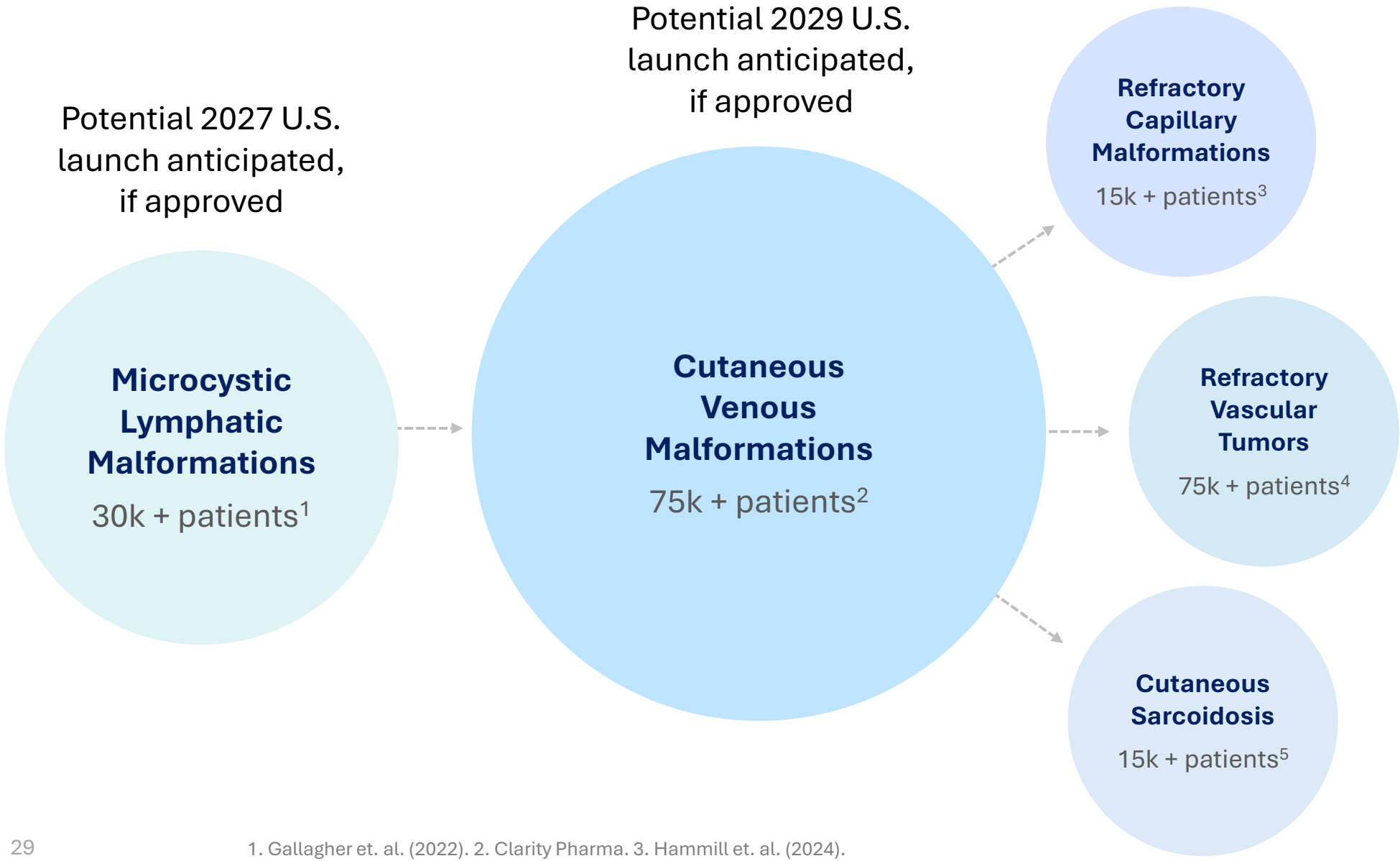
Pipeline in a Product for mTOR-driven skin diseases



Other mTOR-driven diseases, including skin cancers

1. Gallagher et. al. (2022). 2. Clarity Pharma. 3. Hammill et. al. (2024).
4. Anderson et. al (2016); Ji et. al. (2018). 5. Ezeh et. al. (2023)

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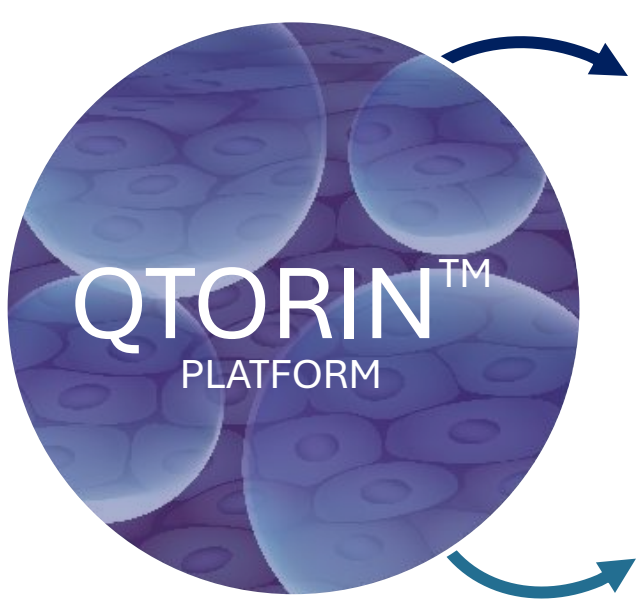
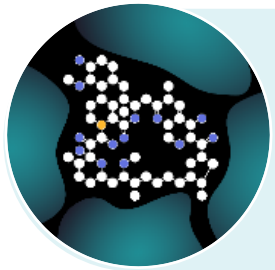
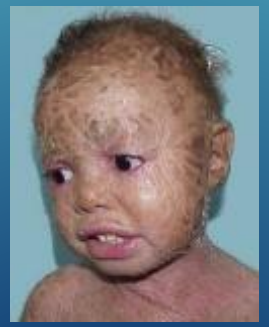
QTORIN™ Platform has Broad Potential Across Rare Dermatological Diseases





QTORIN™ Rapamycin
- Microcystic Lymphatic Malformations
- Venous Malformations
- Additional mTOR-driven indications

Additional QTORIN™-enabled products
- Multiple rare genodermatoses and molecules under evaluation



"We have begun to see interest from investors and companies in developing treatments for a rare disease such as epidermolysis bullosa, but there are many other diseases within dermatology that remain unaddressed"

John Doux, M.D., Barriers and Opportunities Across the Development Divide, *The Society of Investigative Dermatology*, 2015

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QTORIN™ Rapamycin: Landmark Phase 3 Study Sets Stage for Potential U.S. Launch

Highly statistically significant Phase 2 results in Microcystic LMs
100% of patients (n=12) “much” or “very much” improved with QTORIN™ rapamycin on Clinician Global Impression of Change ($p<0.0001$)

Phase 3 designed for success & expedited regulatory pathway
Single arm Phase 3 study coupled with FDA’s Breakthrough Designation; recently awarded FDA Orphan Product Grant up to $2.6mm to support Phase 3 study

U.S. peak sales potential > $1bn in two uncontested indications
Microcystic LMs (estimated > 30k U.S. diagnosed patients) & Cutaneous Venous Malformations (estimated > 75k U.S. diagnosed patients)

QTORIN™ platform is reproducible with broad applicability
To estimated 600 rare skin diseases, most of which have no approved therapies

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Striving to be first for rare disease patients

Sources: Primary prospective research conducted by Clarity Pharma and Sentero Pharma, claims data, Gallagher et. al. (2022).

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Thank You

Striving to be first for rare disease patients

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