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



QTORIN™ Docetaxel: Developing the First Potential FDA-Approved Therapy for Extramammary Paget's Disease

November 19, 2026

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QTORIN™ Docetaxel for Extramammary Paget's Disease (EMPD)

Third product candidate developed from the QTORIN™ platform

1

Serious, Rare, No FDA-approved Therapies

Debilitating, life-threatening genital and perianal skin cancer

2

QTORIN™ Innovation Applied to Clinically Validated Molecule

Builds on human clinical evidence of I.V. docetaxel to transform treatment paradigm to first-line, localized topical therapy

3

First for EMPD Patients

First potential FDA-approved therapy for an estimated >10k U.S. patients[1]

1. Internal analysis, Nicaise et al. (2024), and LapidusData.

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The Patient Perspective

Steve Schroeder,
Founder of myEMPD

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Living with EMPD: The Patient Perspective



Steve Schroeder

myEMPD

- Patient and founder of myEMPD
- Advocates for EMPD awareness, community, and research
- Brings the patient voice to disease research and therapeutic development
- Connects with patients and clinicians around the world

Life-threatening cancer affecting both women and men

Genital and perianal presentation

Excruciating and inadequate surgical procedures

High recurrence rates

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Disease Overview & Scientific Rationale

Dr. Seemal R. Desai

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Dr. Seemal R. Desai, Board-Certified Dermatologist



Seemal R. Desai, MD, FAAD

INNOVATIVE DERMATOLOGY

UT Southwestern Medical Center

- President of the American Academy of Dermatology (AAD), March 2024 - March 2025
- President, Global Vitiligo Foundation
- Clinical Associate Professor of Dermatology – University of Texas Southwestern Medical Center
- Specializes in the treatment of pigmentary disorders, rare diseases and inflammatory dermatoses

Note: Dr. Desai is a consultant to Palvella.

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EMPD is a Rare Genital and Perianal Cancer with No FDA-Approved Therapy

Today

Primary treatment is surgery


Scrotal EMPD[1]


Vulvar EMPD[2]


Perianal EMPD[3]

Opportunity

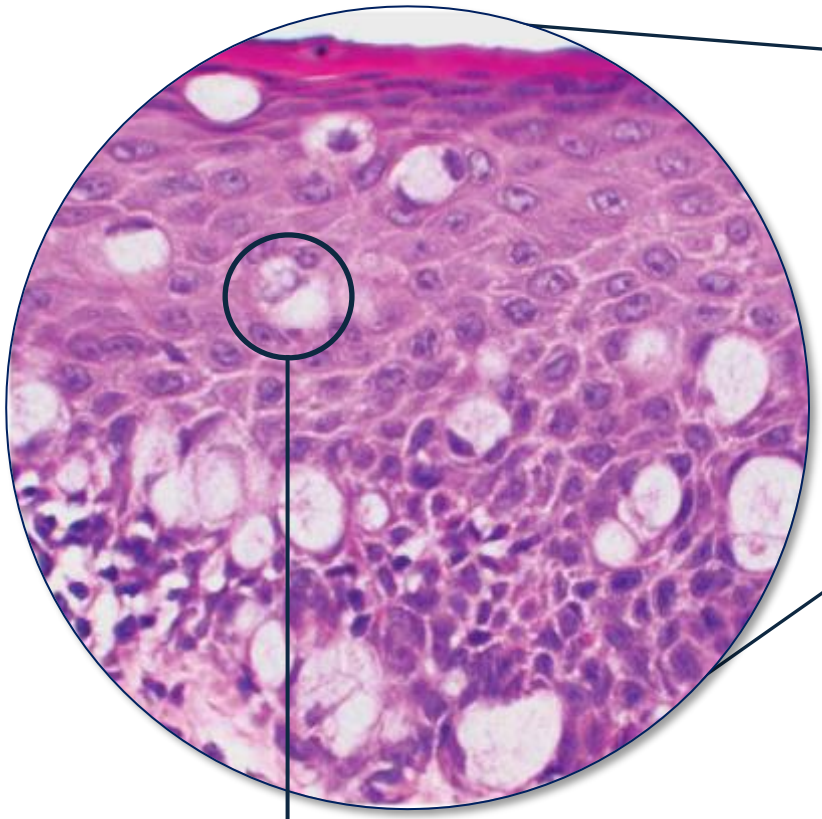
QTORIN™ docetaxel could transform the treatment paradigm to first-line topical therapy

1. Li et al. (2025) 2. Borghi et al. (2018) 3. Cavadas et al. (2022).

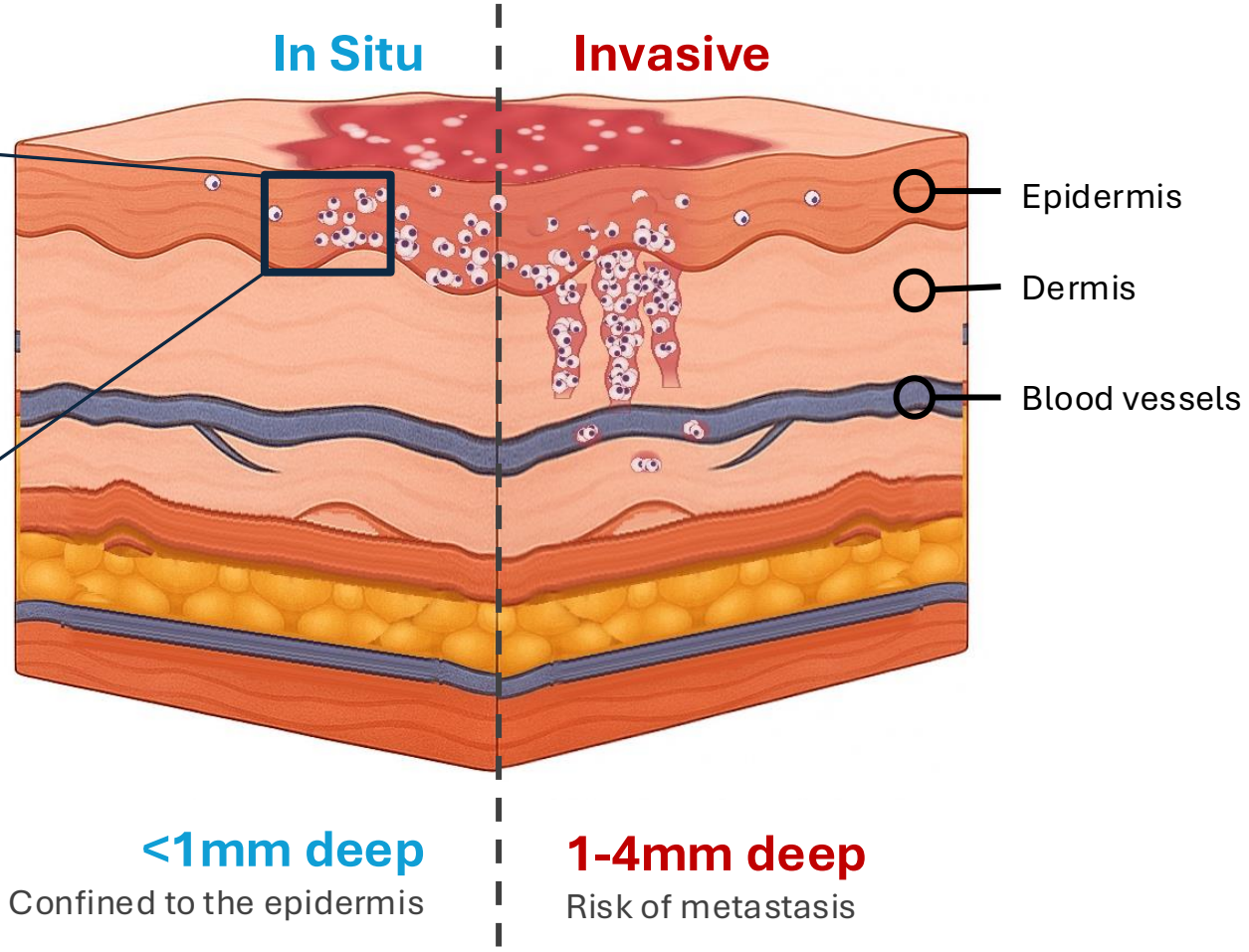
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EMPD Originates in Apocrine-Rich Skin and Progresses to Metastatic Disease

Paget Cells in Upper Epidermis[1]



Paget cell: substantial size, abundant cytoplasm, eccentric nucleus



<1mm deep
Confined to the epidermis

1-4mm deep
Risk of metastasis

1. Shaco-Levy et al. (2010).

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QTORIN™ Docetaxel

Dr. Jeff Martini, Chief Scientific Officer

Dr. David Osborne, Chief Innovation Officer

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Docetaxel: Human Clinical Evidence in EMPD



The Journal of Dermatology

ORIGINAL ARTICLE

Real-World Efficacy of Chemotherapy in Patients With Advanced Unresectable Extramammary Paget Disease: A Retrospective Multicenter Study of 138 Japanese Patients

Azusa Miyashita[1] | Satoshi Fukushima[1] | Koji Yoshino[2] | Hiroshi Kato[3] | Naoya Yamazaki[4] | Shusuke Kawashima[5] | Yuki Yamamoto[6] | Yasuhiro Nakamura[7] | Yukiko Kiniwa[8] | Shoichiro Ishizuki[9] | Takeo Maekawa[10] | Etsuko Okada[11] | Taku Fujimura[12] | Kazuyasu Fujii[13] | Yasuhiro Fujisawa[14] | Jun Asai[15] | Atsushi Otsuka[16] | Ikko Kajihara[1] | Jun Morinaga[17] | Shigeto Matsushita[18]

DOCETAXEL MONOTHERAPY (n=93)[1]

51.6%
ORR

52.7%
≥Grade 3 neutropenia

24.7%
discontinued due to adverse events

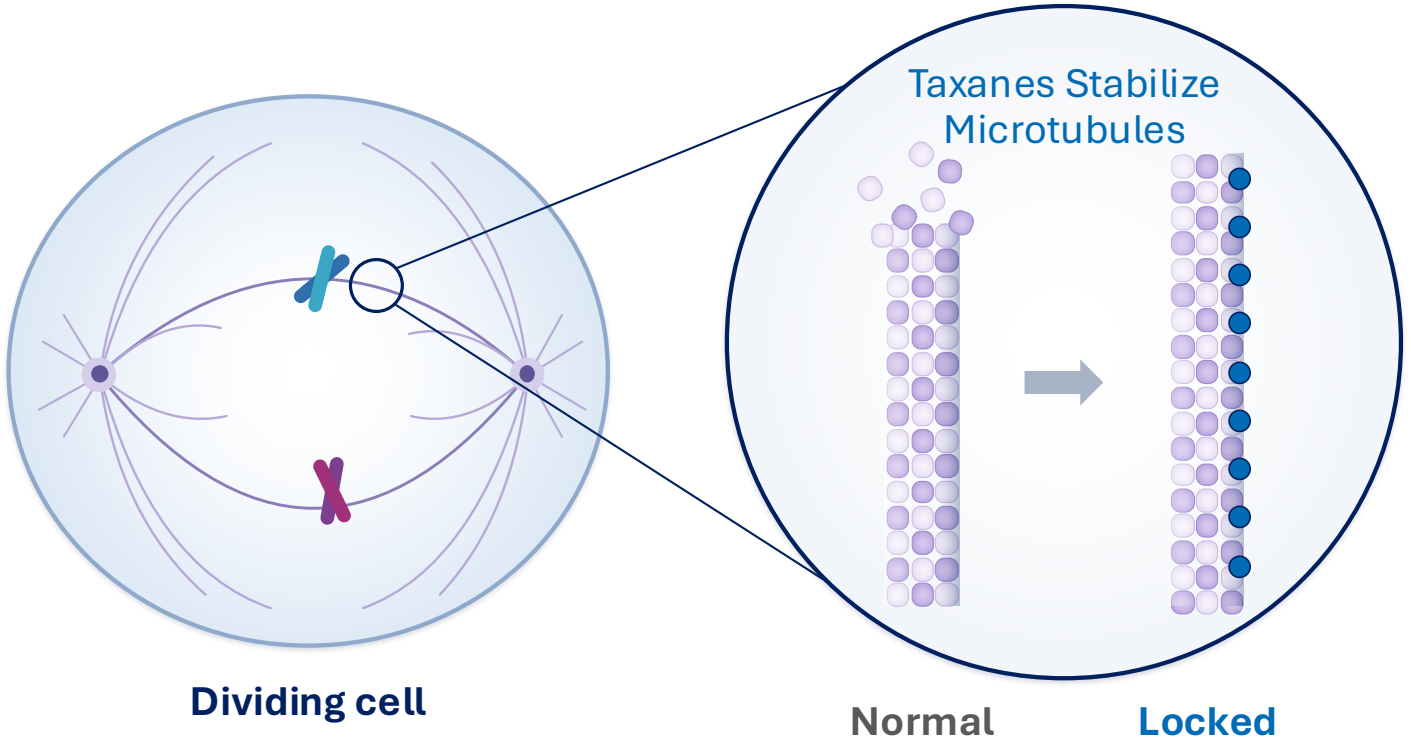
A large and growing real-world evidence base, including over 30 publications, supports docetaxel's clinical benefit in EMPD[2]

1. Miyashita et al. (2026) 2. Docetaxel has not been approved by the FDA for the treatment of EMPD.

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Docetaxel: An Established and Potent Anti-Cancer Agent

Locks microtubules in place, stopping dividing cells such as Paget cells



Normal: microtubules assemble and break down so the cell can divide

Locked: docetaxel stabilizes them, so division halts and the cell dies[1]

- **Potent and known pharmacology**
- **Blocks cell division**
- **Limited by I.V. toxicity**

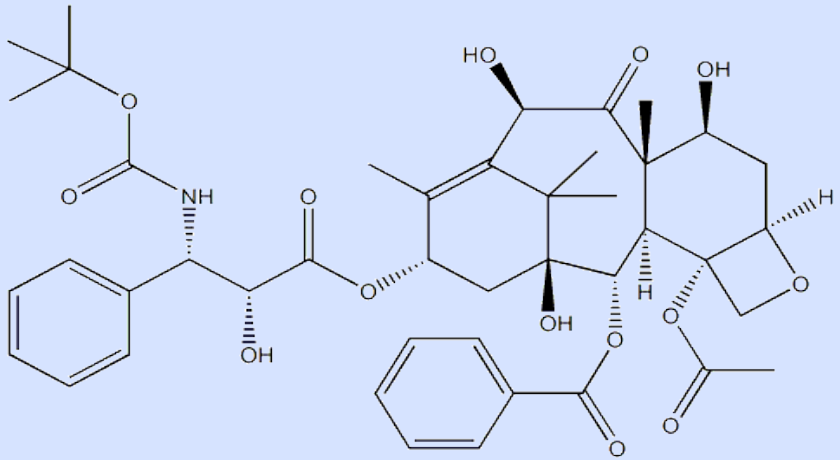
1. Hernandez-Vargas et al. (2007).

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QTORIN™ Docetaxel: Innovation Designed to Overcome Significant Formulation Barriers

By addressing docetaxel's formulation challenges,
QTORIN™ is designed to unlock its clinical and commercial potential in EMPD

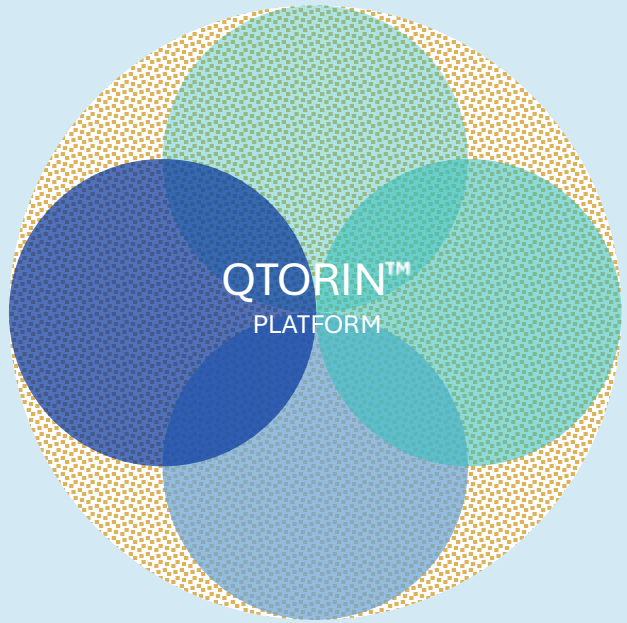
Docetaxel: 807.9 Da



Hydrophobic

Poor Skin Penetration

Unstable



Skin-Targeted

Stable

Tunable Dosing

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QTORIN™ Docetaxel: Progressing Toward First-in-Human Studies

Using QTORIN™, we considered and tested multiple taxanes

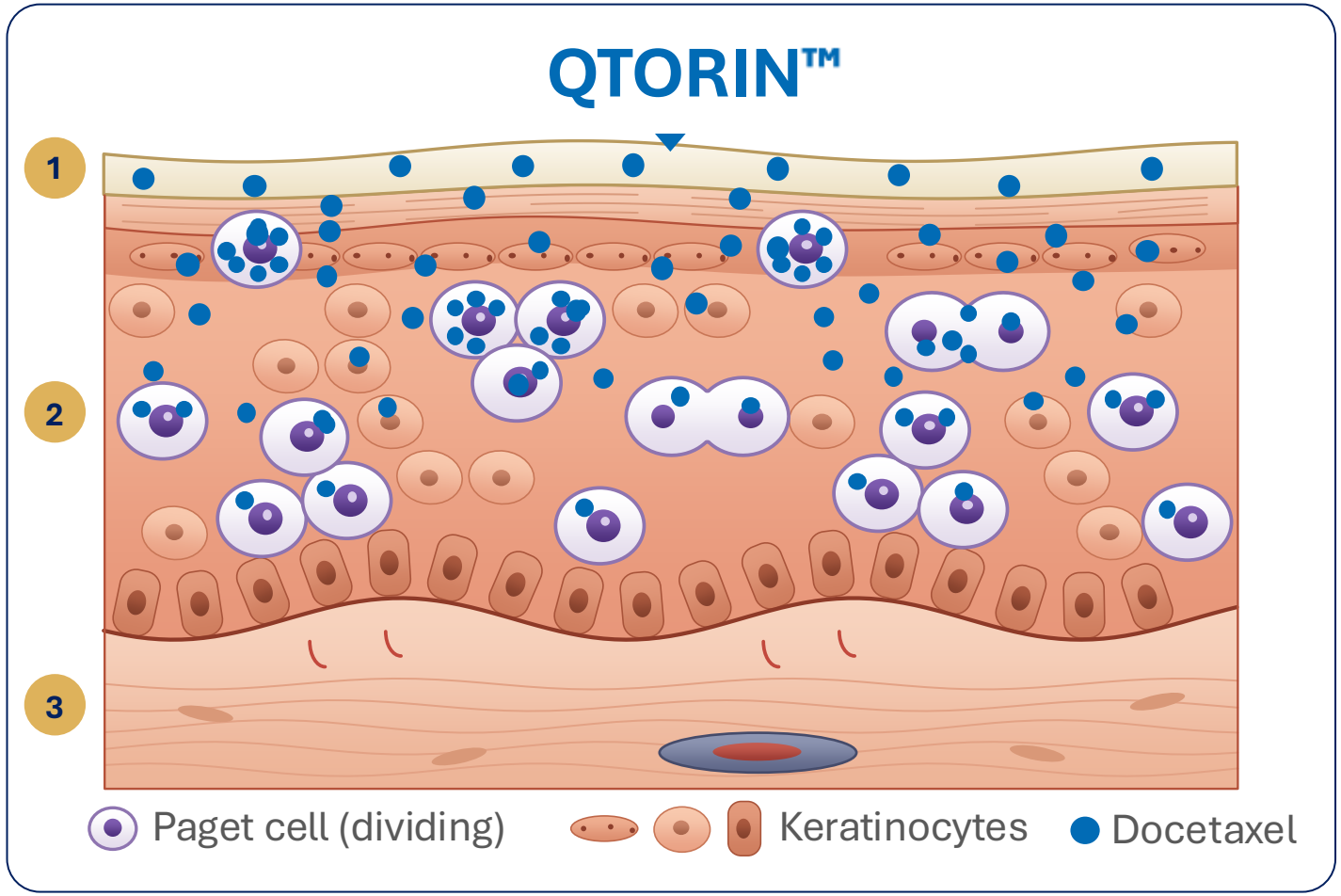
Molecule	Potency	Optimal Skin PK	Stability
Docetaxel	✓	✓	✓
Taxane 2	*Did not meet some or all pre-defined target product attributes*		
Taxane 3			

Milestones Achieved

- ✓ **Selective penetration to the epidermis**
- ✓ Favorable preliminary **drug stability**
- ✓ **Payload fine-tuned** to optimize tolerability
- ✓ **Low systemic absorption** anticipated
- ✓ **IP:** Filed formulation and method-of-use

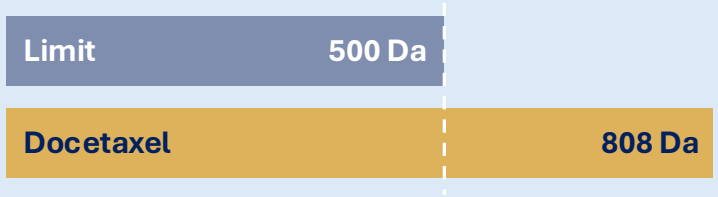
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QTORIN™ Selectively Targets Disease in Epidermis



QTORIN™ is designed to:

1 **Break the 500 Da barrier**



2 **Concentrate in the epidermis**

3 **Limit systemic exposure**

In vitro skin penetration data per Palvella. Note: Docetaxel has not been approved by the FDA for the treatment of EMPD.

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QTORIN™ Docetaxel Clinical Development Plan

QTORIN™ Docetaxel: From Concept to Clinic

IND-enabling study activities initiated

FDA meeting planned 1H 2027

Leveraging 505(b)(2) pathway

Following pre-IND meeting, Palvella plans to advance to a Phase 2 study

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EMPD Aligns with Palvella's Pipeline Strategy

QTORIN™ docetaxel has the potential to be first-line for EMPD

	QTORIN™ Rapamycin / Pitavastatin	QTORIN™ Docetaxel	
	mLMs, cVMs, Clinically Significant Angiokeratomas, DSAP	**EMPD**	
Serious	✓	Highly debilitating and life-threatening cancer	*Significant unmet medical need*
Rare	✓	>10k U.S. patients[2]	
No FDA-approved Therapies	✓	None	
Strong Scientific & Biologic Rationale	✓	Docetaxel stabilizes microtubules, preventing cell division and inducing apoptosis	*Optimizing likelihood of clinical success*
Published Case Studies & Real-World Evidence	✓	Frequent I.V. use in metastatic disease	
Commercially Attractive	✓	Opportunity to be first-in-disease	*Multi-billion-dollar U.S. TAM[1]*

1. Based on internal and third-party estimates. 2. Internal analysis, Nicaise et al. (2024), and LapidusData.

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Key Takeaways

Wes Kaupinen
Founder & Chief Executive Officer

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Thank You

Striving to be first for rare disease patients

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