

HEXIMA LIMITED

ASX ANNOUNCEMENT



29 April 2022

SHARECAFE SMALL CAP “HIDDEN GEMS” WEBINAR

MELBOURNE, AUSTRALIA (29 April 2022): Hexima Limited (ASX:HXL) a clinical stage biotechnology company developing pezadeftide (formerly HXP124), a potential new prescription topical treatment for onychomycosis, is pleased to announce its participation in the ShareCafe Small Cap "Hidden Gems" Webinar, to be held Friday 29 April 2022 from 12:30pm AEST / 10:30am AWST.

Managing Director & CEO, Mr Michael Aldridge will provide an overview of the Company's clinical stage, anti-infective development program. Hexima's lead product candidate, pezadeftide applied in a topical formulation, is a potential new prescription treatment for toenail fungal infections.

This webinar can be viewed live via Zoom and will provide viewers the opportunity to hear from, and engage with, a range of ASX-listed leading micro/mid cap companies.

To access further details of the event and to register at no cost, please copy and paste the following link into your internet browser:

https://us02web.zoom.us/webinar/register/9116505134210/WN_amL0UKucST6hkC3zvU-1Lw

A recorded copy of the webinar will be made available following the event.

A copy of the investor presentation to be delivered during the webinar is attached.

This announcement is authorised for release to ASX by Michael Aldridge, Managing Director & CEO.

Enquiries:

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Chief Operating Officer
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To join our email database and receive company announcements please [click here](#)

ABOUT HEXIMA

Hexima (ASX:HXL) is a clinical stage, anti-infectives focused biotechnology company engaged in the research and development of defensin peptides for applications as human therapeutics. Our lead product candidate, pezadeftide (HXP124) applied in a topical formulation, is a potential new prescription treatment for toenail fungal infections (or onychomycosis). Hexima is currently conducting an Australian phase IIb clinical trial testing pezadeftide for the treatment of onychomycosis. Hexima holds granted, long-life patents protecting pezadeftide in major markets globally. For additional information please visit www.hexima.com.au. You can also find us on [Twitter](#) and [LinkedIn](#) or email us at info@hexima.com.au.



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ABOUT ONYCHOMYCOSIS

Onychomycosis is a common fungal nail infection in the nail plate and nail bed. Prevalence of onychomycosis has been estimated at 10% (Japan) and 13.8% (USA).¹ Onychomycosis is an infectious disease and is difficult to treat with a significant healthcare burden. It causes pain in approximately 50% of patients and in the US results in close to four doctor's visits annually for treatment.² Onychomycosis impacts a patient's quality of life with 51% unable to wear the shoes they would prefer and 66% distressed by the appearance of their nail.³ It is important to treat onychomycosis as the fungi in the nail can be a source of secondary infection in other areas of the body or infect family members and spread to the environment.

Onychomycosis is the most common nail disorder accounting for 50% of all nail diseases. It is particularly prevalent in older, diabetic and immune compromised populations.² The global market for treatments for onychomycosis was approximately US\$3.7 billion in 2018.⁴

TREATMENT OF ONYCHOMYCOSIS

Approved prescription therapies for onychomycosis comprise either oral or topical medications. Oral medications are associated with adverse effects such as nausea, taste disturbance, and flatulence. They can also severely impact liver function and so often require liver function monitoring. The clinical and commercial success of topical medications has been constrained by an inability of anti-fungal agents to effectively penetrate the human nail and the lack of sufficient anti-fungal activity when in contact with the target pathogen.⁵

HEXIMA'S APPROACH

Hexima embraces the significant challenge of new product development for onychomycosis. Hexima has taken a very different approach, building on its many years of ground-breaking research into the evolutionary tools that plants use naturally to fight fungal infections. The result is pezadeftide, a new topical treatment for onychomycosis, with a novel and powerful fungicidal mode of action.

Historically, therapies for onychomycosis have generally focused on new forms of the traditional classes of antifungal agents or improving the topical delivery of systemic antifungal agents. Hexima's technology is a completely novel approach with fundamental differences that address the well-documented limitations of these traditional technologies.

Pezadeftide penetrates the nail more effectively than existing topical treatments and so can more readily target the fungal cells which proliferate in the nail bed. It is also more effective at rapidly killing fungal cells on contact. Together, these properties mean that pezadeftide has the potential to resolve the fungal infection more quickly, leading to faster and more complete clearing of the infected nail area. Consequently, pezadeftide offers the promise to capture significant value in a large and poorly served market.

¹ Tatchibana et al., Journal of Fungi, 2017

² Joseph et al, Supplement to Podiatry Today, 2013

³ Milobratovic et al., Mycoses, 2013

⁴ Persistence Market Research 2018

⁵ Wang et al., Onychomycosis: Diagnosis and Effective Management, 2018

SHARE CAFE

HEXIMA LIMITED (ASX:HXL)

A game-changing treatment for onychomycosis



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HEXIMA LIMITED (ASX:HXL)

DEVELOPING A NOVEL TOPICAL PRODUCT ADDRESSING A CLEAR UNMET NEED IN A LARGE AND GROWING MARKET



CLINICAL-STAGE, INFECTIOUS DISEASE-FOCUSED BIOTECHNOLOGY COMPANY

Lead program is pezadeftide (HXP124), a **potential new topical treatment** for onychomycosis (fungal nail infections)

Exploring other applications for its anti-fungal peptide platform



LARGE AND GROWING MARKET WITH SUBSTANTIAL UNMET NEED

Onychomycosis **affects ~14% of the US population**. Global market for treatments for onychomycosis **US\$3.7 bn**

Current treatments do not meet patient needs

- Topical drugs - long course of treatment, limited efficacy
- Oral drugs - more effective but risk of toxic side effects

Patients and clinicians have a **clear preference for a safe topical product** with a more convenient **shorter course of therapy and better efficacy**



NOVEL, PROPRIETARY MOLECULE WITH UNIQUE MOA

Pezadeftide is a patented biologic with a **novel fungicidal mode of action (MOA)**

Rapidly penetrates the human nail to target the site of infection



PEZADEFTIDE ADDRESSES AN UNMET NEED. GOAL TO BE THE TREATMENT OF CHOICE

Demonstrated in a phase I clinical trial to have a favourable safety profile and deliver effective and rapid anti-fungal treatment

Safe and well tolerated

High efficacy via consumer-friendly topical application

Short, convenient course of therapy, delivers rapid resolution of disease



WELL-DEFINED DEVELOPMENT PATH

Currently in phase II clinical trial – results Q2 2022
Phase III end of 2022



EXPERIENCED MANAGEMENT TEAM

PROVEN TRACK RECORD OF DELIVERING VALUE



MICHAEL ALDRIDGE
Chief Executive Officer



DR. NICOLE VAN DER WEERDEN
Chief Operating Officer



PROF. MARILYN ANDERSON
Chief Science Officer



DR NANCY SACCO
Chief Development Officer



PHILLIP ROSE
Chief Commercial Officer

CEO Peplin, sold to Leo
Pharma in 2009 for \$300M

SVP Corporate Strategy
Questcor, sold to Mallinckrodt
in 2014 for \$5.6B

SVP Corporate & Strategic
Development Codexis, \$357M
partnership with Nestle in PKU
in 2017

Inventor on all Hexima's key
patents

Led discovery and development
program for pezadeftide
CEO of Hexima 2015-2020

Founding scientist of Hexima
Fellow of the Australian
Academy of Science and
Australian Academy of
Technological Sciences

Member of Hexima board of
directors since 2010

Over 20 years leadership in
the pharmaceutical industry.

VP & Head of Clinical
Development roles at Xentria,
Inc. & AnaptysBio, Inc.

Initiated and completed
pivotal studies evaluating
safety and efficacy of
innovative products.

Registered Pharmacist

Specializes in market analysis,
preparation & full strategy
development to maximize
commercial potential.

Consulted at Alza (now J&J),
Reliant Pharmaceuticals (now
GSK) and Peplin Inc. (now LEO).



PEZADEFTIDE IN ACTION

Click to play
animation



EXISTING THERAPIES DO NOT MEET CONSUMER NEEDS

CLEAR MARKET NEED FOR A SAFE, CONVENIENT AND MORE EFFECTIVE TOPICAL PRODUCT

TOPICAL TREATMENTS



Long treatments,
poor efficacy

ORAL DRUGS



Better efficacy but potential
for serious adverse events



Patients with
onychomycosis
reluctant to use **oral
drugs** because of
potential toxicity



Topical products
are therefore
strongly preferred



However, **existing
topicals** suffer from
low efficacy rates and
long courses
of therapy



Patients often **stop
treatment** because
the appearance of
the nail does not
improve for many
months



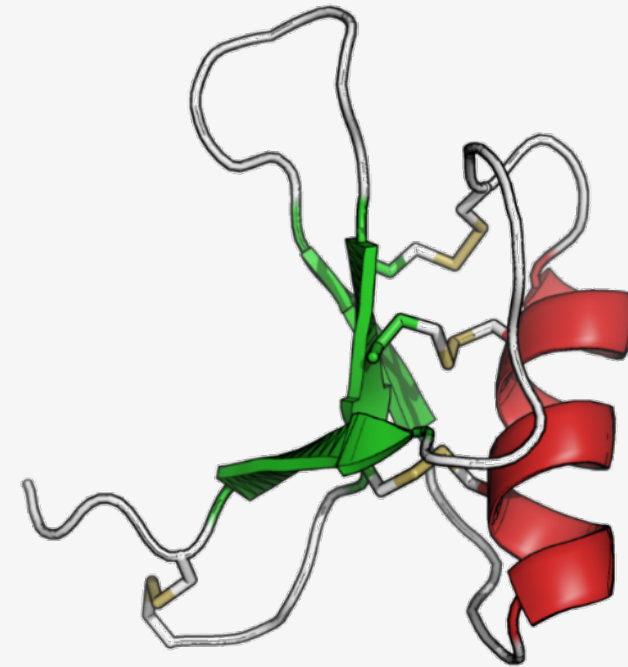
OUR SOLUTION: PEZADEFTIDE A NATURALLY OCCURRING PEPTIDE

ITS UNIQUE PROPERTIES ENABLE RAPID
NAIL PENETRATION AND FUNGAL KILLING

Pezadeftide is a potent broad-spectrum antifungal peptide that has evolved to kill fungal pathogens

- Hydrophilic & highly soluble – drives nail penetration
- Resistant to proteases & extremely stable
- Regulated as a biologic
- Excellent safety profile
- Does not pass through human skin

PEZADEFTIDE MOLECULE



SUCCESSFUL PHASE I CLINICAL TRIAL

HXP124-ONY-001 – TRIAL DESIGN

Randomised, double blind, vehicle-controlled, ascending dose cohort study

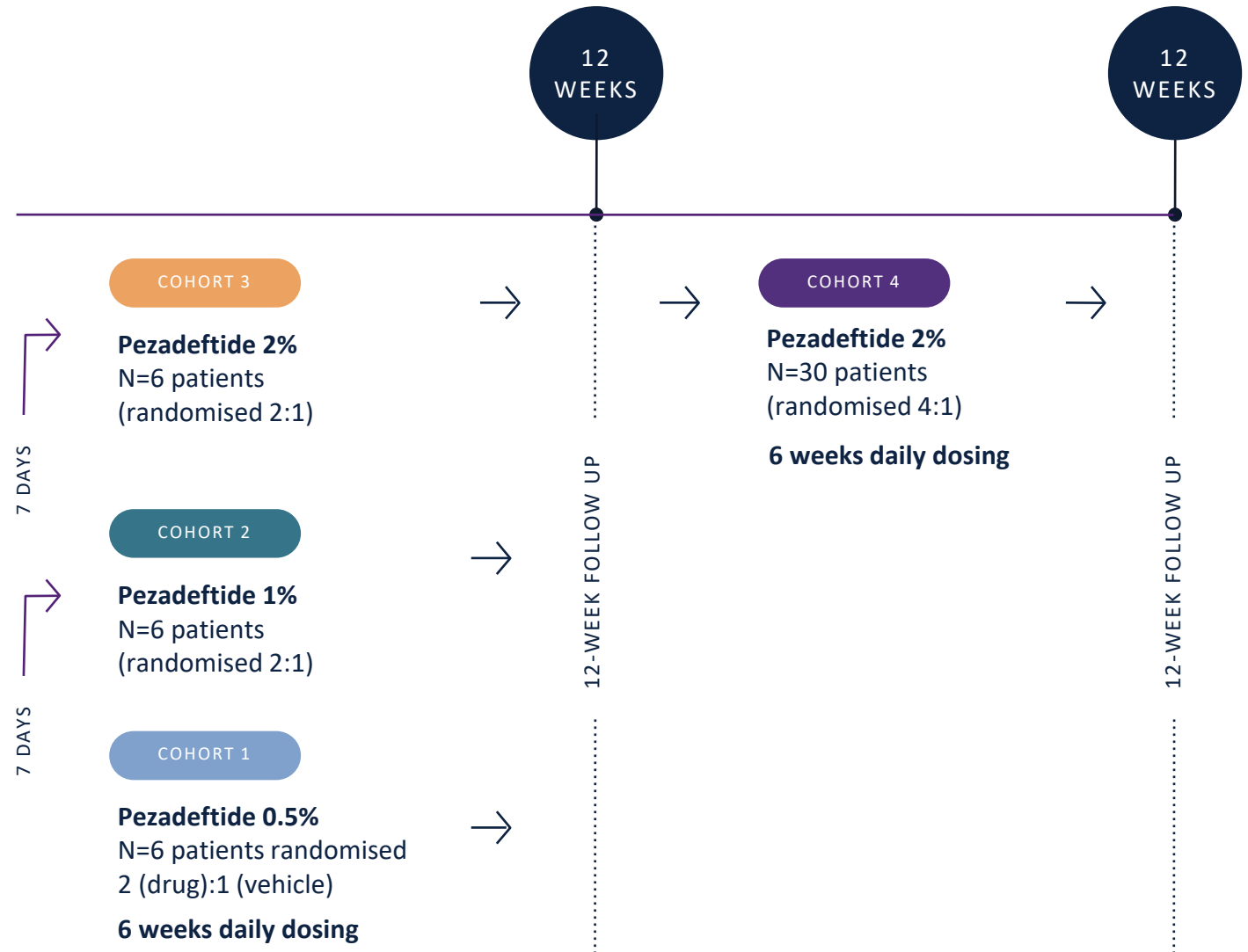
Patients treated nails daily with pezadeftide (or vehicle) for 6 weeks with follow-up at 12 weeks

- 36 patients treated with pezadeftide, 12 treated with vehicle

Cohort 1, 2, 3 escalation cohorts

Cohort 4 expansion cohort

- 30 patients, pezadeftide 2% vs vehicle, 6 weeks dosing



PHASE I: PRIMARY ENDPOINT SAFETY AND TOLERABILITY

HXP124-ONY-001 – NO SYSTEMIC ABSORPTION
AND NO LOCAL REDNESS OR IRRITATION

Pezadeftide is safe and well tolerated

NO DRUG-RELATED ADVERSE EVENTS

Pezadeftide is safe and well tolerated when applied daily for 6 weeks.

NO SYSTEMIC TOXICITY

Pezadeftide accumulated in nails and was still detectable 6 weeks after dosing but was not detected in the bloodstream.

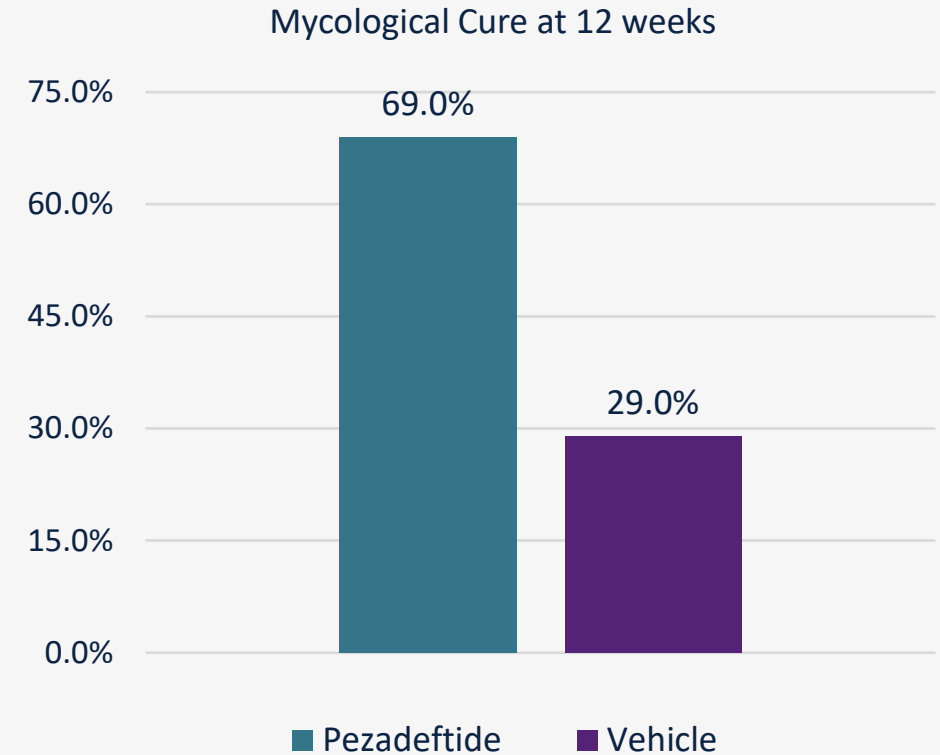


PHASE I: EFFECTIVE AND RAPID ANTI-FUNGAL ACTIVITY

HXP124-ONY-001 – MYCOLOGICAL CURE RATE FOR COHORT 4
30 PATIENTS TREATED AT HIGH DOSE (2%) FOR 6 WEEKS

Mycological cure* was achieved in 69% of pezadeftide-treated nails in Cohort 4 within 12 weeks (vehicle 29%)

- **Mycological Cure* rate at 12 weeks**, >2-fold higher than current treatments, after only 6 weeks of daily treatment



*Mycological cure: KOH stain negative and culture negative

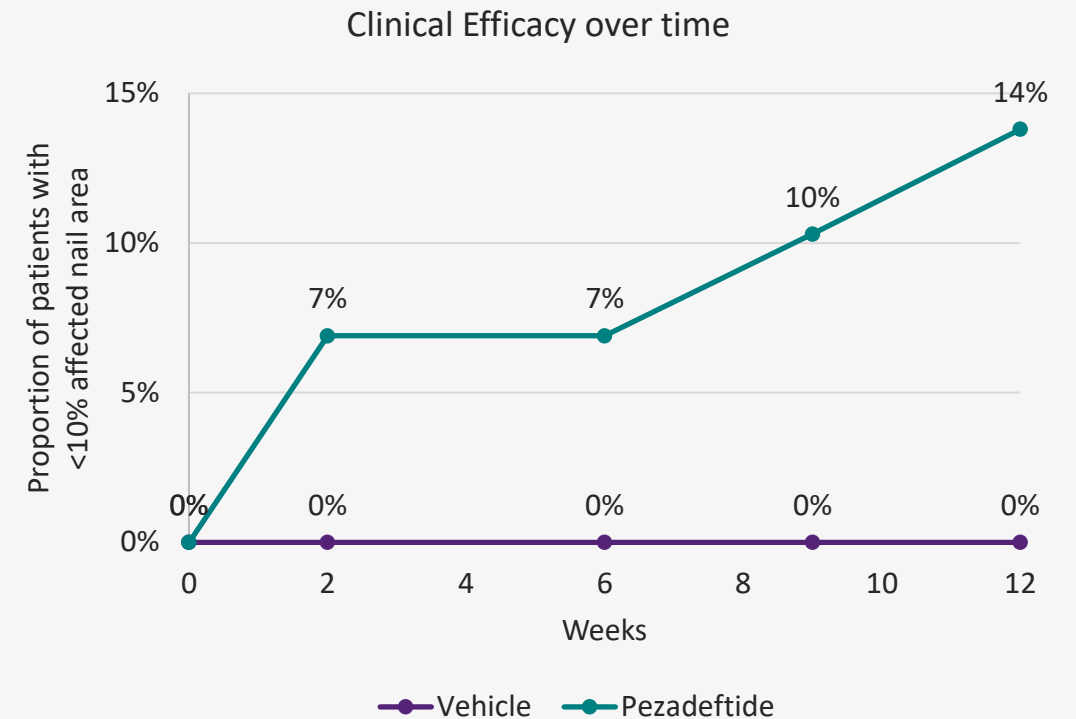


PHASE I: RAPID CLEARANCE OF AFFECTED NAIL AREA

HXP124-ONY-001 – CLEAR NAIL GROWTH FOR COHORT 4
30 PATIENTS TREATED AT HIGH DOSE (2%) FOR 6 WEEKS

Pezadeftide cleared the affected nail area more effectively than vehicle (formulation not containing pezadeftide)

- **Clinical Efficacy*** was achieved in **14%** of **2% pezadeftide-treated nails** within just 12 weeks
- No vehicle-treated nails achieved Clinical Efficacy



*Clinical Efficacy = <10% of the nail area affected.



RAPID AND DRAMATIC IMPROVEMENT IN APPEARANCE OF NAILS

NOTICEABLE IMPROVEMENT IN JUST 2 WEEKS,
ALMOST CLEAR IN 12 WEEKS

Pezadeftide penetrates the nail to kill the fungus, allowing healthy, uninfected nail to grow out

- Clear nail growth continues after dosing has finished

[Click to play animation](#)



POTENTIAL TO DELIVER THE PREFERRED SOLUTION IN A CONSUMER-DRIVEN MARKET

Safe, topical medication



Convenient, short course of therapy



Effective, best-in-class mycological cure



FOR PATIENTS WHO WANT

- An easy-to-apply topical solution
- Rapid improvement in the appearance of the nail
- Early affirmation the drug is working
- A short course of effective treatment

FOR PHYSICIANS WHO WANT

- An effective product that will cure the infection
- A safe product
- To quickly know a patient is responding to therapy

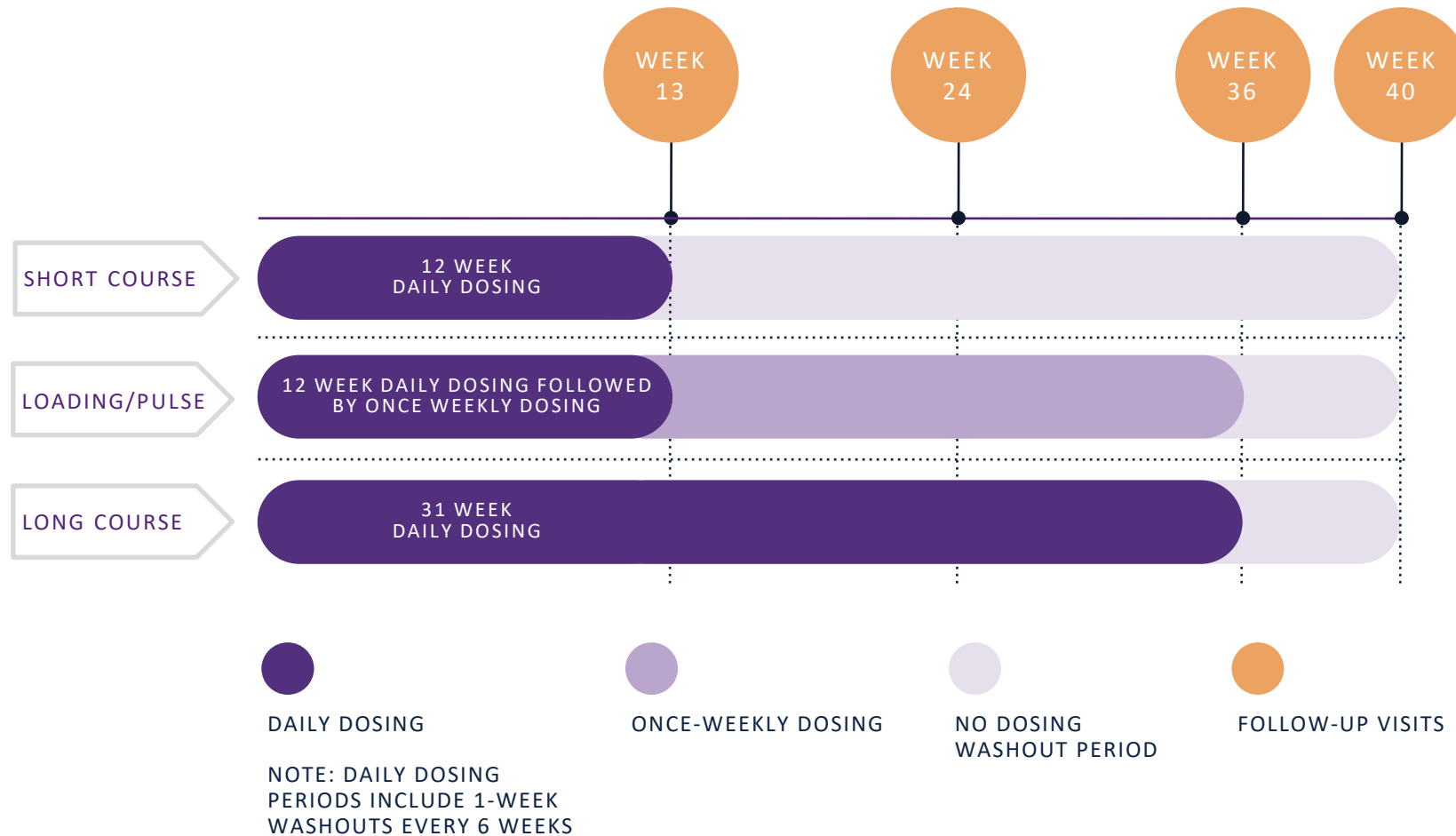
FOR PAYERS WHO WANT

- An effective product that patients will not abandon
- A competitively-priced product



PHASE II CLINICAL TRIAL

HXP124-ONY-002



- Multi-center, randomised, double blind, vehicle-controlled study
- Primary endpoint safety and tolerability, secondary endpoints Mycological Cure and Clinical Efficacy
- Three active (2% pezadeftide) versus vehicle arms to test optimal dosing strategy
- Safety & efficacy assessed at 13, 24, 36 and 40 weeks



PHASE II CLINICAL TRIAL – RESULTS Q2

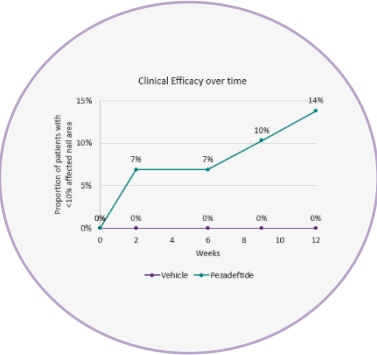
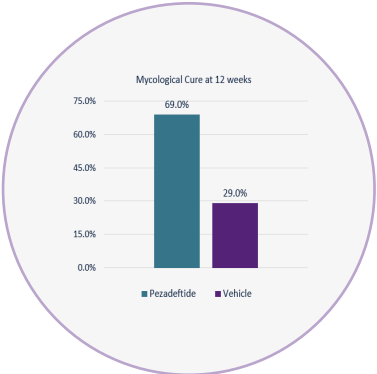
PLATFORM TO ADVANCE TO PHASE III

PHASE I

6-WEEK DAILY DOSING

FOLLOW UP AT 12 WEEKS

SINGLE DOSING REGIMEN



PHASE II

12-36 WEEKS DAILY DOSING

FOLLOW UP AT 40 WEEKS

THREE DOSING REGIMENS

RESULTS Q2 2022

DEFINITION OF SUCCESS

COMPARABLE OR BETTER MYCOLOGICAL CURE

STRONGER EVIDENCE OF CLINICAL CURE

DIFFERENTIAL ACTIVITY ACROSS THREE REGIMENS

PEZADEFTIDE: A POTENTIAL SOLUTION FOR A LARGE AND POORLY SERVED MARKET



POORLY SERVED MARKET

Affects 14% of the population
Strong consumer preference for topical products
Clear unmet medical need



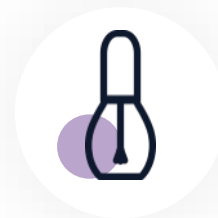
NEW AND UNIQUE

Novel molecule with unique mode of action
Strong patent protection and long patent life



SAFE

No systemic effects
No local redness or irritation



CONVENIENT

Easy to apply
Short treatment duration
Rapid clearing of infected nail
Consumer oriented packaging solution



EFFECTIVE

Efficiently penetrates the nail
Rapidly kills fungus
Best-in-class mycological cure



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