



## **ASX Announcement**

**24 September 2021**

### **ACCESS CHINA Biotech Forum**

MELBOURNE, AUSTRALIA (24 September 2021): Hexima Limited (ASX:HXL), attaches its corporate presentation for the ACCESS CHINA Biotech Forum, a business development forum for pharma and biotech leaders outside China to meet local companies and consider the opportunity for potential development, licensing, and commercial collaborations. Michael Aldridge, CEO of Hexima will present today at 1:00PM (AEST) in the Autumn Showcase event to be held in Suzhou and online.

For more information on the ACCESS CHINA Biotech Forum and to register to attend the event visit the following link:

<https://biotochina.org/2021/08/18/hexima-limited-will-present-access-china-biotech-forum-2021/>

**This announcement is authorised for release to ASX by Michael Aldridge, Chief Executive Officer.**

***Enquiries:***

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**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](http://www.hexima.com.au). You can also find us on [Twitter](#) and [LinkedIn](#).

SEPTEMBER 2021

# 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**



**LARGE AND GROWING MARKET WITH SUBSTANTIAL UNMET NEED**



**NOVEL, PROPRIETARY MOLECULE WITH UNIQUE MOA**



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



**WELL-DEFINED DEVELOPMENT PATH**

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

Exploring other applications for its anti-fungal peptide platform

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**

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

**Rapidly penetrates the human nail** to target the site of infection

Demonstrated in a phase I/IIa 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

Currently in Australian phase IIb clinical trial – results Q2 2022  
File IND with FDA in Q4 2021  
Phase III 2022



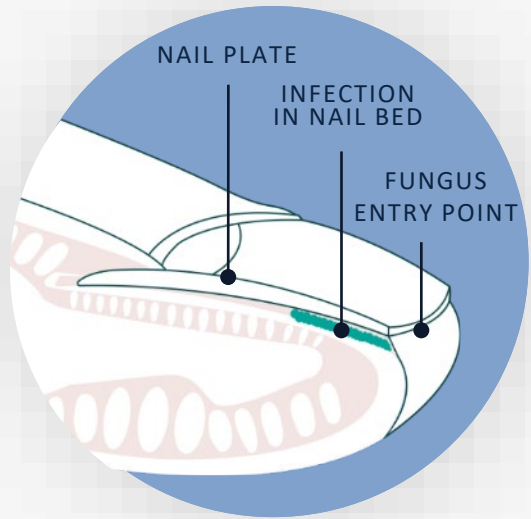
# PEZADEFTIDE IN ACTION

Click to play  
animation



# ONYCHOMYCOSIS (FUNGAL NAIL INFECTION)

COMMON INFECTIOUS DISEASE WITH  
A SIGNIFICANT HEALTHCARE BURDEN



## PATHOPHYSIOLOGY

Dermatophytes (fungi that cause skin disease) typically enter through the distal groove at the end of the nail and proliferate in the nail bed.



Left untreated, the nail becomes thick and brittle and easily separates from the nail bed, causing pain. Also serves as a reservoir for further infections.



Infectious disease: risk factors include increasing age, athlete's foot, diabetes, and immunodeficiency.



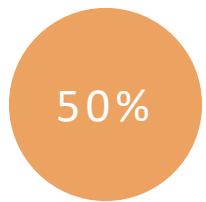
Patients experience pain, discomfort and difficulty wearing shoes. Quality of life is affected by nail dystrophy and unacceptable cosmetic appearance.



Onychomycosis is estimated to affect 10-14% of the population and is the most common nail disorder.

# 4 P.A.

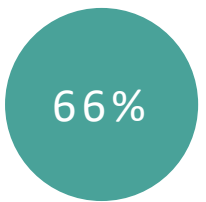
Onychomycosis is responsible for an average of 4 doctors visits annually by patients seeking treatment.



EXPERIENCE PAIN



ARE IMPACTED WEARING SHOES



DISTRESSED BY APPEARANCE OF THEIR NAILS

Tatchibana et al., Journal of Fungi, 2017  
Infection Inspection, Dermatology World, 2017  
Joseph et al, Supplement to Podiatry Today, 2013;  
Milobratovic et al., Mycoses, 2013



# 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



# PEZADEFTIDE: A POTENTIAL GAME-CHANGING SOLUTION

PEZADEFTIDE TARGETS CONSUMER PREFERENCE FOR A CONVENIENT, SAFE AND EFFECTIVE THERAPY

## CONSUMER PREFERENCES

PRODUCT TYPE	 TERBINAFINE ORAL	 TAVABOROLE TOPICAL	 EFINACONAZOLE TOPICAL	 CICLOPIROX TOPICAL	 PEZADEFTIDE TOPICAL
Short Treatment	✓	✗	✗	✗	✓
Efficacious	✓	✗	✗	✗	✓
No systemic toxicity	✗	✓	✓	✓	✓
No local side effects	N/A	✗	✗	✓	✓





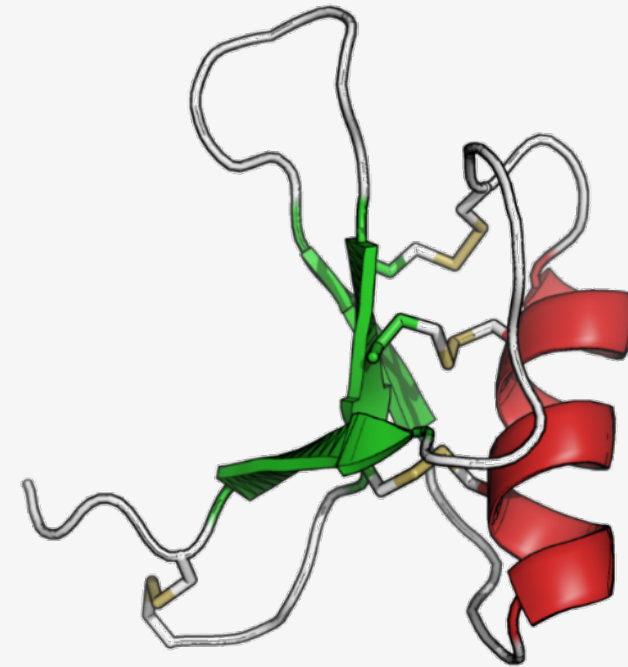
# OUR SOLUTION: PEZADEFTIDE IS A NATURALLY OCCURRING PEPTIDE

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



# EFFECTIVE TOPICAL TREATMENT OF ONYCHOMYCOSIS REQUIRES THREE DRUG PROPERTIES



## Efficient nail penetration

THE DRUG NEEDS TO REACH  
THE FUNGUS IN THE NAIL BED  
WHICH IS THE MAIN SITE OF  
INFECTION



## Efficient fungal cell killing

THE DRUG NEEDS TO RAPIDLY  
KILL THE FUNGAL PATHOGENS  
THAT CAUSE ONYCHOMYCOSIS  
UPON CONTACT



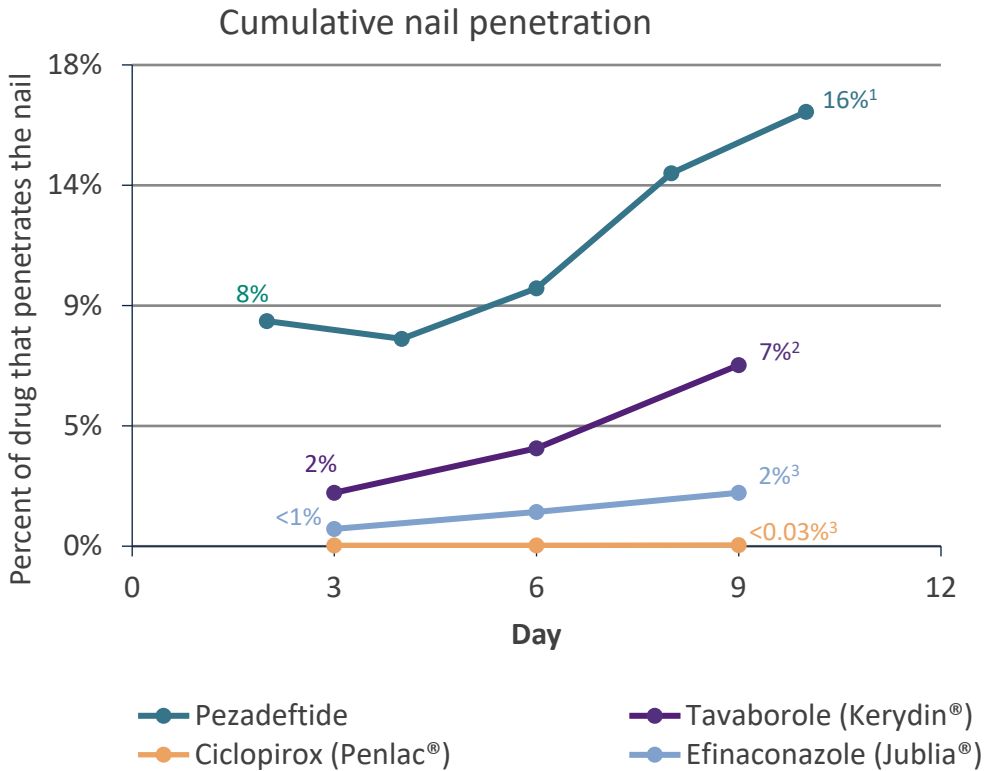
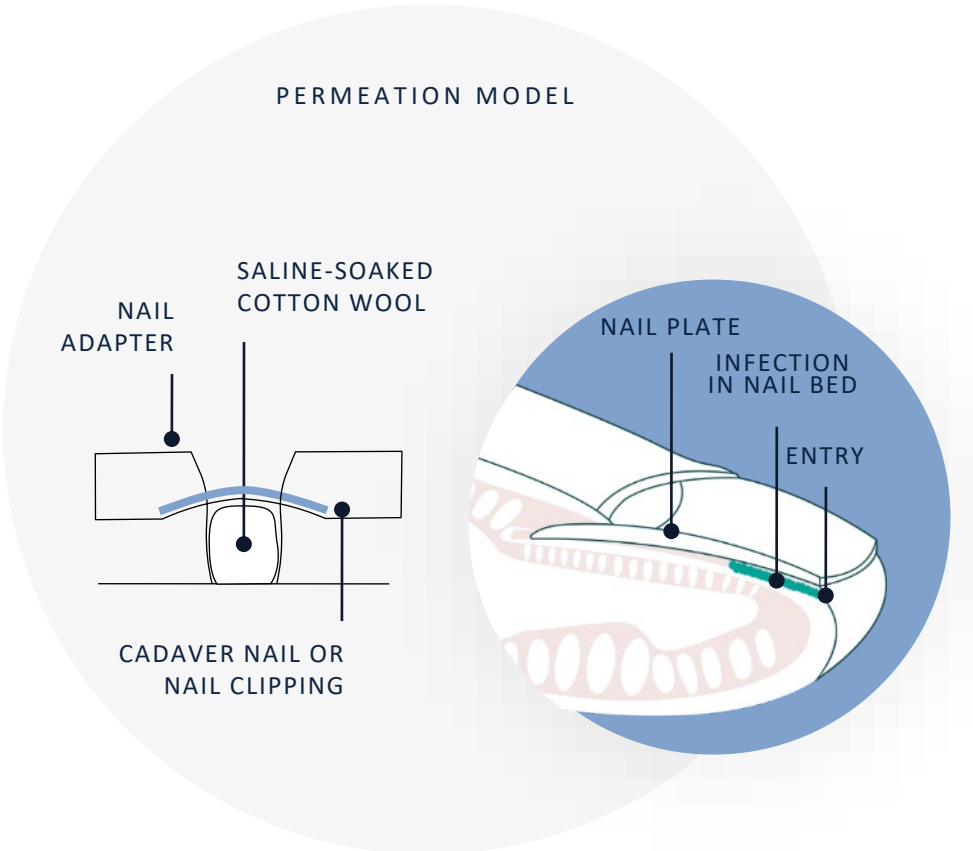
## Activity in the presence of keratin

THE DRUG NEEDS TO WORK IN  
THE NATURAL ENVIRONMENT OF  
THE NAIL BED AND NAIL PLATE  
WHICH ARE RICH IN KERATIN



# TOPICAL TREATMENTS MUST PENETRATE THE NAIL

PEZADEFTIDE PENETRATES NAILS FASTER AND MORE COMPLETELY THAN OTHER TOPICAL PRODUCTS

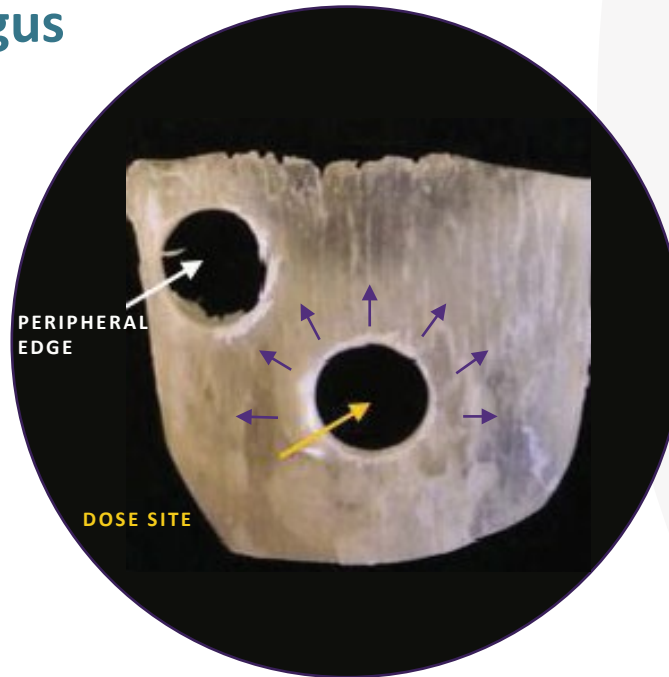


1 Internal study 2 Kaken Pharma and Dow Pharma, Sugiura et al., 2014; 3 UCSF Medical Center, Hui et al., 2006  
Based on method developed by Dr. Howard Maibach. (UCSF Medical Center, Hui et al., 2007)

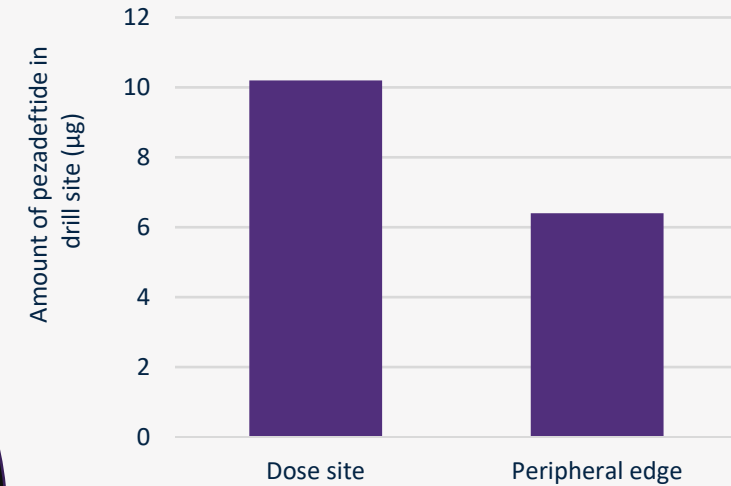
# PEZADEFTIDE DIFFUSES THROUGH THE NAIL PLATE

ACCUMULATES IN NAILS AT THE SITE OF APPLICATION AND  
DIFFUSES TO AREAS THAT ARE NOT DOSED

**Pezadeftide accumulates in  
nails to levels that kill fungus**



## PEZADEFTIDE WITHIN THE NAIL PLATE



HUMAN NAILS DOSED WITH PEZADEFTIDE WERE  
DRILLED TO COLLECT NAIL MATERIAL FROM THE DOSE  
SITE (YELLOW ARROW) AND THE EDGE OF THE NAIL  
(WHITE ARROW)



# SPECIFIC AND RAPID FUNGICIDAL ACTIVITY

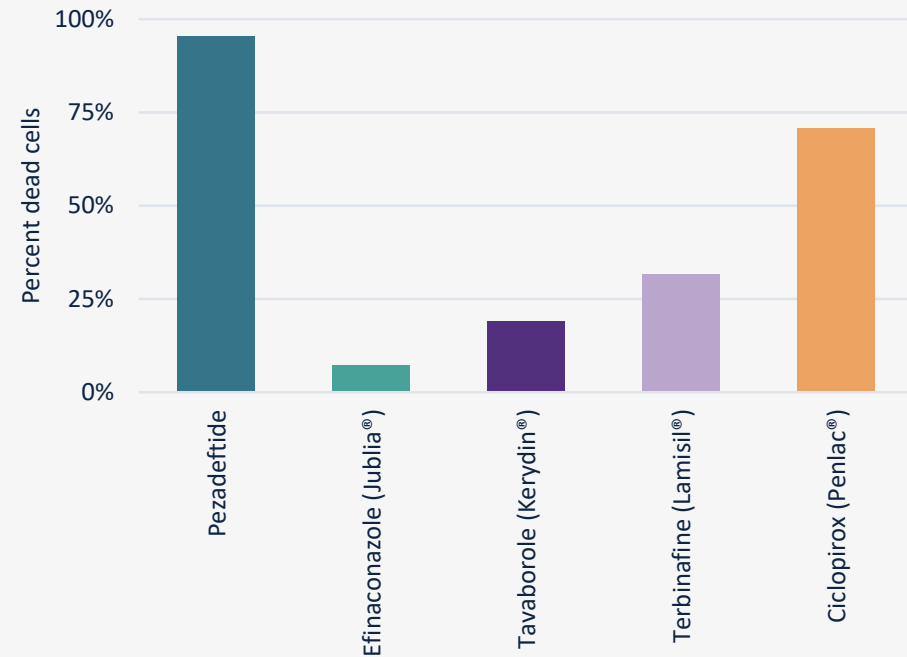
NOVEL FUNGICIDAL MODE OF ACTION ALLOWS RAPID RESOLUTION OF THE INFECTION

## Pezadeftide kills fungal cells in less than 30 minutes via a novel mode of action

- Pezadeftide is specific for fungal cells and does not impact the viability of human cells
- Ineffective killing by drugs currently on the market means the fungus often regrows when treatment is stopped

Note: Internal study

### RAPID FUNGICIDAL ACTIVITY



FLUORESCENCE ASSOCIATED CELL SORTING (FACS) OF PROPIDIUM IODIDE STAINED CELLS WAS USED TO IDENTIFY LIVING AND DEAD CANDIDA ALBICANS CELLS AFTER 30 MIN TREATMENT WITH ANTIFUNGAL AGENTS



# PEZADEFTIDE KILLS FUNGUS GROWING ON NAIL FRAGMENTS

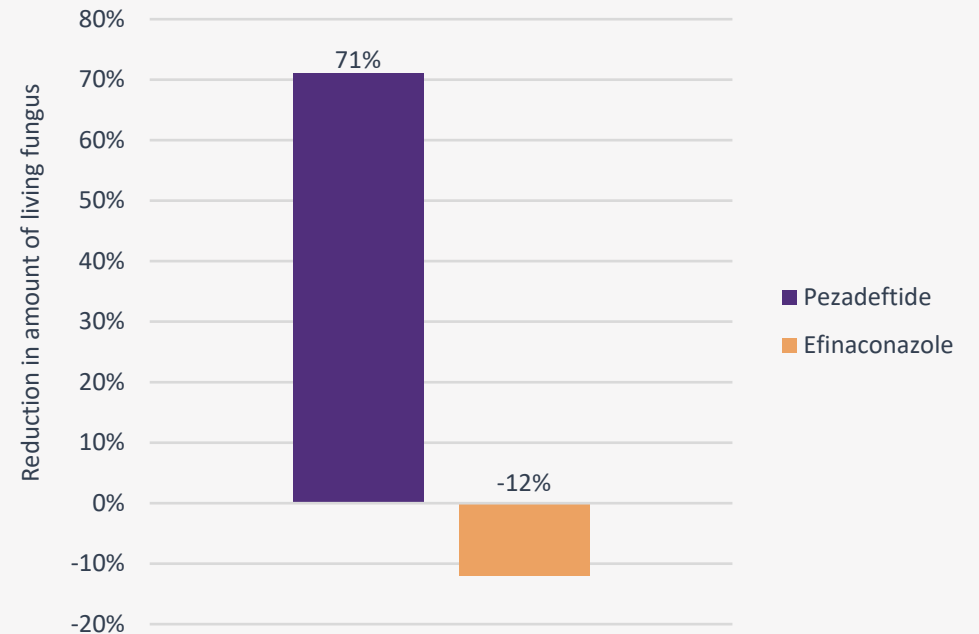
KILLS MORE EFFICIENTLY THAN LEADING TOPICAL PRODUCT

**Pezadeftide kills *T. rubrum* growing on nail fragments more efficiently than efinaconazole**

- Growth on nail fragments mimics the natural infection as fungus use keratin as nutrient source

Note: Internal study

FUNGAL KILLING ON NAIL FRAGMENTS



*T. RUBRUM* CELLS GROWN ON HUMAN NAIL FRAGMENTS WERE TREATED WITH PEZADEFTIDE OR EFINACONAZOLE. VIABILITY OF FUNGAL CELLS WAS MONITORED USING A FLUORESCENT DYE



# SUCCESSFUL PHASE I/IIA CLINICAL TRIAL

HXP124-ONY-001 – TRIAL DESIGN

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

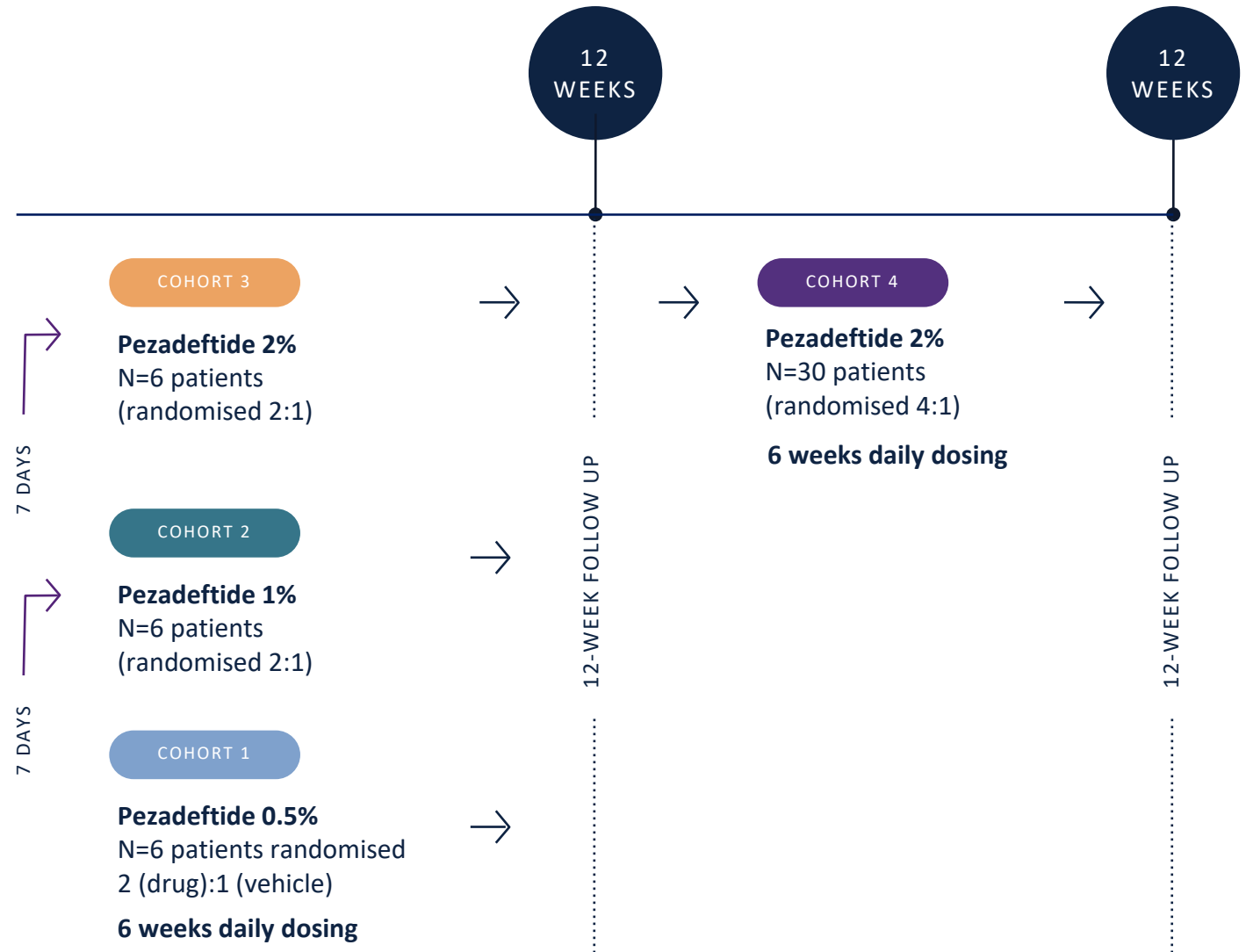
**Patients treated nails daily with pezadeftide (or vehicle) for 6 weeks with follow-up at 12 weeks**

- 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



# 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.



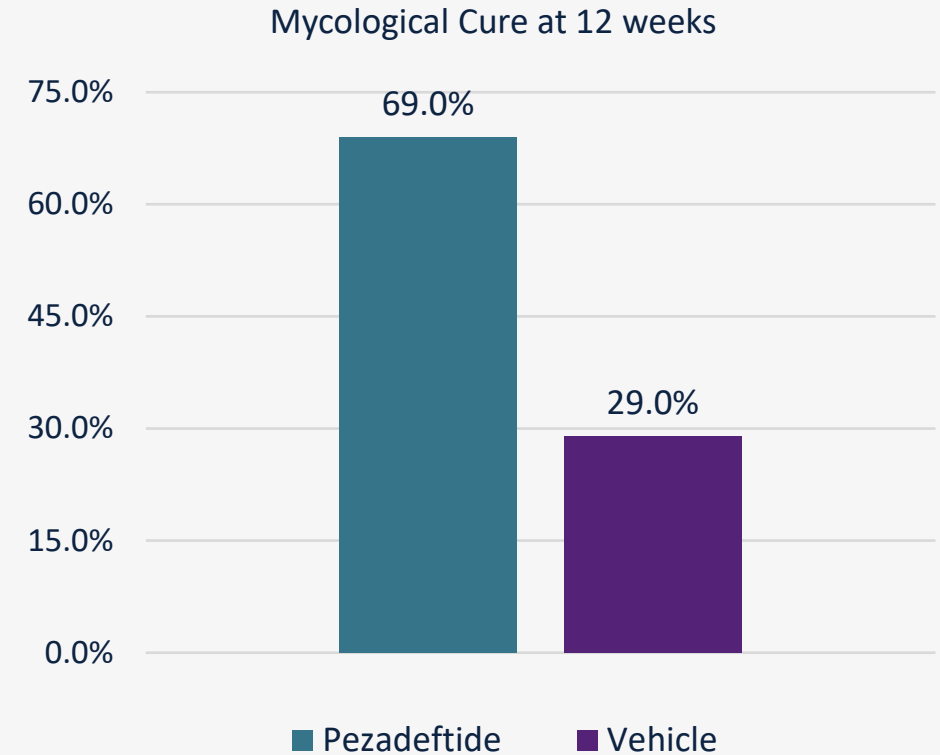


# EFFECTIVE AND RAPID ANTI-FUNGAL ACTIVITY

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

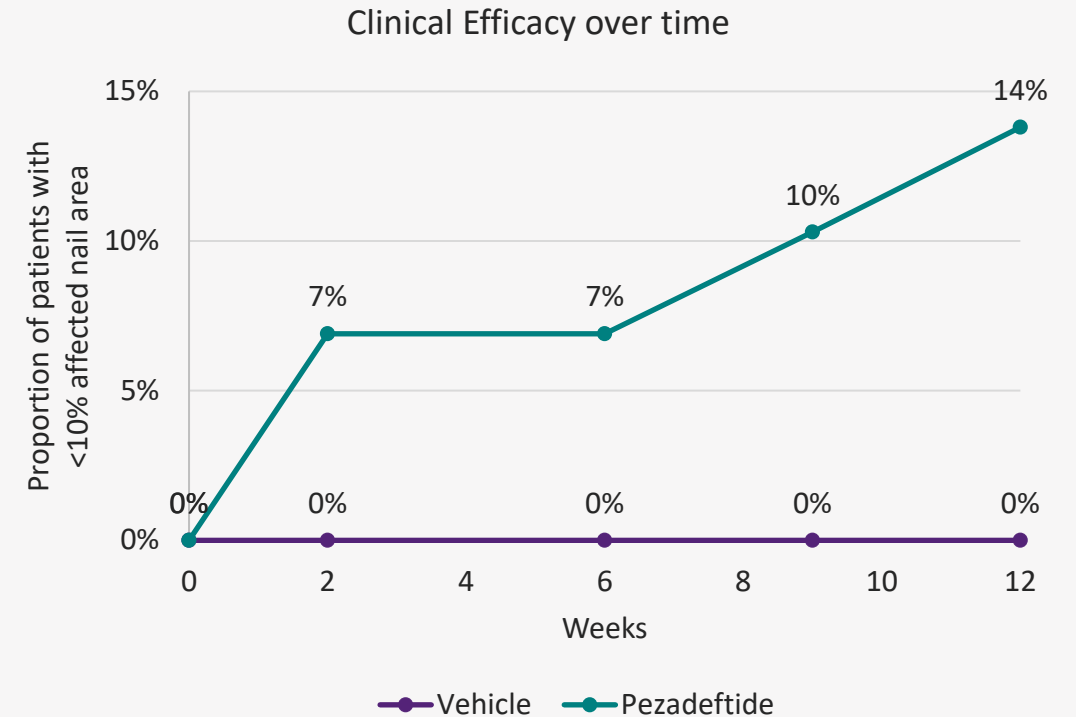


# PEZADEFTIDE RAPIDLY CLEARED THE AFFECTED NAIL AREA

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.

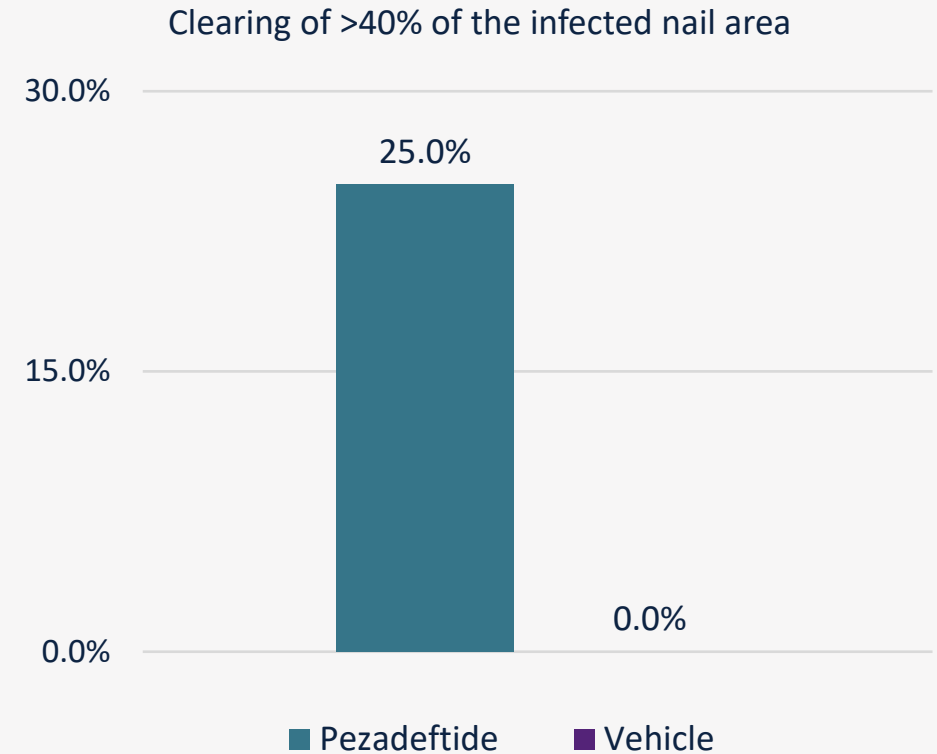


# EXTENSIVE NAIL CLEARING IN JUST 12 WEEKS

HXP124-ONY-001 – PERCENT CLEARING OF INFECTED NAIL AREA FOR COHORT 4 PATIENTS TREATED AT HIGH DOSE (2%) FOR 6 WEEKS

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

- More pezadeftide-treated nails in Cohort 4 showed a greater than 40% reduction in the infected nail area (25%) than vehicle-treated nails (0%)

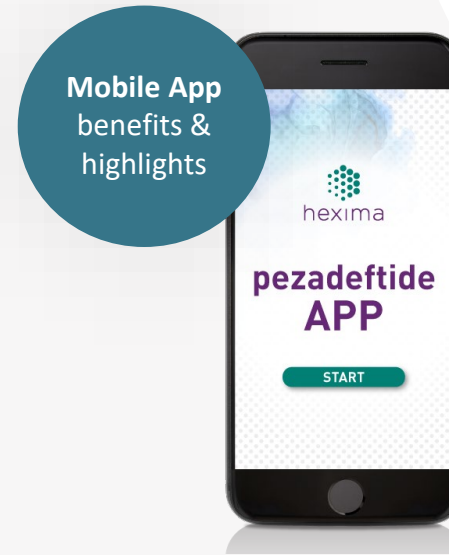


# PATENT FILED ON COMPLIANCEPAK ASSOCIATED MOBILE APPLICATION



## CompliancePak

- No spill / difficult to misplace
- Easy to open / child resistant
- Reinforces FDA use directions
- Connects by QR code to mobile app



## Mobile app

- Reinforces FDA use directions (with video)
- Compliance reminders / confirmation of treatment
- Visual tracking of treatment progress
- Teledoc: diagnosis, prescription and refills



# 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

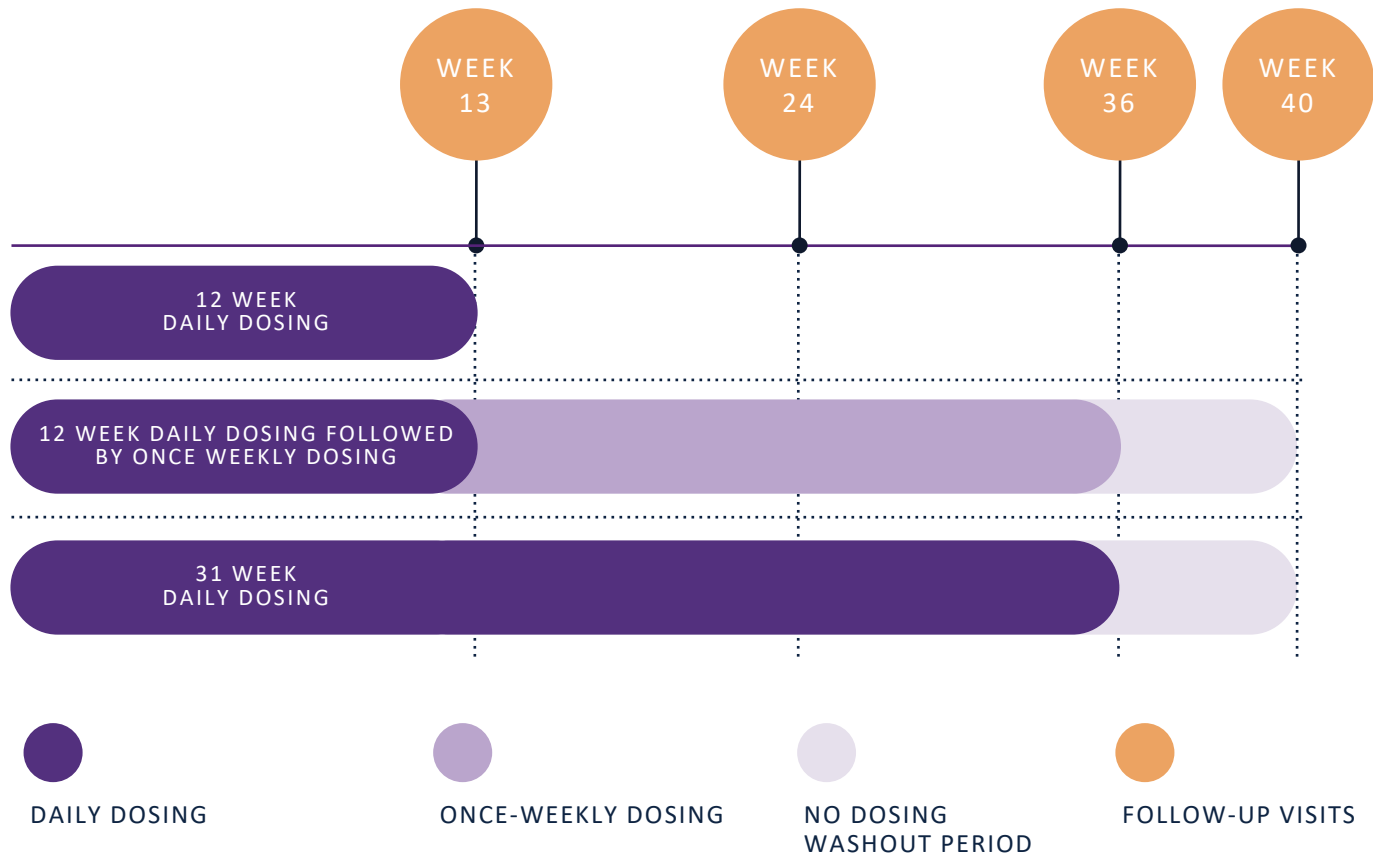
## FOR PAYERS WHO WANT

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



# AUSTRALIAN PHASE IIB CLINICAL TRIAL

HXP124-ONY-002



NOTE: DAILY DOSING PERIODS INCLUDE 1-WEEK WASHOUTS EVERY 6 WEEKS

Enrolment  
completed  
July 2021

- 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, data expected Q2 2022



# A HIGHLY COMPELLING COMMERCIAL OPPORTUNITY

PEZADEFTIDE CAN CAPTURE MARKET SHARE  
IN TOPICAL, ORAL AND OTC MARKETS



## STRONG CLINICAL PROFILE

Market demand for greater efficacy  
with shorter treatment duration.

**Potential for pezadeftide to become  
preferred topical product**



## DIFFERENTIATE VS. STANDARD OF CARE

Topicals; Limited efficacy  
& long treatment. Orals; Safety and  
adverse event concerns

**Clear opportunity to differentiate  
pezadeftide from current drugs and  
drive uptake**



## POTENTIAL FOR MARKET GROWTH

Promotionally sensitive market leads  
to rapid adoption of new products.

**Pezadeftide potential  
to drive growth in prescription  
market**

**Pezadeftide has  
the potential to  
be the leading  
therapy in a large,  
under-served and  
growing market**



# PEZADEFTIDE IS MANUFACTURED RAPIDLY AND ECONOMICALLY

SCALE-UP WITH EUROPEAN CMO  
ON-TRACK

**Pezadeftide is produced in a yeast expression system with a highly competitive cost of goods**

- Pezadeftide has been manufactured to GMP.
- Commercial-scale contract manufacturer engaged
- Pezadeftide successfully produced at large-scale
- Drug product retains activity when stored at room temperature for 24 months



PICTURED  
Fermenter and  
Chromatographic  
purification at  
European CMO





# STRONG PATENT POSITION

ADDITIONAL PROTECTION VIA FORMULATION PATENTS AND MARKET EXCLUSIVITY FOR BIOLOGICS

## Clearly defined growth strategy

- Develop independently in US and EU (ICH) markets
- License and collaborative development in Japan - presently in preliminary discussions with multiple parties

Granted patents (exp 2035) in major markets covering the use of pezadeftide in the treatment of onychomycosis



Granted and pending patents covering stabilising formulation for pezadeftide



12-year US market exclusivity on FDA approval likely available as a biologic drug



# 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



**EFFECTIVE**

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



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