

HEXIMA LIMITED

ASX ANNOUNCEMENT



26 October 2021

HEXIMA PRESENTING AT AUSBIOTECH

MELBOURNE, AUSTRALIA (26 October 2021): Hexima Limited (ASX:HXL) attaches its corporate presentation for the AusBiotech “Australia Biotech Invest & Partnering Conference 2021”. The conference is a preeminent opportunity for companies to present their technology and story to a network of potential international partners and investors. Mr Michael Aldridge, CEO of Hexima, will present today at 2:05PM (AEST). Following the presentation, Mr Aldridge will also take part in a Q&A forum with representatives from other life sciences companies.

For more information on the AusBiotech “Australia Biotech Invest & Partnering Conference 2021” or to register your attendance visit the following link:

<https://www.ausbiotechinvestment.com.au/registration>

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

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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. You can also find us on [Twitter](#) and [LinkedIn](#) or email us at info@hexima.com.au.

OCTOBER 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



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 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



SUCCESSFUL PHASE I/IIA CLINICAL TRIAL

HXP124-ONY-001 – TRIAL DESIGN

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

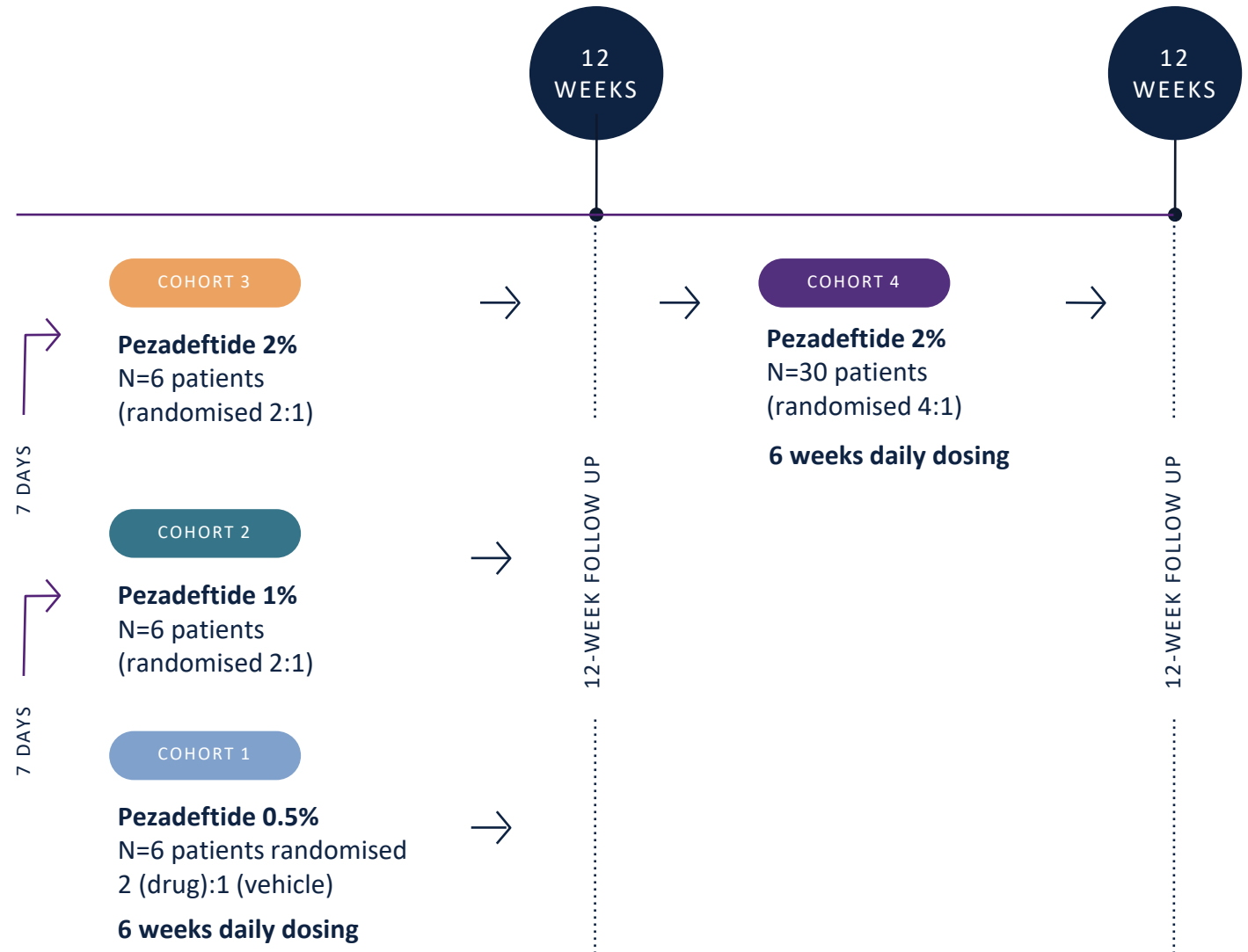
Patients treated nails daily with pezadeftide (or vehicle) for 6 weeks with follow-up at 12 weeks

- 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.

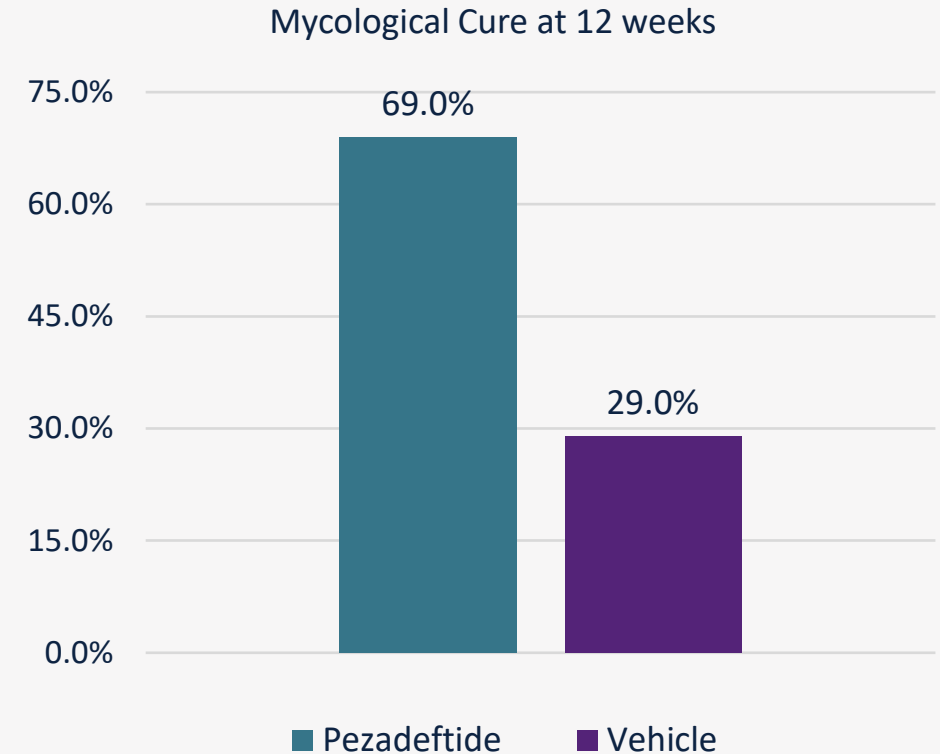


EFFECTIVE AND RAPID ANTI-FUNGAL ACTIVITY

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

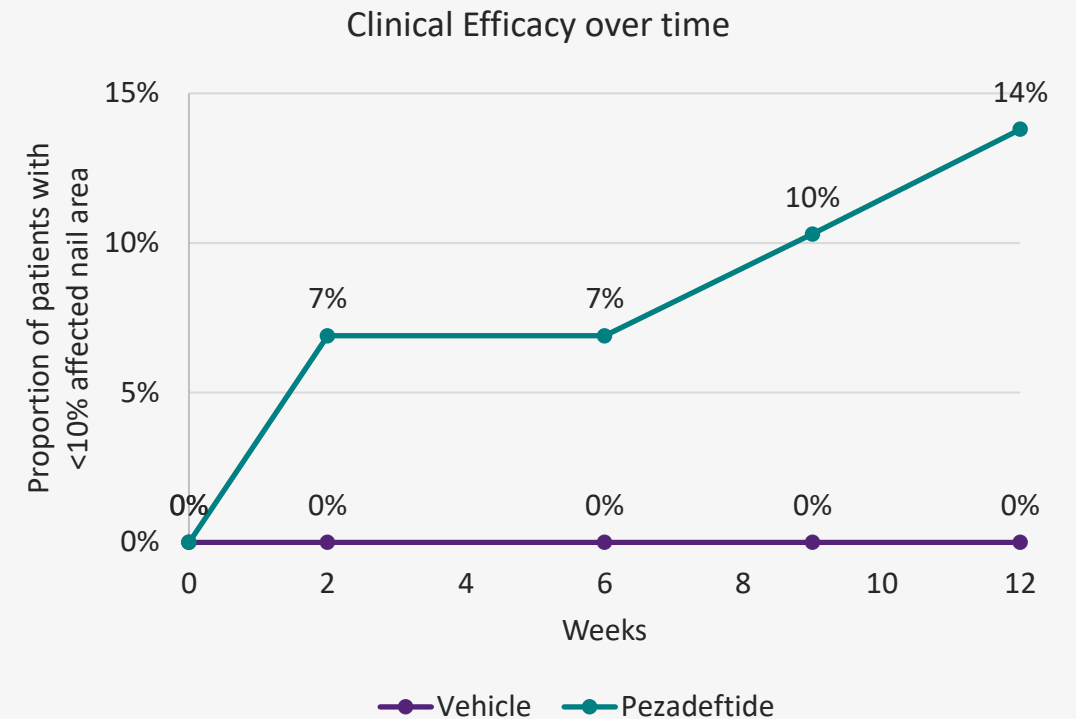


PEZADEFTIDE RAPIDLY CLEARED THE AFFECTED NAIL AREA

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.



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](#)

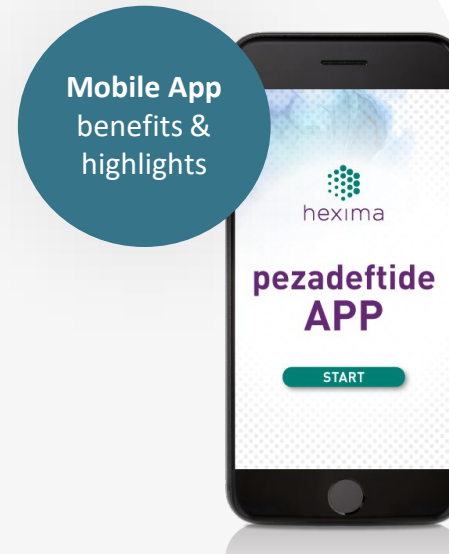


PATENT FILED ON COMPLIANCEPAK ASSOCIATED MOBILE APPLICATION



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

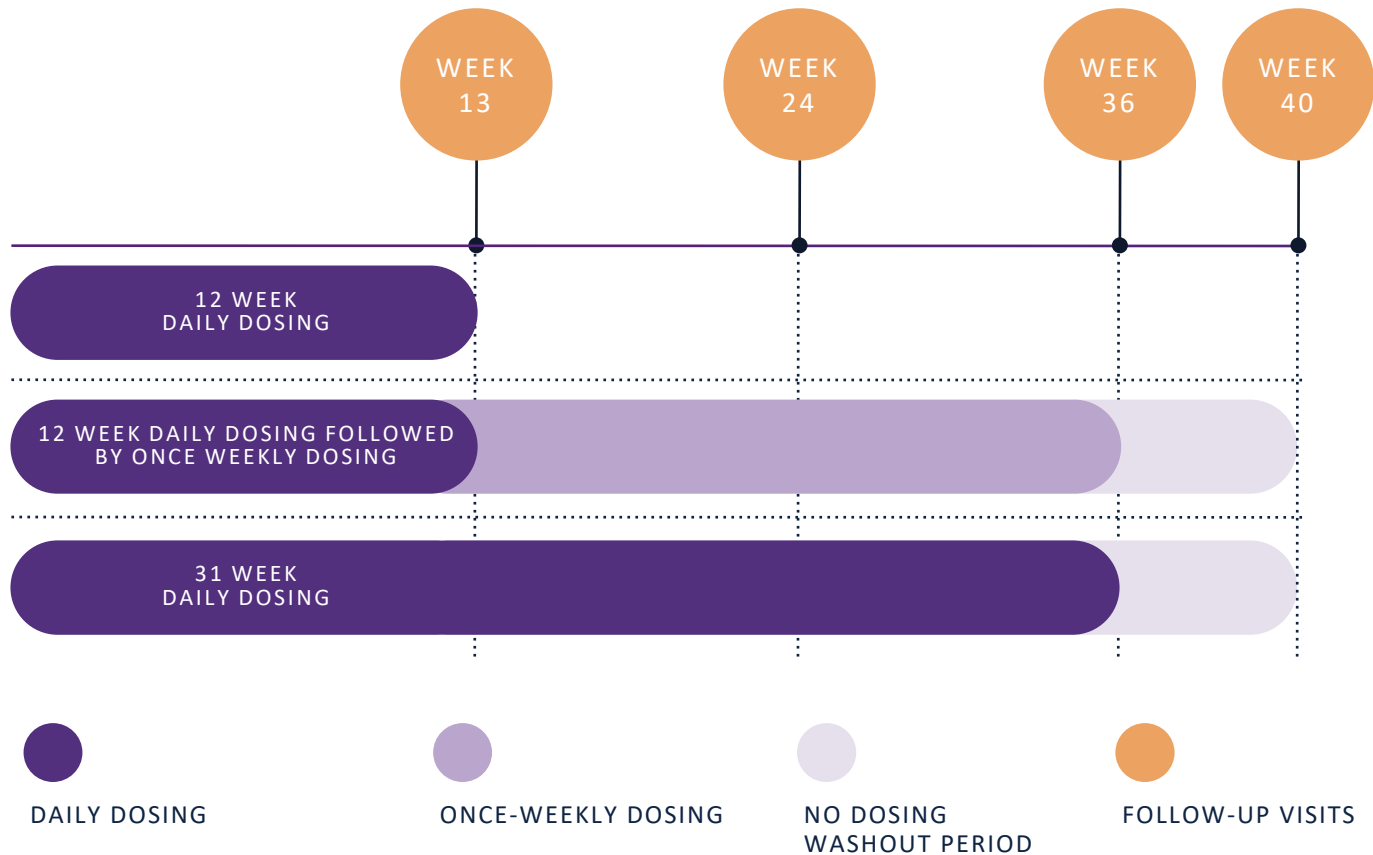
FOR PAYERS WHO WANT

- 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



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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