

ANNOUNCEMENT AND MEDIA RELEASE



22 October 2018

Hexima announces positive results from phase 1/2a clinical trial of HXP124 as a novel topical treatment for fungal nail infections

Melbourne, Australia – Hexima Limited today announced positive results from Part 1 of its ongoing phase 1/2a clinical trial for HXP124 as a novel topical treatment for fungal nail infections (onychomycosis).

“HXP124 substantially reduced the area of infection in patients with a much shorter treatment period than current best-in-class therapies,” said Dr Nicole van der Weerden, Hexima’s CEO. “Because this is the first time this drug has been tested in humans, the data are necessarily from a relatively small number of patients. However, the results are still very encouraging and demonstrate the potential of HXP124 to be a best-in-class topical therapy.”

The trial was designed to address three questions:

1. Is HXP124 safe when applied topically?
2. Is HXP124 effective in treating onychomycosis?
3. Is HXP124 likely to be superior to current best therapies for onychomycosis?

Preliminary findings of the study are as follows:

HXP124 was safe when applied topically. There were no treatment-related adverse events during the study and HXP124 did not cause pain or irritation in the treated toes. HXP124 was also not detected in the bloodstream.

The data indicate that HXP124 is an effective therapy for onychomycosis. 12 of 13 treated nails showed a clear response to the drug. The single patient that did not respond had a suspected dermatophytoma. These are known to be difficult or impossible to treat with topical products.

The area of infected nail in the HXP124-treated patients decreased by 39% in the 12-week period, almost twice as much as the vehicle-treated patients at 21%. (It should be noted that due to the normally slow rate of toenail growth, only partial clearing of the infected nail area could be expected over the 12-week period of the trial. The damaged area cannot be repaired and must be replaced by new nail growth.)

At the 12-week follow-up, 31% of HXP124-treated patients had achieved clinical efficacy (defined as <10% infected nail area). This indicates faster clearance of infected nails than the best-in-class topical products. By comparison, Jublia® (the most effective topical treatment available in the United States) takes four times longer (48-weeks) to produce similar clinical efficacy (31-36% of patients).

The rate of clear nail growth with HXP124 suggests superior efficacy to efinaconazole (Jublia®). HXP124-treated patients averaged 2.4 mm of clear nail growth in 12 weeks. This indicates that about

~10 mm of clear nail growth might be anticipated in 12 months, twice that obtained after Jublia® treatment for 48-weeks (3.8 – 5 mm).

“The team at Hexima is proud to have completed Part 1 of the study, and to have demonstrated that HXP124 was safe and efficacious in this initial study,” said Prof Marilyn Anderson, Chief Science Officer of Hexima. “We look forward to further data updates from this study, and discussions with the FDA relating to the ongoing development of HXP124.”

Background

Hexima’s first in-human clinical trial was a dose-escalation study in which HXP124 has been applied topically to patients with mild to moderate onychomycosis. Patients applied HXP124 at a strength of 0.5%, 1% or 2% daily for 6 weeks. The primary purpose of Phase 1 of the study was to assess the safety and tolerability of HXP124. Secondary endpoints included assessment of clear nail growth and clearance of fungi from the nail over a period of 3-12 months.

The first part of the Phase 1 study, including 18 patients divided into three dose groups, has now concluded.

The study was a vehicle-controlled study, meaning that some participants received the formulation for HXP124 without the active drug (vehicle). The study was also double-blind, meaning neither the patient nor the investigators knew who was receiving the drug and who was receiving the vehicle.

The three cohorts, each consisting of 6 patients, were randomised 2:1, with four patients receiving HXP124 Drug Product and two patients receiving the vehicle (formulation without HXP124). The vehicle contains substances known to control the growth of fungi in the laboratory and had some activity in the Infected Nail Model conducted by MedPharm. Due to the relatively small numbers in each cohort, the results have been analysed together (12 active, 6 vehicle). It should be noted that this part of the trial was not intended to include sufficient patients to provide statistically-significant results. The follow-up period for this part of the study was 12 weeks.

Part 2 of the trial is now fully enrolled and data for the 3-month follow up for Part 2 will be available in Q1 2019. If the results obtained in Part 1 are replicated in the larger patient population in Part 2, Hexima will proceed with a capital raising to fund the next phase of clinical development required to obtain marketing approval in key jurisdictions including the USA and Europe.

About HXP124

HXP124 is a potent antifungal plant defensin peptide. It rapidly kills a broad range of fungal pathogens, including those that cause fungal nail infections (onychomycosis). It rapidly penetrates human nails and retains activity in the nail environment. HXP124 is extremely stable and can be formulated without the need for harmful organic solvents. These attributes make HXP124 an excellent candidate for a novel topical therapy for onychomycosis. HXP124 is currently being evaluated in a Phase 1/2a, double-blind, vehicle-controlled, first-in-human study of the safety, tolerability, and efficacy in patients with mild to moderate onychomycosis.

About Hexima

Hexima is a clinical-stage biotechnology company actively engaged in the discovery and development of plant derived proteins and peptides for applications as human therapeutics. Hexima is developing

its lead compound, the plant defensin HXP124, as a treatment for fungal nail infections (onychomycosis). Hexima's antifungal technology platform is applicable across several areas including human and animal disease. For additional information about Hexima please visit www.hexima.com.au.

About onychomycosis

Onychomycosis is an infection that can cause toenails and fingernails to thicken, discolour, split or disfigure. Dermatophytic, or fungal, infection is the most common cause of onychomycosis, and toenails are most commonly affected. The infection may be of aesthetic concern initially, but without treatment, nails can thicken and disfigure to the extent that they cause irritation, pain and difficulty walking.

The onychomycosis treatment market was valued at US\$3.06 billion in 2015 and is projected to reach US\$4.7 billion by 2021. The two main treatment regimens for onychomycosis are topical and oral anti-fungal therapies. Current topical treatments offer limited efficacy because they do not penetrate the nail sufficiently to treat the infection under the nail, and/or they only slow growth of the fungus rather than killing it, giving the fungus the opportunity to regrow when the treatment is stopped. Furthermore, treatment times with current topical treatments are long (requiring daily application for up to a year). Oral treatments are more effective because they can reach the infection site through the circulatory system and they offer shorter treatment times (usually three months). However, oral anti-fungal treatments are associated with serious side effects and are not recommended for those with liver disease or heart conditions. Furthermore, about 20-25% of patients fail to respond to oral drugs.

Company enquiries:

Dr Nicole van der Weerden

n.vanderweerden@hexima.com.au

Tel: +61 (0) 3 9479 1210

Join our email database to receive program updates:

Tel: +61 (0) 3 9479 1210

Info@hexima.com.au

www.hexima.com.au

Part 1 results of HXP124 phase I/IIa clinical trial for onychomycosis



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Purpose and design of the phase I/IIa clinical trial



- Regulatory bodies require new drugs to be tested in phase I clinical trials to assess the safety of the drug candidate in a small number of participants before proceeding to large-scale trials designed to assess efficacy.
- Hexima's first-in-human clinical trial is a dose-escalation study in which HXP124 is applied topically to patients with mild to moderate onychomycosis (fungal nail infection). Patients applied HXP124 at a strength of 0.5%, 1% or 2% daily for 6 weeks. The primary purpose of the study is to assess the safety and tolerability of HXP124. Secondary endpoints include assessment of clear nail growth and clearance of fungi from the nail over a period of 3-12 months.
- The trial was designed to address 3 questions:
 1. Is HXP124 safe when applied topically?
 2. Is HXP124 effective in treating onychomycosis?
 3. Is HXP124 likely to be superior to current best therapies for onychomycosis?
- The first part of the Phase 1 study has now concluded. The follow-up period for this part of the study was 12 weeks. Due to the slow rate of toenail growth, only partial clearing of the infected nail area could be expected over the 12-week period of the trial. The damaged area cannot be repaired and must be replaced by new nail growth. It should be noted that this part of the trial was not intended to include sufficient patients to provide statistically-significant results. There were three cohorts, each consisting of 6 patients randomised 2:1 (4 active, 2 vehicle). Due to the relatively small numbers in each cohort, the results have been analysed together (12 active, 6 vehicle).
- It should also be noted that this study was a vehicle-controlled study, in which the placebo group received an intended formulation for HXP124 but without any active drug. The vehicle contains substances known to control the growth of fungi *in vitro* and had some activity in the Infected Nail Model conducted by MedPharm.

Q1. Is HXP124 safe when applied topically?

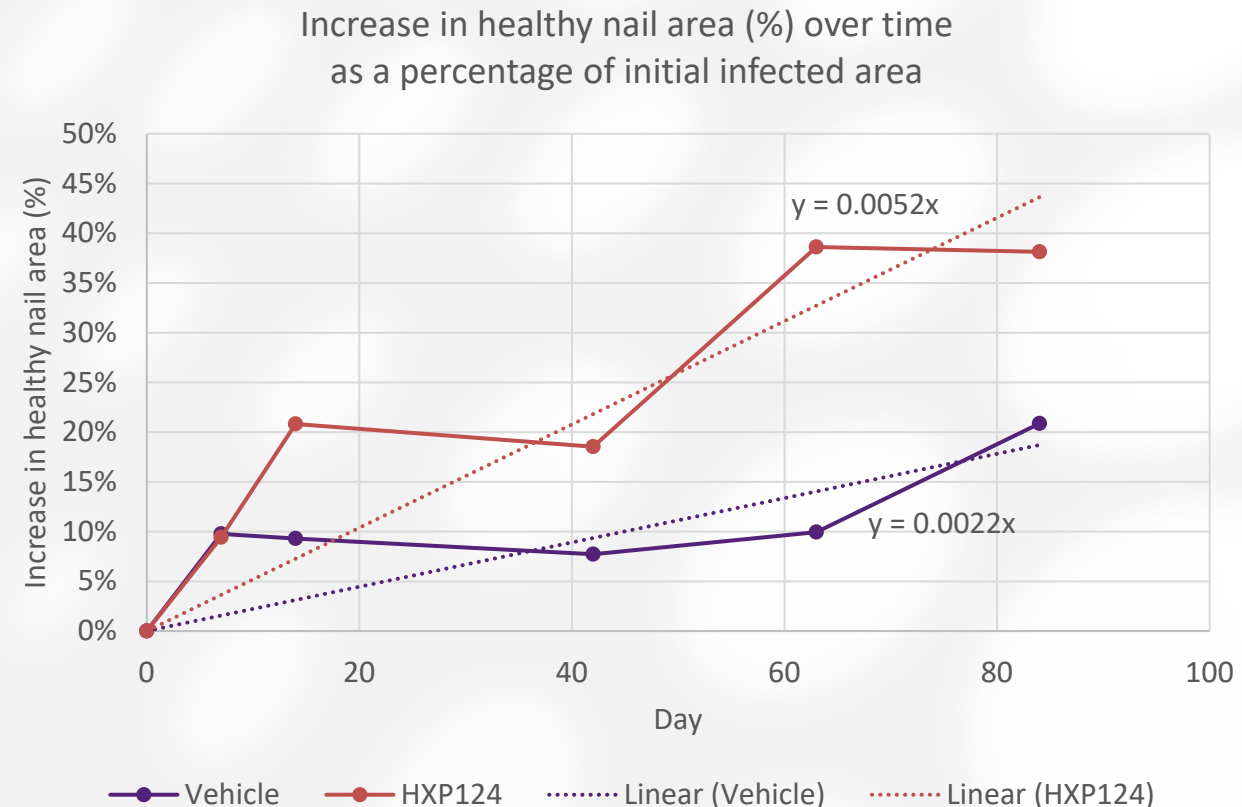


- HXP124 is safe when applied topically over the period of the study.
 - No drug-related adverse events.
 - HXP124 did not cause pain or irritation.
 - HXP124 was not detected in the bloodstream.

Q2. Is HXP124 an effective treatment for onychomycosis?



- The data indicate that HXP124 is an effective therapy for onychomycosis.
- 12 of 13 treated nails showed a clear response.
 - The single patient not showing an apparent response had a suspected dermatophytoma. These are known to be difficult to treat with topical products.
- The area of infected nail in the HXP124-treated patients decreased by almost twice as much as the vehicle-treated patients (39% vs 21%).

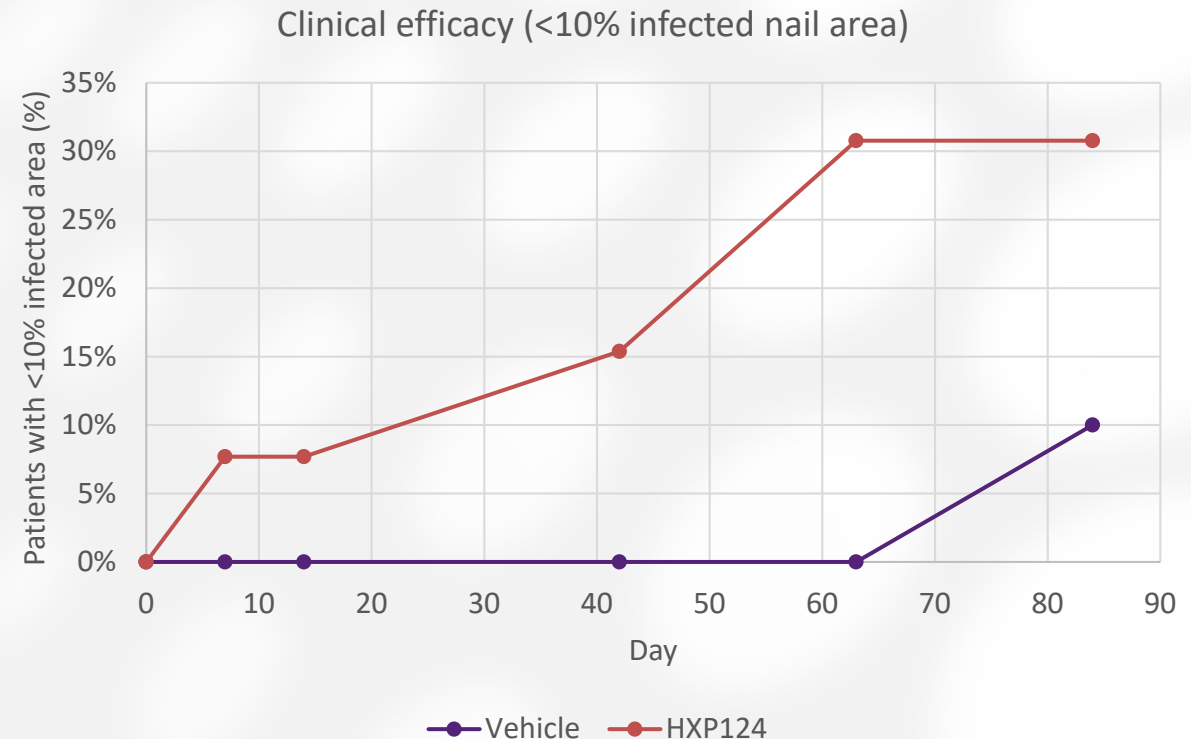


Q3. Is HXP124 likely to be superior to current therapies?



➤ 31% of HXP124-treated patients achieved clinical efficacy (defined as <10% of the nail area infected) within 12 weeks.

- It takes 48-weeks of treatment with Jublia® to produce clinical efficacy in 31-36% of patients.

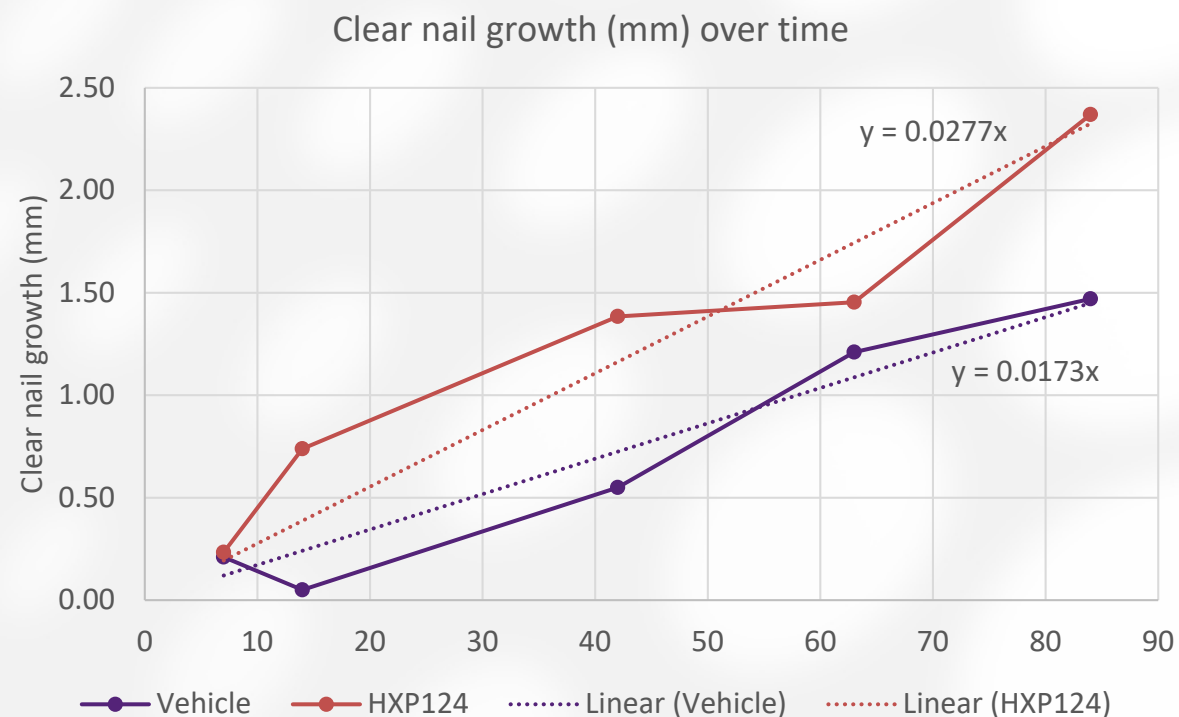


Q3. Is HXP124 likely to be superior to current therapies?



➤ Rate of clear nail growth suggests a path of superior efficacy to efinaconazole (Jublia®).

- HXP124-treated patients averaged 2.4 mm of clear nail growth in 12 weeks.
- Extrapolating these data suggests ~10 mm of clear nail growth in 12 months, twice that of Jublia®.
- Treatment with Jublia® for 48-weeks produces clear nail growth of 3.8 – 5 mm.



Selected images of HXP124-treated patients

Baseline



Week 12



Baseline



Week 12



Baseline



Week 12



Baseline



Week 12

