



ASX Announcement

15 July 2021

Presentation of Phase I/IIa study data at American Podiatric Medical Association (APMA) and Investor Webinar

MELBOURNE, AUSTRALIA (15 July 2021): Hexima Limited (ASX:HXL), is pleased to announce that it will present further analysis of the clinical data from its Phase I/IIa clinical trial of pezadeftide (HXP124) for the treatment of onychomycosis¹ at the upcoming American Podiatric Medical Association (APMA) meeting in Aurora, Colorado. The Company will hold an investor briefing on 29 July to review the data presented.

Joining the annual APMA 2021 Annual Scientific Meeting held from July 29 to August 1, is an important opportunity to share Hexima's data on pezadeftide's potential in the management of onychomycosis and discuss with leading physicians in this specialty. In the US, Podiatrists tend to manage most cases of onychomycosis and importantly write 80% of all prescriptions for onychomycosis¹.

Hexima CEO Michael Aldridge commented, "Presenting at the APMA meeting provides a valuable opportunity to highlight the impressive safety and efficacy data we have seen from Hexima's phase I/IIa clinical study and to discuss the significant potential of pezadeftide with this important group of future prescribers as we ensure the development of pezadeftide effectively meets the needs of patients with onychomycosis."

Alongside the APMA meeting, Hexima will hold an investor webinar at 9 am AEST 29 July 2021 to review the data that will be presented. Attendees can register to attend using the link below.

Investor Webinar: 29 July 2021, 9 am AEST

Registration link: https://zoom.us/webinar/register/WN_lxv6voHySM-bsm6C6xgC8A

This announcement is authorised for release to ASX by Dr Nicole van der Weerden, COO

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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 (previously referred to as 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

¹ Clinical study HXP124-ONY-001; ANZCTR registration number: ACTRN12618000131257



onychomycosis. Hexima holds granted, long-life patents protecting pezadeftide in major markets globally. For additional information about Hexima please visit www.hexima.com.au. You can also find us on [Twitter](#) and [LinkedIn](#).

About Onychomycosis

Onychomycosis is a common fungal nail infection in the nail plate and nail bed. Prevalence of onychomycosis has been estimated at between 10% (Japan) and 13.8% (USA)ⁱⁱ. 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 treatmentⁱⁱⁱ. 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^{iv}. 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 more prevalent in older, diabetic and immune compromised populations^v. The global market for treatments for onychomycosis was approximately US\$3.7 billion in 2018^{vi}.

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^{vii}.

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 azole class 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 effective at rapidly killing fungal cells by a novel fungicidal mode of action. 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.

ⁱ ClearView Healthcare Partners proprietary market research, 2019

ⁱⁱ Tatchibana et al., Journal of Fungi, 2017

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- iii Joseph et al, Supplement to Podiatry Today, 2013
 - iv Milobratovic et al., Mycoses, 2013
 - v Joseph et al, Supplement to Podiatry Today, 2013
 - vi Persistence Market Research 2018
 - vii Wang et al., Onychomycosis: Diagnosis and Effective Management, 2018