

HEXIMA LIMITED

ASX ANNOUNCEMENT



24 June 2022

PHASE II PRELIMINARY RESULTS

MELBOURNE, AUSTRALIA (24 June 2022): Hexima Limited (ASX:HXL) announces that based on its preliminary review, the results of its phase II clinical study of pezadeftide for the treatment of onychomycosis (HXP124-ONY-002) are inconclusive and will require further detailed investigation and evaluation. The results seen in this study do not appear to correlate with results observed in its prior phase I study (HXP124-ONY-001) and do not support moving directly into a phase III program. Hexima intends to conduct a detailed review of the complete clinical trial data set and study conduct and expects to report its findings when complete.

ENDS

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.

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