



ASX Announcement

20 May 2021

INN designation for HXP124

First in a new class of anti-fungal agents

Hexima to present at ShareCafe: Friday 21 May at 12:30 PM (AEST)

MELBOURNE, AUSTRALIA (20 May 2021): Hexima Limited (ASX:HXL) a clinical stage biotechnology company developing HXP124, a new prescription topical treatment for onychomycosis, is pleased to announce that The International Nonproprietary Names (INN) Programme and Classification of Medical Products of the World Health Organization (WHO) has selected "*pezadeftide*" as the non-proprietary name for Hexima's HXP124.

Importantly, the suffix "*-deftide*", representing defensin-derived anti-microbial peptides, establishes *pezadeftide* as the first in a new class of anti-fungal molecules.

Michael Aldridge CEO of Hexima commented, "The designation of *pezadeftide* as the first in a new class of anti-microbial peptides highlights the important role that Hexima is playing bringing novel, powerful and broad-spectrum fungicidal molecules as potentially valuable tools in the ever-escalating battle with constantly evolving fungal pathogens."

Hexima expects "*pezadeftide*" to be included in List 126 of proposed INN, to be published in WHO Drug Information and to be confirmed following a four month public review and comment period.

Webinar presentation - ShareCafe

On Friday 21 May, Hexima CEO Michael Aldridge will present at the **ShareCafe Hidden Gems Webinar** at 12:30pm AEST.

Mr Aldridge will provide a company overview and discuss the strategic direction of Hexima, including the significance of this new INN designation and recognition of HXP124 as the first in a new class of anti-fungal agents. This presentation will be followed by a brief Q&A session with investors.

To register for this free event, please click [here](https://us02web.zoom.us/webinar/register/5416151767246/WN_HmagqoTQTZmM8P080dfAwg) or paste the following URL into your browser https://us02web.zoom.us/webinar/register/5416151767246/WN_HmagqoTQTZmM8P080dfAwg.

A recorded copy of the presentation will be made available following the event.

Footnote: International Nonproprietary Names (INN) identify pharmaceutical substances or active pharmaceutical ingredients. Each INN is a unique name that is globally recognised and is public property. A nonproprietary name is also known as a generic name. The selection of a new INN follows a global procedure coordinated by the World Health Organisation. Source: www.who.int/teams/health-product-and-policy-standards/inn/



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 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).^[2] Onychomycosis is an infectious disease and is difficult to treat with 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.^[3] 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.^[4] It is important to treat onychomycosis as the fungi in the nail and 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.^[3] The global market for treatments for onychomycosis was approximately US\$3.7 billion in 2018.^[5]

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.^[6]

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 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.

Notes:

1. ClearView Healthcare Partners proprietary market research, 2019
2. Tatchibana et al., Journal of Fungi, 2017
3. Joseph et al, Supplement to Podiatry Today, 2013
4. Milobratovic et al., Mycoses, 2013
5. Persistence Market Research 2018
6. Wang et al., Onychomycosis: Diagnosis and Effective Management, 2018

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

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