HEXIMA LIMITED ASX ANNOUNCEMENT



22 March 2022

HEXIMA TO PRESENT PEZADEFTIDE'S NOVEL FUNGICIDAL MODE OF ACTION AT AMERICAN ACADEMY OF DERMATOLOGY ANNUAL MEETING

AAD's annual meeting commences Friday 25 March in Boston, MA Mode of Action presentation to be available following release of AAD embargo

MELBOURNE, AUSTRALIA (22 March 2022): Hexima Limited (ASX:HXL) a clinical stage biotechnology company developing pezadeftide (formerly HXP124), a potential new prescription topical treatment for onychomycosis, announces that it will present pezadeftide's novel fungicidal mode of action at the annual meeting of the American Academy of Dermatology on 25 March 2022 in Boston, MA.

The American Academy of Dermatology is the largest, most influential and representative dermatology group in the United States. Dermatologists represent the key thought-leading specialty medical group in the management of onychomycosis in the US.

Following the release of AAD's embargo at 7:00 AM Friday March 25th (EDT) (10:00 PM AEDT), the mode of action presentation will be available to all stakeholders via Hexima's website at:

https://hexima.com.au/presentation-at-american-academy-of-dermatology-march-2022.

In addition, Hexima's CEO and COO will host a webinar on 5th April 2022 at 9:00 AM AEST to discuss recent progress, upcoming milestones and the mechanism of action of pezadeftide against fungal pathogens. Register for the webinar here: <u>https://bit.ly/3CTn5fP</u>

Hexima CEO, Michael Aldridge said "We are pleased to have been invited to present pezadeftide's novel activity at the AAD. Pezadeftide's powerful and broad spectrum anti-fungal mode of action, together with its ability to rapidly penetrate human nail underscores its potential as a new and powerful treatment for onychomycosis. The challenge of treating onychomycosis remains a significant unmet medical need."

As previously announced Hexima expects to initiate its first US clinical trial in mid 2022, and the Company's overall timetable of development activities including the release of phase II data in Q2 2022 and the subsequent initiation of phase III remains on track.

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

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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 <u>www.hexima.com.au</u>. You can also find us on <u>Twitter</u> and <u>LinkedIn</u> or email us at <u>info@hexima.com.au</u>.

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

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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