ASX Announcement

26 July 2021

Completion of enrolment in phase IIb clinical trial

MELBOURNE, AUSTRALIA (26 July 2021): Hexima Limited (ASX:HXL), a clinical stage biotechnology company, is pleased to announce that it has completed enrolment of patients into its phase IIb clinical trial evaluating pezadeftide (HXP124) as a potential new topical treatment for onychomycosis. The study is on schedule and Hexima expects to announce results from the trial in Q2 2022.

This is an important achievement in pezadeftide's advanced clinical development program. Fifteen clinical sites across Australia and New Zealand enrolled a total of 117 patients into the study. Patients were randomly assigned to three different treatment arms. In each treatment arm patients receive either pezadeftide or the vehicle (without pezadeftide) control. The assignment of vehicle versus active is blinded to both the patient and the investigator. Patients will be monitored at follow-up visits for the safety and efficacy of pezadeftide through to the end of the study. The study also collects patient satisfaction measures.

Dr Robert Rosen, Managing Director of Southderm Dermatology, Sydney, and one of the Lead Investigators on the HXP124-ONY-002 study, says "Onychomycosis is a common and difficult to treat condition and we welcome innovation in this area. We look forward to assessing whether pezadeftide applied topically can be a safe and effective treatment for this disease."

Hexima expects this phase IIb clinical trial[1] to represent its last large multi-centre clinical trial ahead of initiating a phase III program in Q3 2022. In preparation, Hexima expects to file an IND with FDA in Q4 2021 and then conduct an FDA-required small single-centre, maximal use, safety study in the US in H1 2022.

Michael Aldridge CEO of Hexima commented, "We are very pleased to have completed enrolment in this advanced and comprehensive study, following some early challenges with COVID-19 related lockdowns,"

"We expect to build on the very promising preliminary efficacy we saw in our phase I/IIa clinical trial. Our goal is to demonstrate the potential of pezadeftide to be a safe and effective treatment in a convenient, consumer friendly, topical format for this very common and difficult to treat infectious disease" he continued.

Dr Peter Welburn, Hexima's Chief Development Officer continued "The results of this study will be pivotal in determining the optimal dosing strategy for our global phase III program and we anticipate entering discussions with FDA in the second half of 2022."

Hexima will hold an investor webinar at 9 am AEST on 29 July to share clinical data from its phase I/IIa clinical study that will be presented at the American Podiatric Medical Association (APMA) Annual

[1] HXP124-ONY-002 – ANZCTR registration number - CTRN12620000697987

Meeting in Colorado on 30 July 2021. The Company will also give an update on progress of its phase IIb clinical study. 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_Ixv6voHySM-bsm6C6xgC8A

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

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).[1] 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.[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 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.[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 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 HXP124 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.

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[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