ASX Announcement

12 May 2021

Grant of Australian Patent over HXP124

Strengthens Layers of Patent Protection

MELBOURNE, AUSTRALIA (12 May 2021): Hexima Limited (ASX:HXL) is pleased to announce the grant of an Australian patent covering HXP124 and its proprietary method for the treatment of fungal nail infections. The patent, 2015336933, is described as "A method of treatment" and provides protection until 2035 (subject to any available patent term extension).

The award of this patent strengthens Hexima's patent portfolio which includes similar granted patents in the United States, Japan and Singapore and patent filings in these and other jurisdictions.

Hexima CEO Michael Aldridge said "Patent protection of HXP124 in major markets is a central element in Hexima's IP strategy; and we are also pursuing patents in key markets covering our formulation technology which will broaden our patent protection. Hexima also expects to benefit from the 12-year period of market exclusivity afforded a biologic drug, such as HXP124, on approval as a therapeutic product by the US FDA."

About Hexima

Hexima (ASX:HXL) is a clinical stage, infectious disease focused biotechnology company engaged in the research and development of defensin peptides for applications as human therapeutics. Our lead product candidate, 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 HXP124 for the treatment of onychomycosis. Hexima holds granted, long-life patents protecting HXP124 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 HXP124, 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.

HXP124 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, HXP124 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, Managing Director & CEO

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