NailMail

Investor News



NailMail is Hexima's regular quarterly newsletter to shareholders, investors and interested parties. If you have any questions or comments you may wish to review our website at www.hexima.com.au.

Following Hexima's public offering and listing on ASX on 1 December 2020 we intend to circulate NailMail each calendar quarter.

Phase IIb clinical trial

We are running a phase IIb clinical trial in Australia and New Zealand enrolling up to 132 patients with onychomycosis. This study is seeking to identify the optimal course of therapy for HXP124 and is comparing 3 treatment arms.



The patients receiving treatment with HXP124 are being compared to patients being treated with a formulation without HXP124.

The results of this clinical trial will be key to the planning of our phase III clinical trial program in the US. Hexima is a biotechnology company engaged in the research and development of plant-derived 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 a 132 patient Australian phase IIb clinical trial of HXP124 for onychomycosis. Hexima holds granted, long-life patents protecting HXP124 in major markets globally.

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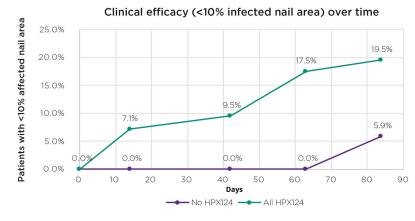


HXP124

HXP124 addresses important shortcomings of available treatments for onychomycosis. It is a broad spectrum and powerful antifungal agent which penetrates human nails very rapidly. In a phase I/IIa clinical trial, HXP124 applied daily for just 6 weeks was:

- More effective, clearing fungus from the nail two-times more effectively than current bestin-class (oral and topical) products at the same time point
- Faster acting, cleared fungus with a dramatically shorter course of therapy than current topical products
- Safe and well tolerated, with no treatment area irritation or treatment-related adverse events
- Locally acting, HXP124 effectively penetrates nails but is not detected in the blood stream and has not presented any systemic toxicity

In our view these product features meet a well-defined and under-served market for the treatment of onychomycosis and, subject to completion of successful clinical trial and product development programs, HXP124 has the potential to capture significant market share in major global pharmaceutical markets.



Important developments and milestones in Q3 2020

The last few months have been a productive period for the Hexima team. We are pleased to note the following important milestones:

Operational Progress:

First patient treated in Phase IIb clinical trial: The first patient has been treated in our Australian phase IIb clinical trial. Ten clinical sites in Australia and New Zealand are now active and are recruiting patients into this 132-subject trial.

Equity Capital Raising: We raised a total of \$8.5 million before costs in a private placement (\$5.5 million) and public offering (\$3.0 million) adding 307 new shareholders to our register.

ASX Listing: On 1 December 2020 Hexima's shares commenced trading on ASX under the ticker code "HXL". You can follow trading in the "Investors" section of our website at www.hexima.com.au

Management changes:

Michael Aldridge accepted the role as our CEO. Michael is based in the San Francisco Bay Area and has a 20 plus year career in the leadership of emerging growth pharmaceutical product development companies. Previously Michael led Peplin, which developed Picato, a topical treatment for AK or sunspots. Peplin was sold to LEO Pharma in 2009.

Nicole van der Weerden our previous CEO has assumed the role of COO and remains firmly at the helm of the critical technical operations at Hexima.

Peter Welburn has joined our team as Chief Development Officer. Peter has a long career in drug development and steered the Picato program at Peplin from its earliest pre-clinical stage through to global phase III trials and onto the market.

Board changes:

Dan O'Brien and John Bedbrook stepped back from their roles as non-executive directors. Jonathan West continues as Chairman and Justin Yap and Scott Robertson as nonexecutive board members.



Milestones to look forward to in 2021

2021 will be an exciting year on multiple fronts as we progress our phase IIb trial in Australia and prepare for development activities in the US. Major events to look out for include:

- Completion of patient enrolment into our phase IIb clinical trial
- Scale-up of our drug manufacturing in Europe in anticipation of US phase III trials
- Filing an IND with FDA to formally initiate our US development activities
- Formation of our global Scientific Advisory Board, comprised of leading international dermatologists and podiatrists.

Together with our regular financial and operational reporting to ASX, we have a full year of news.



