



Hexima completes enrolment for dose escalation stage of phase 1/2a clinical trial of HXP124 as a novel topical treatment for fungal nail infections

Melbourne, Australia – Hexima Limited is pleased to announce today that it has completed enrolment for the dose escalation stage of its phase 1/2a clinical trial of HXP124 in patients with fungal nail infections.

Hexima's CEO Dr Nicole van der Weerden said "The HXP124 clinical trial is progressing well and it is very encouraging to complete enrolment for Part 1 of the study. Recruitment for Part 2 continues to progress well and we expect to have data from the trial before the end of the year."

Hexima's first-in-human clinical trial is a dose escalation study of HXP124 which is applied topically to patients with mild to moderate onychomycosis (fungal nail infection). Part 1 of the study is a dose escalation stage to test the safety of HXP124 at increasing doses of 0.5%, 1% or 2%. Part 2 of the study will test the highest safe dose in a larger group of patients. Recruitment for this second stage is now underway. The primary endpoint of the study is to assess the safety and tolerability of HXP124. Secondary endpoints will include assessment of clear nail growth and looking for clearance of fungi from the nail over a period of 3-12 months. Preliminary trial results are expected to be available in late 2018.

About Hexima

Hexima is a biotechnology company actively engaged in the discovery and development of plant derived proteins and peptides for applications as human therapeutics and for agricultural crop protection. Hexima's antifungal technology platform is applicable across several areas including human and animal disease. For additional information about Hexima please visit www.hexima.com.au.

About onychomycosis

Onychomycosis is an infection that can cause toenails and fingernails to thicken, discolour, split or disfigure. Dermatophytic, or fungal, infection is the most common cause of onychomycosis, and toenails are most commonly affected. The infection may be of aesthetic concern initially, but without treatment, nails can thicken and disfigure to the extent that they cause irritation, pain and difficulty walking.

The onychomycosis market was valued at US\$3.06 billion in 2015 and is projected to reach US\$4.7 billion by 2021. The two main treatment regimens for onychomycosis are topical and oral anti-fungal therapies. Current topical treatments offer limited efficacy because they do not penetrate the nail sufficiently to treat the infection under the nail, and/or they only slow growth of the fungus rather than killing it, giving the fungus the opportunity to regrow when the treatment is stopped. Furthermore, treatment times with current topical treatments are long (up to a year). Oral treatments are more effective because they can reach the infection site through the circulatory system and they offer shorter treatment times (usually three months). However, oral anti-fungal treatments are

associated with serious side effects and consequently, are not recommended for those with liver disease or heart conditions. Furthermore, about 20-25% of patients fail to respond to oral drugs.

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