ANNOUNCEMENT

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Hexima announces further positive results from phase 1/2a clinical trial of HXP124 as a novel topical treatment for fungal nail infections

Melbourne, Australia – Hexima Limited today announced additional positive results from the second part of its ongoing phase 1/2a clinical trial for HXP124 as a novel topical treatment for fungal nail infections (onychomycosis).

"These latest results confirm our interim data that HXP124 substantially reduced the area of infection in patients with a much shorter treatment period than current best-in-class therapies," said Dr Nicole van der Weerden, Hexima's CEO. "We now have data from a total of 36 patients treated with HXP124 and, while this sample size is still relatively small, the continued positive effect gives us confidence that HXP124 will be an effective treatment for onychomycosis with a highly differentiated value proposition and substantially shorter treatment time."

The trial was designed to address three questions:

1. Is HXP124 safe when applied topically?
2. Is HXP124 effective in treating onychomycosis?
3. Is HXP124 likely to be superior to current best therapies for onychomycosis?

Preliminary findings of the study are as follows:

HXP124 was safe when applied topically. There were no treatment-related adverse events during the study and HXP124 did not cause pain or irritation in the treated toes. HXP124 was also not detected in the bloodstream.

The data indicate that HXP124 is an effective therapy for onychomycosis. After only 6 weeks of treatment (relative to the 48 weeks required for current topical therapies) and 6 weeks of follow-up, 15 of 41 (37%) treated nails showed a reduction in the infected nail area of more than 40%. This indicates that the infection has been controlled and the damaged nail area is being replaced by new, clear nail growth. (It should be noted that due to the normally slow rate of toenail growth, only partial clearing of the infected nail area could be expected over the 12-week period of the trial. The damaged area cannot be repaired and must be replaced by new nail growth.) In the vehicle-treated group, only 3 out of 17 nails (18%) showed a similar level of reduction.

At the 12-week follow-up, 20% of HXP124-treated patients had achieved clinical efficacy (defined as <10% infected nail area). This indicates faster clearance of infected nails than the best-in-class topical products. By comparison, Julia® (the most effective topical treatment available in the United States) takes four times longer (48-weeks) to produce clinical efficacy in 31-36% of patients. In the vehicle treated nails, only 6% achieved clinical efficacy by 12 weeks.

Treatment with HXP124 enhanced clearance of fungi from infected nails. After 6 weeks of treatment and 6 weeks of follow-up, Mycological Cure rates (defined as the absence of fungal elements in nail

clippings as assessed by microscopy and culture) were 52.4% for HXP124-treated nails versus 23.5% for vehicle-treated. Once again this indicates faster clearance of the infection than Jublia® which takes 48 weeks of treatment to achieve mycological cure rates of 53-55%.

"We are very pleased that our clinical data continues to look very strong and we look forward to taking HXP124 into the next stage of clinical development and getting this much needed treatment into the hands of patients." said Prof Marilyn Anderson, Chief Science Officer of Hexima. "

Based on these strong results, Hexima is conducting a capital raising to fund the next phase of clinical and non-clinical development required to obtain marketing approval in key jurisdictions including the USA and Europe.

Background

Hexima's first in-human clinical trial was a dose-escalation study in which HXP124 has been applied topically to patients with mild to moderate onychomycosis. Patients applied HXP124 at a strength of 0.5%, 1% or 2% daily for 6 weeks. The primary purpose of Phase 1 of the study was to assess the safety and tolerability of HXP124. Secondary endpoints included assessment of clear nail growth and clearance of fungi from the nail over a period of 3-12 months.

The treatment and initial follow-up stages of the Phase 1 study, involving a total of 48 patients (36 treated with HXP124, 12 treated with vehicle), has now concluded.

The study was a vehicle-controlled study, meaning that some participants received the formulation for HXP124 without the active drug (vehicle). The study was also double-blind, meaning neither the patient nor the investigators knew who was receiving the drug and who was receiving the vehicle. The vehicle contains substances known to control the growth of fungi in the laboratory and had some activity in the Infected Nail Model conducted by MedPharm.

About HXP124

HXP124 is a potent antifungal plant defensin peptide. It rapidly kills a broad range of fungal pathogens, including those that cause fungal nail infections (onychomycosis). It rapidly penetrates human nails and retains activity in the nail environment. HXP124 is extremely stable and can be formulated without the need for harmful organic solvents. These attributes make HXP124 an excellent candidate for a novel topical therapy for onychomycosis.

About Hexima

Hexima is a clinical-stage biotechnology company actively engaged in the discovery and development of plant derived proteins and peptides for applications as human therapeutics. Hexima is developing its lead compound, the plant defensin HXP124, as a treatment for fungal nail infections (onychomycosis). 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 treatment 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 (requiring daily application for 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 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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