HEXIMA LIMITED

# ASX ANNOUNCEMENT

**11 July 2022**

## PHASE II RESULTS

MELBOURNE, AUSTRALIA (11 July 2022): Hexima Limited (ASX:HXL) announces the results of its phase II clinical study of pezadeftide (HXP124) for the treatment of onychomycosis (HXP124-ONY-002).

HXP124-ONY-002 was designed and conducted as a phase II, multi-centre, randomized, double-blind, vehicle-controlled study to investigate the efficacy, safety and tolerability of pezadeftide (HXP124) in three dosing cohorts in patients with mild to moderate onychomycosis.

Subjects were randomised to receive once daily topical application of 2% (20 mg/mL) pezadeftide or vehicle to all infected toenails in one of three cohorts (randomization 3:1 pezadeftide to vehicle):

**Cohort 1** : 2 treatment periods of 6 weeks; N=29 pezadeftide, 9 vehicle
**Cohort 2** : 2 treatment periods of 6 weeks plus once-weekly maintenance dosing for 23 weeks; N=30 pezadeftide, 10 vehicle
**Cohort 3** : 5 treatment periods of 6 weeks plus 1 treatment period of 1 week; N=30 pezadeftide, 9 vehicle.

A total of 117 patients were enrolled; 14 were withdrawn or dropped out prior to completing the study. Patients were assessed for safety and efficacy at scheduled visits (weeks 13, 24, 36) during the course of the study and at the final follow-up visit at week 40. Inclusion and exclusion criteria were generally consistent with those adopted in pivotal clinical studies of the leading branded topical product in the US market.

There was a balanced distribution of patients between cohorts according to age, weight, height, and BMI, 80% were male, 20% female and 89% of enrolled patients were Caucasian. Completers were defined as having complied and received 85% or more of drug doses.

Pezadeftide was well-tolerated and safe, with only three Serious Adverse Events (fall, angina and depression) reported and none reported as drug-related. Overall, Adverse Events (144) were primarily mild, with no unexpected Treatment Emergent Adverse Events, and were similar in reported and observed for pezadeftide and vehicle-treated patients, regardless of Cohort.

The summary of efficacy as at week 40 is shown in the table below. These endpoints are the pre-defined efficacy parameters in the phase II study and are as defined by FDA. There was no consistent effect observed in pezadeftide-treated patients at week 40 compared to vehicle-treated, with the best efficacy results observed in Cohort 2.

| **Efficacy Endpoint** | Cohort 1 | | Cohort 2 | | Cohort 3 | |
|---|---|---|---|---|---|---|
| | Vehicle (N=9) | HXP124 (N=26) | Vehicle (N=7) | HXP124 (N=26) | Vehicle (N=9) | HXP124 (N=27) |
| Mycological cure (%) | 0 | 3 (11.5%) | 0 | 5 (19.2%) | 1 (11.1%) | 2 (7.4%) |
| Complete or almost complete cure (%) | 0 | 0 | 0 | 1 (4.0%) | 1 (11.1%) | 0 |
| Clinical efficacy (%) | 0 | 0 | 1 (14.3%) | 4 (15.4%) | 1 (11.1%) | 1 (3.7%) |
| Complete cure (%) | 0 | 0 | 0 | 0 | 0 | 0 |

- Mycological cure : Negative fungal culture and negative fungal microscopy
- Complete or almost complete cure: <5% toenail still affected and Mycological cure
- Clinical efficacy : <10% toenail still affected
- Complete cure : 100% clear toenail and Mycological cure

These data provide evidence of modest activity of pezadeftide in the treatment of onychomycosis, an observation generally supported by a *post hoc* and blinded review of the clinical appearance of the treated nails conducted by an independent clinician, a member of Hexima's Scientific Advisory Board. However, after careful consideration Hexima does not believe the data support the Company's goal of developing a safe, more effective and convenient topical therapy with a shorter course of treatment.

Accordingly, Hexima intends to wind down its development program of pezadeftide for the treatment of onychomycosis in an orderly fashion, and will make no further significant investment.

Specifically:

1. Hexima's phase II study of pezadeftide (HXP124-ONY-002) is largely complete. Other than regular closing-out of sites and finalising study reports, Hexima anticipates no further meaningful related expenditure on this activity;
2. Hexima has an open IND with FDA to initiate a phase I maximal use clinical trial (HXP124-ONY-003) in the US. That study has not commenced and Hexima has placed it on hold and will incur no further meaningful related expenditure on this activity;
3. Hexima has initiated an orderly process of winding up its various manufacturing and non-clinical development activites in a cost efficient manner;
4. Expenses associated with non-essential employees and contractors are being managed in a cost effective and orderly manner.

Hexima has initiated a process of exploring strategic options for the Company seeking to secure value for Hexima's intellectual property and residual cash resources. These discussions are very preliminary and the contemplated transaction or transactions may or may not occur. The Board is unable to provide further information at this stage.

As of 30 June 2022, Hexima had cash of $4.0 million. Hexima expects to receive, under the Australian Government R&D Tax Incentive scheme together with other short term receivables, a further $5.6 million. This is likely to be offset by estimated current and near term liabilities (including the costs associated with the activities described above through to 30 September 2022) of $9.2 million. This analysis does not include certain non-current tangible assets including Hexima's glasshouse facility which is currently leased to a third party and which was valued in Hexima's accounts as at 31 December 2021 at $0.9 million. Hexima has initiated a process of seeking expressions of interest in the purchase or longer term lease of the facility.

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ENDS

**This announcement is authorised for release to ASX by Hexima's Board of Directors**

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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 II 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 or email us at info@hexima.com.au.

*This announcement contains or may contain forward-looking statements that are based on management's beliefs, assumptions and expectations and on information currently available to management. All statements that address operating performance, events or developments that we expect or anticipate will occur in the future are forward-looking statements.*

*Management believes that these forward-looking statements are reasonable when made. You should not place undue reliance on forward-looking statements because they speak only as of the date when made. Hexima does not assume any obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise. Hexima may not actually achieve the projections or expectations disclosed in forward-looking statements. Actual developments or events could differ materially from those disclosed in the forward-looking statements.*