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Hexima

Healthcare

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Pezadeftide – a novel antifungal agent

Hexima is a pure-play biotech focused on the progression of its sole clinical asset, pezadeftide. The company aims to develop pezadeftide as a novel topical treatment for onychomycosis (fungal nail infection). Pezadeftide belongs to a novel class of molecules known as plant defensins, which are stable, soluble and possess antimicrobial activity. Following encouraging safety and efficacy results from randomised, double-blind, ascending dose-controlled Phase I/IIa trials, a Phase IIb clinical study is currently underway, with results expected in Q222.

Clear demand in a growing market

Onychomycosis is a fungal infection that is estimated to affect 10–14% of the global population and, if left untreated, can result in pain, difficulty wearing shoes and distress at the appearance of nails. The 2014 FDA approval of topical agent Jublia/Clenafin (current market leader with global sales of c US$230m in 2020), and subsequent entrants, have drastically increased the market size for onychomycosis therapeutics, highlighting a clear patient preference for topical treatments. The market value for onychomycosis treatment in 2020 was more than US$4.2bn, although topical treatments are only a subset of this. Hexima aims to capture a significant share of this market segment.

Plant defensins: A new class of therapeutics

Defensins represent a diverse class of plant-derived peptides that possess antimicrobial activity. Hexima has identified pezadeftide as a novel plant defensin with antifungal activity and has built a strong IP portfolio around this asset. Current standards of care in onychomycosis suffer from poor efficacy and long treatment times as well as toxicity with oral therapies. Hexima has shown pezadeftide to have a rapid and high activity against the various fungal causes of onychomycosis, the ability to penetrate the human nail plate easily and interestingly no activity against human cells. If approved, these attributes could allow pezadeftide to compete successfully with current onychomycosis treatment regimes.

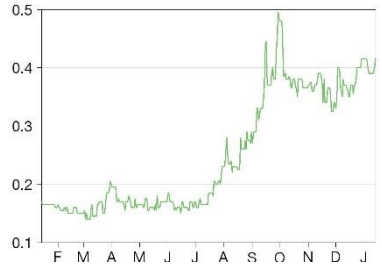
Phase IIb trial underway

The Phase I/IIa trial of pezadeftide in onychomycosis was a randomised, double-blind, multiple ascending dose study to assess the safety, tolerability and effectiveness of pezadeftide, with a daily topical application over a six-week period. At the highest concentration investigated (2.0%), no treatment-related adverse events were reported in any participant and pezadeftide was shown to not be systemically absorbed. The Mycological Cure rate at 12 weeks was shown to be 69% compared to 29% for the control, and clinical efficacy was demonstrated. The Phase IIb trial will assess 2% pezadeftide for further safety and efficacy in three active arms to identify dosing frequency. Data are expected in Q222. In 2021, Hexima raised A$11m and in 2022 we expect the company to engage in partnering deals and/or capital raises to further develop pezadeftide.

Price	**A$0.41**
Market cap	**A$68m**

US$0.7159/A$

Share price graph



Share details

Code	HXL
Listing	ASX
Shares in issue	165m

Business description

Hexima is a biotechnology company focused on the development of its only clinical-stage asset, pezadeftide, for the treatment of onychomycosis. The market for onychomycosis is large (US$4.2bn) and competitive, especially with the introduction of new topical agents. After good Phase I/IIa data, pezadeftide is now in Phase IIb trails, with results expected in Q222.

Bull

- Hexima has identified a clear demand for topical treatments in onychomycosis.
- Demonstrated human safety and efficacy of pezadeftide.
- Strong IP portfolio built around plant defensin platform.

Bear

- Single product risk.
- Partners and/or a capital raise will be needed in the near future to continue development.
- The onychomycosis market is competitive.

Analysts

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