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Hexima Winding-Up After HXP124 Fails Nail Fungus Trial

HEXIMA

Hexima fell a further 48.15 percent on news that following the failure of HXP124 to show efficacy for nail fungus it had begun the process of winding-up activities.

Last month, Hexima fell 84.6 percent to four cents on news that its phase II clinical study of pezadeftide (HXP124) for onychomycosis was “inconclusive … [and did] not support moving directly into a phase III program” (BD: Jun 24, 2022).

Hexima said the results “do not appear to correlate with results observed in its prior phase I study (HXP124-ONY-001) and do not support moving directly into a phase III program”. Last year, Hexima said it had enroled 117 patients in its phase IIb, randomized, controlled study of pezadeftide (HXP124) for onychomycosis or nail fungus (BD: Jul 26, 2021).

In 2020, Hexima returned to the ASX following a $3.3 million initial public offer at 20 cents a share to fund the HXP124 for onychomycosis trial (BD: Dec 4, 2020).

Previously, Hexima said it had it raised $40 million in an initial public offer to list on the ASX in 2007 and delisted in 2011 (BD: Nov 22, 2013).

In 2020, the company said it received $5.5 million in a placement for the phase IIb trial.

Today, Hexima said that subjects were randomised to receive once daily topical application of 2.0% (20mg/mL) pezadeftide or vehicle to all infected toenails in one of three cohorts: two treatment periods of six weeks; two treatment periods of six weeks plus once-weekly maintenance dosing for 23 weeks; five treatment periods of 6 weeks plus one treatment period of one week.

The company said that of 117 patients enrolled, 14 were withdrawn or dropped out prior to completing the study, with patients assessed for safety and efficacy at scheduled visits during the study and at the final follow-up visit at week-40.

Hexima said that pezadeftide was well-tolerated and safe, with three serious adverse events (fall, angina and depression) reported and none drug-related, with 114 adverse events primarily mild, with no unexpected treatment emergent adverse events, and were similar for pezadeftide and control patients, regardless of cohort.

The company said 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.

Hexima said that the data provided “evidence of modest activity of pezadeftide in the treatment of onychomycosis … [but it did] not believe the data [supported] 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,” the company said.

Hexima said it had an open investigational new drug application with the US Food and Drug Administration to begin a phase I maximal use clinical trial in the US, but that study had not begun and was on hold with no further meaningful related expenditure.

The company said it had begun a process of winding up its manufacturing and non-clinical development activities with expenses associated with non-essential employees and contractors “being managed in a cost effective and orderly manner”.

Hexima said it was exploring options to secure value for its intellectual property and residual cash of $4.0 million at June 30, 2022, with a Federal Research and Development Tax Incentive of $5.6 million expected, offset by liabilities of about $9.2 million, but did not include non-current tangible assets including its glasshouse facility, leased to a third party and valued at $900,000, for which it was seeking expressions of interest for the purchase or longer-term lease.

Hexima fell 1.3 cents or 48.15 percent to 1.4 cents with 42.4 million shares traded.