

NEW EQUITY INVESTMENT IN HEDGEPATH PHARMACEUTICALS AHEAD OF COMMENCING PHASE IIB TRIAL WITH SUBA-ITRACONAZOLE IN SKIN CANCER

18 May 2015, Melbourne Australia: Mayne Pharma Group Limited (ASX: MYX) today announced that it has finalised an agreement with US-based HedgePath Pharmaceuticals, Inc (HPPI) to invest US\$2.5m cash in return for additional common stock in HPPI and warrants to purchase HPPI common stock. This funding will be used to accelerate HPPI's clinical development program using Mayne Pharma's patented oral formulation of Itraconazole, known as SUBA-Itraconazole, to treat certain cancers.

A Phase IIb study in patients with Basal Cell Carcinoma Nevus Syndrome (BCCNS), or more commonly known as Gorlin's Syndrome, will commence during the second quarter with preliminary trial results expected early in 2016. The trial design cleared by FDA, is a single arm, Phase IIb, multi-centre, open-label, non-placebo-controlled study with a 40 patient target.

BCCNS results from a genetic mutation, which causes the Hedgehog pathway¹ to function improperly leading to the chronic formation of basal cell tumours. Industry sources estimate that there are approximately 10,000 patients in the United States with BCCNS, which could potentially qualify for SUBA-Itraconazole under the FDA's Orphan Drug Designation Program for treatment of BCCNS in this patient population.

If the BCCNS study achieves the expected clinical end points, HPPI plan to initiate discussions with FDA to see if the results from this trial could potentially serve as the basis for a New Drug Application submission. In addition, HPPI will look to broaden the development program to include other cancer types including selected lung and prostate cancers.

Mayne Pharma's CEO, Mr Scott Richards said "We are excited about increasing our stake in HPPI and accelerating the development and commercialisation of our patented SUBA-Itraconazole for the treatment of cancer. The body of evidence supporting the use of itraconazole in cancer is well established and we believe our SUBA-Itraconazole product provides a number of advantages over conventional Itraconazole, including improved bioavailability and more consistent blood levels to improve the therapeutic effect. Dr Ilana Stancovski, our Chief Scientific Officer, will now lead the Joint Development Committee that is responsible for the development and execution of the clinical programs at HPPI."

Following this investment, Mayne Pharma's equity stake in HPPI will increase from 41.5% to 49.4% and this investment will be consolidated into the financial accounts. An independent valuation of the investment will also be completed which may result in a non-cash unrealised gain for accounting purposes. Mayne Pharma has also received warrants to purchase additional

¹The Hedgehog signalling pathway is a major regulator of cellular processes in vertebrates, including cell differentiation, tissue polarity and cell proliferation.



shares in HPPI which if exercised would increase Mayne Pharma's ownership to 51.1% on a fully diluted basis.

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About Mayne Pharma

Mayne Pharma is an ASX-listed specialty pharmaceutical company that develops and manufactures branded and generic products, which it distributes globally; either directly or through distribution partners and also provides contract development and manufacturing services.

Mayne Pharma has a 30-year track record of innovation and success in developing new oral drug delivery systems and these technologies have been successfully commercialised in numerous products that have been marketed around the world.

Mayne Pharma has two drug development and manufacturing facilities based in Salisbury, Australia and Greenville, USA with expertise in formulation complex oral dose forms including highly potent compounds, controlled substances, modified release products and inherently unstable compounds.

About SUBA-Itraconazole in cancer

SUBA-Itraconazole is a patented formulation, which has improved absorption and significantly reduced variability compared to conventional itraconazole capsules. These benefits provide enhancements to patients and prescribers with reduced intra- and inter-patient variability, enabling a more predictable clinical response and a reduction in the amount of active drug administered in order to deliver the required therapeutic blood levels.

Although itraconazole is used extensively to treat fungal infections globally, the product appears to have notable anti-cancer effects. In clinical studies of patients, itraconazole administration has been associated with improved disease control in patients with advanced lung cancer, skin cancer and prostate cancer. HPPI's SUBA-Itraconazole cancer development program will investigate the use of the product as an inhibitor of two key mechanisms in the progression of cancer.

Recent clinical studies investigating itraconazole in cancer include:

- **Skin cancer** – Itraconazole was tested in an Exploratory Phase II study in patients with basal cell carcinoma (BCC) and showed itraconazole has anti-BCC activity by reducing BCC cell proliferation by 45%, hedgehog activity by 65% and tumour area by 24%. The Phase II study was led by Stanford University and published in February 2014 (Kim et al. *Journal of Clinical Oncology* 2014, 32:745-751).
- **Lung cancer** - Itraconazole was tested in a Phase II study in conjunction with Pemetrexed in metastatic nonsquamous non-small-cell lung cancer patients and showed significant improvements in median overall survival. The median overall survival of advanced lung cancer patients was extended from 8 months with current first-line treatment (namely, pemetrexed disodium) to 32 months when treated in combination with oral itraconazole. The Phase II study was led by Johns Hopkins University and published in October 2013 (Rudin et al. *Journal of Thoracic Oncology* 2013, 8:619-623).
- **Prostate cancer** - Itraconazole was tested as a treatment for men with metastatic castrate resistant prostate cancer in a multi-institutional Phase II trial led by Johns Hopkins University and published in February 2013 (Antonarakis et al. *The Oncologist* 2013, 18:163-173), which showed a



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significant correlation between higher itraconazole blood levels and slowing the progression of the cancer and an extension in the duration of progression-free survival.

About HedgePath Pharmaceuticals

HedgePath Pharmaceuticals, Inc. is a clinical stage biopharmaceutical company that is seeking to repurpose the FDA approved antifungal pharmaceutical itraconazole as a potential treatment for cancer. HPPI is the exclusive licensee in the US of a patented formulation of itraconazole, called SUBA-Itraconazole (developed by Mayne Pharma), which clinical studies have shown to have greater bioavailability than conventional itraconazole capsules. Based on published research, HPPI believes that inhibiting the Hedgehog pathway could delay or possibly prevent the development of certain cancers in humans. Leveraging research undertaken by key investigators in the field, HPPI plans to explore the effectiveness of SUBA-Itraconazole as a cancer inhibitor and to pursue its potential commercialization.

