ASX Announcement

MAYNE PHARMA ANNOUNCES US COMMERCIAL RIGHTS FOR SUBA®-ITRACONAZOLE IN BCCNS

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- Mayne Pharma has assumed control of SUBA®-itraconazole BCCNS program from HedgePath Pharmaceuticals, Inc. (HedgePath)
- Mayne Pharma has committed up to US$5 million in HedgePath to pursue further development programs in select cancer indications
- A global Phase 3 clinical trial for SUBA-itraconazole in BCCNS is expected to commence in 2019

Mayne Pharma Group Limited (ASX: MYX) is pleased to announce the US rights for SUBA-itraconazole in patients with Basal Cell Carcinoma Nevus Syndrome (BCCNS, commonly known as Gorlin Syndrome), have returned to the Company following a revision of the Supply and License Agreement (SLA) with HedgePath Pharmaceuticals, Inc.

Under the terms of the revised SLA, Mayne Pharma will pay a 9% royalty on net sales of SUBA®-itraconazole for the treatment of BCCNS in the US to HedgePath and has committed up to US$5 million to HedgePath who has rights to progress the development of SUBA-itraconazole in a revised field of oncology indications which includes lung cancer, prostate cancer and certain proliferative disorders.

The first US$3 million of funds is expected to be paid by mid-2019 with the balance of funds paid at HPPI's election based on meeting a funding milestone in the next two and a half years. Mayne Pharma is providing the funds as a discounted advance rate against future BCCNS royalties or, in certain circumstances, in return for equity. As part of the revised SLA, Mayne Pharma has obtained US rights for all other oncology indications outside of prostate cancer, lung cancer and certain proliferative disorders, including exclusive rights for those indications to intellectual property developed by HedgePath.

Mayne Pharma's CEO, Mr Scott Richards said "We remain very excited about the repurposing of SUBA-itraconazole in cancer and are pleased with the results that have been achieved in the Phase IIb clinical trial conducted by HedgePath in BCCNS. This clinical trial which was conducted in 38 BCCNS patients demonstrated that SUBA-itraconazole was well tolerated with the majority of target lesions decreasing in size, including 27% completely disappearing over the duration of the study. BCCNS is a serious condition for which surgery is the standard of care. Repeated surgeries often result in disfigurement and other quality of life issues. The Phase IIb clinical trial results suggest that SUBA-Itraconazole provides an effective and safe alternative to address the need for a non-surgical treatment."

"Having US rights for BCCNS will allow Mayne Pharma to assume full control of this program at a critical stage and make the required investments to bring this product to patients in multiple markets worldwide. A Phase III global pivotal clinical trial is expected to commence later in calendar 2019. We expect this study to be a randomised, multi-centre, placebo-controlled study."

"Mayne Pharma remains committed to supporting HedgePath and its leadership to pursue the clinical development, registration and commercialisation of SUBA-itraconazole for the treatment of other oncology indications in the US. The management of HedgePath have successfully progressed the BCCNS program through its first major clinical program. We believe out-licensing our SUBA-itraconazole intellectual property through the partnership with HedgePath, provides Mayne Pharma shareholders with a significant stake in potentially multiple novel cancer programs. In the US, there are around 400,000 new cases of lung and prostate cancers reported per annum[1]. We look forward to working with the HedgePath to further these development programs."

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About Mayne Pharma

At Mayne Pharma we believe that everyone deserves medicines that are better, safe and more affordable. That's why our people are determined to create innovative products and services for our changing world.

Mayne Pharma is an ASX-listed specialty pharmaceutical company focused on applying its drug delivery expertise to commercialise branded and generic pharmaceuticals. Mayne Pharma also provides contract development and manufacturing services to more than 100 clients worldwide.

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 product development and manufacturing facilities based in Salisbury, Australia and Greenville, USA with expertise in formulation of complex oral and topical dose forms including potent compounds, 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.

Whilst 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. HedgePath Pharmaceuticals, Inc., a clinical stage biopharmaceutical company has been seeking to repurpose SUBA-itraconazole as a potential treatment for certain cancers and is investigating the use of the product as an inhibitor of the Hedgehog pathway.

[1] National Cancer Institute

About Gorlin Syndrome (BCCNS)

Gorlin Syndrome (BCCNS) is a rare, genetic mutation which causes the Hedgehog pathway (a major regulator of processes in cells) to function improperly, leading to the chronic formation of basal cell tumours, including potentially disfiguring lesions on the face. With no FDA-approved drugs available for Gorlin Syndrome, the standard of care is surgery. People with severe Gorlin Syndrome may have as many as 30 surgeries per year, which can be repetitive, scarring and disfiguring. Industry sources estimate that there are approximately 10,000 patients in the United States with BCCNS.

In June 2016, the SUBA-itraconazole BCCNS program qualified for the FDA's Orphan Drug Designation as it is a rare disease which affects fewer than 200,000 people in the US. In August 2017, the European Medicines Agency granted SUBA-itraconazole Orphan Drug Designation for BCCNS. An orphan designation provides a drug developer with certain benefits and incentives including a period of marketing exclusivity if regulatory approval is received for the designated indication.