



MAYNE PHARMA ANNOUNCES NEW CHRONIC BREATHLESSNESS INDICATION FOR KAPANOL® BY TGA

19 February 2019, Adelaide Australia: Mayne Pharma Group Limited (ASX: MYX) is pleased to announce that the Therapeutic Goods Administration (TGA) has approved KAPANOL® low dose sustained-release 10mg and 20mg morphine capsules for the treatment of chronic breathlessness in patients with advanced disease.

Mayne Pharma's CEO, Mr Scott Richards said "The repurposing of low dose morphine for chronic breathlessness is a world first registration for this indication. More than 70,000 Australians suffer from chronic breathlessness and will now have access to KAPANOL to manage their breathlessness symptoms. Many of the patients suffering from this condition are housebound and limited in their day-to-day activities. The clinical studies undertaken by Palliative Care Clinical Studies Collaborative (PaCCSC), under Professor David Currow, have shown the use of KAPANOL in severe breathlessness can reduce their debilitating breathlessness symptoms."

Following an independent approach from Prof Currow, Mayne Pharma collaborated with government and academia on this program with funding also provided via grants obtained by PaCCSC from the National Health and Medical Research Council.

An application to the Pharmaceutical Benefits Advisory Committee has been made to expand the Pharmaceutical Benefits Scheme (PBS) reimbursement of KAPANOL to include this new treatment of chronic breathlessness.

This program is another example of the Company's strategy to repurpose existing drugs into new therapeutic areas. The Company continues to progress the repurposing of SUBA®-itraconazole into certain cancers following completion of the Phase IIb clinical trial in Basal Cell Carcinoma Nevus Syndrome (BCCNS, commonly known as Gorlin Syndrome), with plans to commence a Phase III global pivotal trial this year in patients with BCCNS. In addition, the Company is working with the Kinghorn Cancer Centre and Hudson Institute of Medical Research to further understand and investigate the potential for SUBA-itraconazole as a novel treatment for various cancers.

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ASX Announcement

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 KAPANOL

KAPANOL (morphine sulfate pentahydrate) 10mg, 20mg, 50mg and 100mg capsules, modified release, are an opioid analgesic indicated for the relief of chronic pain unresponsive to non-narcotic analgesia. KAPANOL capsules contain polymer-coated pellets which provide sustained-release of morphine sulfate after they are swallowed.

KAPANOL (morphine sulfate pentahydrate) 10mg and 20mg capsules are also indicated for the symptomatic reduction of chronic breathlessness in the palliative care of patients with distressing breathless due to severe chronic obstructive pulmonary disease (COPD), cardiac failure, malignancy or other cause. KAPANOL should only be used after treatments for the underlying cause(s) of the breathlessness have been optimised and non-pharmacological treatment are not effective. Treatment with KAPANOL in this setting should only be initiated by a specialist knowledgeable in its use.

KAPANOL (morphine sulfate pentahydrate) is listed on the PBS as a restricted benefit for use in chronic severe disabling pain. The condition must be unresponsive to non-opioid analgesics. An application to the Pharmaceutical Benefits Advisory Committee has been made to expand the Pharmaceutical Benefits Scheme (PBS) reimbursement of KAPANOL to include this new treatment of chronic breathlessness

Healthcare professionals in consultation with their patients should consider both the potential risks and benefits of each medicine. Information is available from the Product Information and Consumer Medicines Information (CMI). A summary of this information is provided below, please review the CMI for further information¹.

KAPANOL should not be used in patients with an allergy to morphine sulfate pentahydrate, other opioids or any of the ingredients in the medicine. KAPANOL should not be used in the following: patients taking a medicine for depression called a 'monoamine oxidase inhibitor' or have taken one within the past two weeks; patients with heart problems which affect the rhythm of the heartbeat and patients with a prior history of drug abuse. Patients with any lung or breathing problems should not take KAPANOL, it helps breathing but may also cause uncomfortable side effects or side effects that may shorten their life. Not for use in children¹.

Treatment with KAPANOL for chronic breathlessness should only be started by a specialist. KAPANOL has physical and psychological drug dependence potential and withdrawal symptoms. Tolerance may occur. Prescription and monitoring of the patient's opioid use should be one doctor's responsibility. KAPANOL may cause serious, life-threatening, or fatal respiratory depression. Use with caution in patients with the following conditions: kidney or liver disease, under activity of the adrenal or thyroid gland, increased prostate size, narrowing of the urinary bladder tract, biliary tract disease or inflammation of the pancreas,

a condition associated with fits or convulsions, or diarrhoea. Use with caution in patients who have had a head injury or increased pressure in the head, low blood pressure or abnormal curvature of the spine¹.

Like other medicines, KAPANOL can cause some side-effects. The most commonly reported side-effects are: drowsiness, sweating, confusion, dizziness, headache, nausea or vomiting, constipation, dry mouth or itchy skin. Other side effects include: allergic reaction, withdrawal symptoms, blurred vision, flushing of the face, faintness or heart palpitations and hallucinations¹.

Some combinations of medicines may increase the risk of having serious side effects, such as central nervous system depressants, sedatives, benzodiazepines, hypnotics, general anaesthetics, phenothiazines, other tranquilizers and alcohol. Immediate release oral morphine solution should NOT be used with KAPANOL when KAPANOL is prescribed for the reduction of chronic breathlessness. Some medicines and KAPANOL may interfere with each other. These include: medicines to treat depression, psychiatric or mental disorders; other pain relievers and other opioids. These also include medicines used to relieve heartburn or treat stomach ulcers, medicines to help sleep, relax muscles, lower blood pressure, diuretics and St John's wort (*Hypericum perforatum*), a herbal remedy¹.

References

1. The KAPANOL (morphine sulfate pentahydrate) approved Product Information, dated 6 February 2019.

To access the Consumer Medicines Information Leaflet:

<https://www.maynepharma.com/products/australian-products/specialty-brands/kapanol-capsules/>