

MAYNE PHARMA ACQUIRES RIGHTS TO GENERIC DURAGESIC® PATCH FOR THE US

9 March 2017, Adelaide, South Australia

- Mayne Pharma Group Limited (ASX: MYX) adds fentanyl transdermal delivery system (TDS) to its US generic product portfolio
 - The deal strengthens alliance with Corium International, Inc. (Corium), a new strategic partnership established following the acquisition of a portfolio of US generic products from Teva Pharmaceutical Industries Limited (Teva Portfolio) in August 2016
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Mayne Pharma is pleased to announce it has acquired the rights to the fentanyl transdermal delivery system (TDS), 25 mcg/hr, 50 mcg/hr, 75 mcg/hr and 100 mcg/hr from Par Pharmaceutical, Inc. (Par). This product was developed by Corium, a specialty pharmaceutical company focused on the development and manufacture of transdermal and transmucosal delivery systems.

Fentanyl TDS is an AB-rated generic equivalent to Duragesic®, indicated for the management of pain in opioid-tolerant patients, severe enough to require daily treatment. Mayne Pharma has assumed Par's manufacturing and supply agreement with Corium, acquired select inventory and the rights to market the product in the US from today. According to IMS Health, the annual market sales for the fentanyl patch were approximately US\$560 million for the 12 months ending 31 December 2016.

Mayne Pharma's CEO, Mr Scott Richards, said "We are very pleased to have partnered with Corium on another complex, difficult-to-develop and manufacture product. The US transdermal patch market is valued at more than US\$3.3 billion and is a well-regarded advanced drug delivery system that can better control drug release and can also lead to improved patient convenience and compliance."

"Mayne Pharma's first marketed patch was Clonidine, indicated for the treatment of hypertension and is one of Mayne Pharma's top five generic products by sales. Our alliance with Corium now includes two marketed and one pipeline product that is filed with the US Food and Drug Administration and reinforces one of the key strategic benefits of the Teva Portfolio acquisition to access a pipeline of new product opportunities through leveraging relationships with active pharmaceutical ingredient suppliers and contract development and manufacturing companies."

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ASX Announcement

About Mayne Pharma

Mayne Pharma is an ASX-listed specialty pharmaceutical company focused on applying its drug delivery expertise to commercialise branded and generic pharmaceuticals, providing patients with access to better and more affordable medicines. 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 the formulation of complex oral dose forms including highly potent compounds, controlled substances, modified-release products and inherently unstable compounds.

For further information, please visit www.maynepharma.com

About Corium

Corium International, Inc. is a commercial-stage biopharmaceutical company focused on the development, manufacture and commercialisation of specialty pharmaceutical products that leverage the company's broad experience with advanced transdermal and transmucosal delivery systems. Corium has multiple proprietary programs in preclinical and clinical development, focusing primarily on the treatment of neurological disorders, with lead programs in Alzheimer's disease. Corium has developed and is the sole commercial manufacturer of seven prescription drug and consumer products with partners Mayne Pharma, Endo Pharmaceuticals and Procter & Gamble.

The company has two proprietary transdermal platforms: Corplex™ for small molecules and MicroCor®, a biodegradable microstructure technology for small molecules and biologics, including vaccines, peptides and proteins. The company's late-stage pipeline includes a contraceptive patch codeveloped with Agile Therapeutics and additional transdermal products that are being developed with other partners.

For further information, please visit www.coriumgroup.com

Duragesic® is a registered trademark of Johnson & Johnson Corporation.

WARNING: ADDICTION, ABUSE AND MISUSE; LIFE-THREATENING RESPIRATORY DEPRESSION; ACCIDENTAL EXPOSURE; NEONATAL OPIOID WITHDRAWAL SYNDROME; CYTOCHROME P450 3A4 INTERACTION; and EXPOSURE TO HEAT

- Fentanyl transdermal system exposes users to the risks of opioid addiction, abuse and misuse, which can lead to overdose and death. Assess each patient's risk prior to prescribing, and monitor regularly for the development of these behaviour or conditions.
- Serious, life-threatening, or fatal respiratory depression may occur. Monitor closely, especially during initiation or following a dose increase.
- Accidentally exposed to fentanyl transdermal system, especially in children, can result in fatal overdose of fentanyl.
- Prolonged use of fentanyl transdermal system during pregnancy can result in neonatal opioid withdrawal syndrome, which may be life-threatening if not recognized and treated. If opioid use is required for a prolonged period in a pregnant woman, advise the patient of the risk of neonatal opioid withdrawal syndrome and ensure that appropriate treatment will be available.

- Initiation of cytochrome P450 3A4 inhibitors (or discontinuation of cytochrome P450 3A4 inducers) can result in a fatal overdose of fentanyl from fentanyl transdermal system.
- Avoid exposing the fentanyl transdermal system application site and surrounding area to direct external heat sources. Temperature dependent increases in fentanyl release from the system may result in overdose and death.

Indication and Usage

Fentanyl transdermal system is indicated for the management of pain in opioid-tolerant patients, severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate.

Patients considered opioid-tolerant are those who are taking, for one week or longer, at least 60 mg of morphine daily, or at least 30 mg of oral oxycodone daily, or at least 8 mg of oral hydromorphone daily, or an equianalgesic dose of another opioid.

Limitations of Use

Because of the risks of addiction, abuse, and misuse with opioids, even at recommended doses, and because of the greater risks of overdose and death with extended-release opioid formulations, reserve fentanyl transdermal system for use in patients for whom alternative treatment options (e.g., non-opioid analgesics or immediate-release opioids) are ineffective, not tolerated, or would be otherwise inadequate to provide sufficient management of pain.

Full prescribing information, including warnings, can be found [here](#).

To report a suspected adverse reaction from one of our products, please contact Mayne Pharma at 1-844-825-8500 or maynepharmamc@dlss.com, or the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.