

MAYNE PHARMA ADDS TWO SPECIALTY PRODUCTS TO ITS AUSTRALIAN PORTFOLIO

15 Sep 2017, Adelaide Australia:

- Mayne Pharma Group Limited (ASX: MYX) received Therapeutic Goods Administration (TGA) approval for Monurol® (fosfomycin) granules used for the treatment of urinary tract infections (UTIs)
 - Recently launched Urorec® (silodosin) capsules for the relief of lower urinary tract symptoms associated with benign prostatic hyperplasia (BPH)
 - Both products receive 5 years of data exclusivity¹ as new chemical entities (NCEs) in Australia
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Mayne Pharma Group Limited (ASX: MYX) is pleased to announce it has received TGA approval for Monurol (fosfomycin trometamol) (3g) granules and has recently launched Urorec (silodosin) (8mg) capsules in Australia. Both products are new chemical entity approvals from the TGA, and the first two approvals of this kind by Mayne Pharma.

Monurol is a single dose antibiotic used for the treatment of acute uncomplicated urinary tract infections (UTIs) in females over 12 years old. There are currently no other single dose antibiotics approved for this indication in Australia. Mayne Pharma licensed the Australian rights to Monurol from Zambon S.p.A.. The product has been approved for marketing in over 80 countries, including US, Germany, France, Italy and Spain with global brand and generic sales of A\$220million as reported by QuintilesIMS².

Urorec is indicated for the relief of lower urinary tract symptoms (LUTS) associated with benign prostatic hyperplasia in adult men. Urorec blocks alpha-1 adrenergic receptors in the prostate, bladder and urethra to reduce LUTS symptoms. Mayne Pharma licensed the Australian rights to Urorec from Recordati. The drug has been approved for marketing in over 50 countries including US, Canada, France, Spain and Italy with global brand and generic sales of A\$750million as reported by QuintilesIMS².

Mayne Pharma's CEO Scott Richards said, "We are very pleased to announce TGA approval of two NCE products for the Australian market. Monurol is an antibiotic for the treatment of urinary tract infections which is estimated to impact one in two women over their lifetime with 13% of adult women estimated to be diagnosed each year³. Urorec will provide another treatment option for men suffering symptoms of an enlarged prostate. BPH is a male disease that can seriously impact the quality of life of men as they age. Roughly 70% of all men suffer from BPH by age 60 rising to 80% of those aged 70 years or older⁴. The BPH market for alpha blockers like Urorec is worth over A\$45m in Australia, according to QuintilesIMS²."

"Both products will be promoted by the Australian sales team targeting urologists and other related healthcare practitioners. In certain mature markets, Monurol has captured 25-40% share of the UTI prescription market and Urorec has captured 10-30% of the BPH alpha blocker market by volume². We expect these products will drive strong growth of our Australian business over the



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coming years. Urorec was launched in August and Monurol is expected to launch in December 2017.”

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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. 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 complex oral dose forms including highly potent compounds, controlled substances, modified release products and inherently unstable compounds.

References

1. Mayne Pharma received a 5-year period of protection for the information it provided in its application to the TGA for approval for the products. Data exclusivity commences from the date on which the new product is registered and the effect is that generic competitors are not permitted for the period of exclusivity from using an innovator company's data in support of their own application for approval of a generic product.
2. QuintilesIMS, MAT 30 June 2017.
3. Griebeling TL. Urinary tract infection in women. In: Litwin MS, Saigal CS, eds. *Urological Diseases in America*. U.S. Department of Health and Human Services, Public Health Service, National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases. Washington, DC: US Government Printing Office; NIH Publication No. 07-5512, 589-619.
4. Parsons JK. Benign Prostatic Hyperplasia and Male Lower Urinary Tract Symptoms: Epidemiology and Risk Factors. *Current Bladder Dysfunction Reports*. 2010;5(4):212-218. doi:10.1007/s11884-010-0067-2.

Monurol® is a registered trade mark of Zambon SpA

Urorec® is a trade mark registered by Recordati and owned by Kissei Pharmaceutical Co. Ltd