



## **MAYNE PHARMA LAUNCHES GENERIC KAPVAY® IN THE U.S.**

**July 16, 2018, Greenville, N.C.:** Mayne Pharma Group Limited (ASX: MYX) is pleased to announce the launch of clonidine extended-release (ER) tablets, 0.1mg in the United States.

Clonidine ER tablets are a generic alternative to Concordia International Corp's Kapvay® tablets and indicated for the treatment of attention deficit hyperactivity disorder as monotherapy or as adjunct to stimulant medications.

According to IQVIA, annual U.S. sales of clonidine ER tablets were approximately \$60 million for the 12 months ending April 30, 2018.

Mayne Pharma's CEO Scott Richards said, "The launch of clonidine ER tablets is our sixth generic product launch this calendar year. This product was developed internally and will be manufactured in Greenville, N.C., leveraging our potent handling and modified-release drug delivery capabilities."

Mayne Pharma directly markets more than 60 products and has a growing pipeline of approximately 30 products targeting U.S. markets with IQVIA sales greater than \$5 billion. Mayne Pharma expects several product launches throughout the coming year with 14 drug applications pending at the U.S. Food and Drug Administration targeting U.S. markets with sales greater than \$2.5 billion.

### **Important Safety Information**

Clonidine hydrochloride extended-release tablets are contraindicated in patients with a history of hypersensitivity reaction to clonidine. Reactions have included generalized rash, urticaria, and angioedema.

*Hypotension/bradycardia/syncope:* Titrate slowly and monitor vital signs frequently in patients at risk for hypotension, heart block, bradycardia, syncope, cardiovascular disease, vascular disease, cerebrovascular disease or chronic renal failure. Measure heart rate and blood pressure prior to initiation of therapy, following dose increases, and periodically while on therapy. Avoid concomitant use of drugs with additive effects unless clinically indicated. Advise patients to avoid becoming dehydrated or overheated.

*Somnolence/sedation* has been observed with clonidine hydrochloride extended-release tablets. Consider the potential for additive sedative effects with CNS depressant drugs. Caution patients against operating heavy equipment or driving until they know how they respond to clonidine hydrochloride extended-release tablets.

*Cardiac conduction abnormalities* may worsen sinus node dysfunction and atrioventricular (AV) block, especially in patients taking other sympatholytic drugs. Titrate slowly and monitor vital signs frequently.





## News Release

Most common adverse reactions (incidence at least 5% and twice the rate of placebo) as monotherapy in ADHD include somnolence, fatigue, irritability, nightmare, insomnia, constipation, and dry mouth.

Most common adverse reactions (incidence at least 5% and twice the rate of placebo) as adjunct therapy to psychostimulant in ADHD include somnolence, fatigue, decreased appetite, and dizziness. *Full prescribing information, including warnings, can be found [here](#).*

**To report SUSPECTED ADVERSE REACTIONS, contact Mayne Pharma at 1-844-825-8500 or the FDA at 1-800-FDA-1088 or [www.fda.gov/medwatch](http://www.fda.gov/medwatch).**

**For further information contact:**

Lisa Pendlebury +61 419 548 434, [lisa.pendlebury@maynepharma.com](mailto:lisa.pendlebury@maynepharma.com)

**About Mayne Pharma**

*Mayne Pharma is an ASX-listed specialty pharmaceutical company focused on applying its drug delivery expertise to commercialize 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 commercialized in numerous products that have been marketed around the world.*

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

*Kapvay® is a registered trademark of Concordia Pharmaceuticals Inc.*

