



Mayne Pharma Announces Launch of Temozolomide Capsules in the US

... major milestone, IDT's generic Temozolomide is now on market in the US

22 November 2016, Melbourne: Mayne Pharma Group Limited (Mayne Pharma, ASX:MYX) has today announced the U.S. launch of IDT's generic temozolomide 5mg, 20mg, 100mg, 140mg, 180mg and 250mg capsules.

"The U.S. launch of IDT Australia Limited's first ever drug product is a significant moment in the Company's history." said IDT's managing director Dr Paul MacLeman. "It represents the culmination of several years of effort in delivering on our announced strategy for revenue and profit growth via the development and commercialisation of IDT's own drug portfolio. Following on the back of last week's audit of IDT's manufacturing facility by the U.S. Food and Drug Administration, Temozolomide is the first of these products, with more to come."

For further details please see below for the complete announcement from Mayne Pharma.

ENDS

For further information please contact:

IDT Australia Limited
Dr Paul MacLeman
Managing Director
(03) 9801 8888

Monsoon Communications
John Beveridge
(03) 9620 3333

About IDT

IDT Australia Ltd recently acquired a portfolio of 23 generic drugs to manufacture and sell via US distribution partners. With IDT's 2013 Temozolomide ANDA filing this signifies IDT's move to rapidly become a specialty generics business with near term revenue build up.

IDT (ASX:IDT) is a public Australian pharmaceutical manufacturing company based in Boronia, Victoria, Australia. It has extensive experience in the development and production of high potency and high containment pharmaceutical products for local and international clients. IDT's facilities are fully cGMP compliant and are regularly audited by the US FDA and Australian TGA. With an experienced team of specialists within world-class facilities, IDT provides a full-scale service for new drug development and scale-up, commercial active drug manufacture as well as a variety of oral and injectable finished drug dose forms.

Through CMAX, its clinical research services business based adjacent to the new Royal Adelaide Hospital in South Australia, IDT also provides full Phase I clinical trials management and delivery, recruitment in specific disease states for Phase II and Phase III trials as well as offering trial packaging, distribution and pharmacy services from the cGMP Boronia facilities.

MAYNE PHARMA LAUNCHES TEMOZOLOMIDE CAPSULES IN U.S. – GENERIC ALTERNATIVE TO TEMODAR®

21 November 2016, Adelaide Australia: Mayne Pharma Group Limited (Mayne Pharma) is pleased to announce the U.S. launch of temozolomide capsules, 5mg, 20mg, 100mg, 140mg, 180mg and 250mg, which is a generic version of branded Temodar®. Temozolomide capsules are indicated for the treatment of adult patients with newly diagnosed cancerous brain tumors known as glioblastoma multiforme concomitantly with radiotherapy and then as maintenance treatment.

Temozolomide capsules had U.S. sales of approximately US\$150m for the 12 months ending 30 September 2016, according to IMS Health.

Mayne Pharma will distribute the drug on behalf of its partner, IDT Australia Ltd (IDT), which developed the product and is manufacturing the product.

“Since entering the United States in 2012, Mayne Pharma has aggressively expanded its product portfolio, through internal product development, strategic acquisition, in-licensing and working collaboratively with partners like IDT”, said Scott Richards, CEO of Mayne Pharma. “Mayne Pharma now directly markets more than 50 products and we have a growing pipeline of more than 40 generic and branded drug products targeting U.S. markets with IMS Health sales greater than \$6 billion.”

###

For further information contact:

Lisa Pendlebury, +61.3.8614.7777 or lisa.pendlebury@maynepharma.com

About Mayne Pharma

Mayne Pharma is a publicly traded specialty pharmaceutical company listed on the Australian Securities Exchange (ASX: MYX). The company develops and manufactures branded and generic products globally—either directly or through distribution partners—while applying its drug-delivery expertise for contract development and manufacturing services.

Mayne Pharma has a 30-year track record of innovation and success in developing new oral drug delivery systems; these technologies have been successfully commercialized in numerous products marketed around the world. Mayne Pharma has drug development and manufacturing facilities in Greenville, North Carolina, USA, and Salisbury, Australia, and offers expertise in formulating complex oral dose forms including highly potent compounds, controlled substances, modified-release products and inherently unstable compounds. Within the United States, Mayne Pharma’s operations consist of:

- U.S. Generic Products, which develops, manufactures, markets and distributes generic drug products,
- U.S. Specialty Brands, which markets and distributes branded pharmaceuticals within the United States, and
- Metrics Contract Services, which provides contract pharmaceutical development services to third parties globally. Learn more about the company online at www.maynepharma.com.

Temodar® is the registered trademark of Merck Sharp & Dohme Corp.