



MAYNE PHARMA ANNOUNCES FDA ACCEPTANCE OF NEW DRUG APPLICATION FOR ITS ANTIFUNGAL SUBA®-ITRACONAZOLE CAPSULE

2 May 2018, Adelaide Australia: Mayne Pharma Group Limited (ASX: MYX) is pleased to announce its New Drug Application (NDA) for SUBA®-Itraconazole capsules has been accepted for review by the US Food and Drug Administration (FDA). Mayne Pharma is seeking FDA approval for SUBA-Itraconazole for the treatment of systemic fungal infections. Consistent with FDA review timelines, Mayne Pharma expects the review to be completed in early CY2019.

Mayne Pharma's SUBA-Itraconazole is a proprietary, patented formulation that enhances the solubility and absorption of conventional itraconazole oral formulations.

In the US, the indications for itraconazole capsules include three systemic fungal infections: histoplasmosis, blastomycosis and refractory aspergillosis. These serious, potentially life-threatening infections most commonly occur in individuals with a history of immunosuppressant treatment, cancer, transplants (solid organ or bone marrow), or HIV/AIDS. Due to their underlying conditions, it is often difficult to achieve target blood levels of itraconazole with conventional oral itraconazole preparations.

Mayne Pharma's CEO, Mr Scott Richards said "We are very pleased that the NDA for SUBA-Itraconazole has been accepted for review. The conventional formulation of oral itraconazole suffers from poor and unpredictable bioavailability resulting in significant inter- and intra-patient variability, which is a frustration to prescribers. The unique formulation of SUBA-Itraconazole capsules, which has improved bioavailability and significantly reduced variability to existing products, represents a significant innovation."

"The notification from the FDA indicates that the application is sufficiently complete to permit a substantive review. Our team looks forward to working closely with the FDA throughout the review process. Product launch is expected to occur in CY2019 and the Company plans to directly commercialise SUBA-Itraconazole through its own sales and marketing infrastructure calling on a range of specialists that treat patients with, or at risk of, these systemic fungal infections."

Mayne Pharma has received regulatory approval for SUBA-Itraconazole capsules in Australia, Argentina, Belgium, Germany, Mexico, Italy and Spain and is seeking approval in other countries around the world. The US anti-fungal triazole market has a current value of US\$500m according to IQVIA and based on the clear unmet clinical need in serious systemic infections, the addressable market is estimated at US\$200m¹ in which SUBA-Itraconazole is expected to perform strongly.

Mayne Pharma directly markets more than 60 products in the US including three patent protected dermatology products Fabior®, Sorilux® and Doryx® MPC and more than 55 generic products. Mayne Pharma's pipeline comprises more than 30 drug products including five branded projects of which two are in phase two clinical development.

¹ Management estimate



ASX Announcement

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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.

About SUBA-Itraconazole

SUBA-Itraconazole is an improved formulation of itraconazole, a product used to treat fungal infections. SUBA-Itraconazole has improved bioavailability and significantly reduced variability compared to the originator and provides enhancements to patients and prescribers with reduced inter- and intra-patient variability and therefore: (i) a more predictable clinical response and (ii) enabling a reduction in active drug quantity to deliver the required therapeutic blood levels. It also does not need to be taken with food, and can be co-administered with drugs that lower gastric acidity without any reduction in itraconazole bioavailability, increasing patient convenience. Itraconazole is one of the broadest spectrum antifungal drugs on the market and can be used to treat both superficial infections of the skin and nail (ie. Onychomycosis) and to treat systemic fungal infections of the major organs (ie. Histoplasmosis and Blastomycosis). These systemic infections can be life threatening to immunocompromised patients.