ASX Announcement

TOLSURA™ (SUBA®-ITRACONAZOLE) ANTIFUNGAL CAPSULE NOW AVAILABLE IN THE UNITED STATES

30 January 2019, Adelaide Australia: Mayne Pharma Group Limited (ASX: MYX) is pleased to announce the launch of TOLSURA™ (SUBA®-itraconazole) 65mg capsule in the United States. TOLSURA is a new formulation of itraconazole indicated for the treatment of systemic fungal infections including blastomycosis (pulmonary and extrapulmonary), histoplasmosis (including chronic cavitary pulmonary disease and disseminated, non-meningeal histoplasmosis) and aspergillosis (pulmonary and extrapulmonary, in patients who are intolerant of or who are refractory to amphotericin B therapy).

The company has also completed the recruitment and training of a specialised field sales team who are now promoting the benefits of TOLSURA to infectious disease physicians.

These serious infections most commonly occur in vulnerable or immunocompromised patients, for example, those with a history of cancer, transplants (solid organ or bone marrow), HIV/AIDS, or chronic rheumatic disorders, and are often associated with high mortality rates or long-term health issues.

The Company received US Food and Drug Administration (FDA) approval for TOLSURA in December 2018.

Mayne Pharma's CEO, Mr Scott Richards said "We are very pleased to launch TOLSURA - a new formulation of itraconazole incorporating Mayne Pharma's proprietary SUBA-technology to improve the bioavailability of poorly soluble drugs. TOLSURA provides a new treatment option for patients and physicians fighting these life-threatening fungal infections. This launch has enabled Mayne Pharma to establish a new institutional sales team focused on hospital based infectious disease specialists. We look forward to bringing further specialty product innovations to market over the coming years with our pipeline of products under development."

Mayne Pharma directly markets more than 60 products in the US including four branded products FABIOR® (tazarotene) foam, SORILUX® (calcipotriene) foam, DORYX® MPC (doxycycline hyclate) delayed-release tablets and TOLSURA (SUBA-itraconazole) capsules.

For further information contact:
Lisa Pendlebury +61 419 548 434, lisa.pendlebury@maynepharma.com

About Mayne Pharma

At Mayne Pharma we believe that everyone deserves medicines that are better, safe and more affordable. That's why our people are determined to create innovative products and services for our changing world.

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 of complex oral and topical dose forms including potent compounds, modified-release products and inherently unstable compounds.

About TOLSURA (SUBA-itraconazole) capsules

Indications and Usage

TOLSURA is an azole antifungal indicated for the treatment of the following fungal infections in immunocompromised and non-immunocompromised adult patients:

- Blastomycosis, pulmonary and extrapulmonary
- Histoplasmosis, including chronic cavitary pulmonary disease and disseminated, non-meningeal histoplasmosis, and
- Aspergillosis, pulmonary and extrapulmonary, in patients who are intolerant of or who are refractory to amphotericin B therapy.

Limitations of Use:
TOLSURA is not indicated for the treatment of onychomycosis
TOLSURA is NOT interchangeable or substitutable with other itraconazole products

IMPORTANT SAFETY INFORMATION

WARNING: CONGESTIVE HEART FAILURE and DRUG INTERACTIONS
See full prescribing information for complete boxed warning.

- Congestive Heart Failure
  TOLSURA can cause or exacerbate congestive heart failure (CHF). When itraconazole was administered intravenously to healthy human volunteers and dogs, negative inotropic effects were seen. If signs or symptoms of congestive heart failure occur or worsen during administration of TOLSURA, reassess the benefit-risk of continuing treatment.
- Drug Interactions
  - Co-administration of certain drugs that are metabolized by human CYP3A4 enzymes are contraindicated with TOLSURA because plasma concentrations of such drugs are increased.
  - Co-administration with colchicine, fesoterodine and solifenacin is contraindicated in subjects with varying degrees of renal or hepatic impairment.
  - Co-administration with eliglustat is contraindicated in poor or intermediate metabolizers of CYP2D6 and in subjects taking strong or moderate CYP2D6 inhibitors.
  - Increased plasma concentrations of some of these drugs can lead to QT prolongation and ventricular tachyarrhythmias including occurrences of torsades de pointes, a potentially fatal arrhythmia.

Contraindications

- Co-administration with certain drugs that either affect metabolism of itraconazole or whose metabolism is affected by itraconazole.
- Hypersensitivity to itraconazole

Warnings and Precautions

- Hepatotoxicity: Serious hepatotoxicity, including liver failure and death were reported with the use of itraconazole. Discontinue treatment if signs of liver dysfunction occur
- Cardia Dysrhythmias: Life-threatening cardiac dysrhythmias and/or sudden death have occurred in patients using certain drugs that are metabolized by human CYP450 enzymes concomitantly with oral itraconazole and/or other CYP3A4 inhibitors.
- Peripheral Neuropathy: This has been reported in patients on long-term therapy with itraconazole. Monitor and promptly evaluate neurologic symptoms.
- Hearing loss: Reversible or permanent has been reported in patients. Discontinue treatment if hearing loss occurs

Adverse Reactions

Most common adverse reactions (incidence ≥ 1%) are nausea, rash, vomiting, edema, headache, diarrhea, fatigue, fever, pruritus, hypertension, abnormal hepatic function, abdominal pain, dizziness, hypokalemia, anorexia, malaise, decreased libido, somnolence, albuminuria, impotence.

To report SUSPECTED ADVERSE REACTIONS, contact Mayne Pharma at 1-844-825-8500 or FDA at 1-800-FDA-1088 or *www.fda.gov/medwatch*.

For more information about TOLSURA, please refer to the prescribing information available here.