ASX Announcement

MAYNE PHARMA RECEIVES FDA APPROVAL FOR DORYX MPC TABLETS

23 May 2016, Adelaide Australia: Mayne Pharma Group Limited (ASX: MYX) is pleased to announce it has received US Food and Drug Administration (FDA) approval for Doryx® MPC (doxycycline hyclate delayed-release tablets) in 60mg and 120mg dose strengths. Doryx MPC is a new formulation that incorporates a modified polymer coat designed to further retard the release of doxycycline in the acidic environment of the stomach.

Doryx MPC, a tetracycline-class antimicrobial, is indicated for the treatment of a number of infections, including adjunctive therapy for severe acne[1]. Acne is the most prevalent skin disease in the United States affecting some 45 million people of all ages[2].

Mayne Pharma's CEO, Mr. Scott Richards, said "We are very pleased to announce the approval of Doryx MPC tablets which incorporates Mayne Pharma's multi-particulate drug delivery technology. Reformulation of existing molecules plays a key role in improving patient compliance and clinical outcomes and we believe dermatologists will appreciate having access to Doryx MPC, which has a modified polymer coat to further delay the release of the active ingredient in the stomach. Launch of Doryx MPC is expected to occur in the third quarter of 2016."

Mayne Pharma was granted US Patent No. 9,295,652 by the United States Patent and Trademark Office (USPTO) relating to this new formulation with an expiry date of 2034. The Company has received a Notice of Allowance from the USPTO for an additional US patent (application number 14/939,936) also related to Doryx MPC and continues to pursue further patent protection.

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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 Doryx MPC (doxycycline hyclate delayed-release tablets)

The usual dose of oral doxycycline is 240 mg on the first day of treatment (administered 120 mg every 12 hours), followed by a maintenance dose of 120 mg daily. In the management of more severe infections (particularly chronic infections of the urinary tract), 120 mg every 12 hours is recommended.

Doryx MPC is not substitutable on a mg per mg basis with other oral doxycyclines. Do not chew or crush tablets.

When switching from Doryx to Doryx MPC:

- A 60 mg dose of Doryx MPC will replace a 50 mg dose of Doryx
- A 120 mg dose of Doryx MPC will replace a 100 mg dose of Doryx.

Indication and Usage

Doryx MPC (doxycycline hyclate delayed-release tablets) is a tetracycline-class antimicrobial indicated as adjunctive therapy for severe acne. To reduce the development of drug-resistant bacteria as well as to maintain the effectiveness of Doryx MPC and other antibacterial drugs, Doryx MPC should be used only as indicated.

Selected Safety Information about Doryx MPC (doxycycline hyclate delayed-release tablets)

Doxycycline is contraindicated in patients who have shown hypersensitivity to any of the tetracyclines. Tetracycline-class drugs, like Doryx MPC (doxycycline hyclate delayed-release tablets), can cause fetal harm when administered to a pregnant woman. Doryx MPC should be avoided if possible by nursing mothers, taking into account the importance of the drug to the mother. Doryx MPC should not be used in children during tooth development (up to the age of 8 years). Concurrent use of tetracycline-class antibiotics with oral contraceptives may reduce their effectiveness.

Clostridium difficile associated diarrhea (CDAD) has been reported with nearly all antibacterial agents including doxycycline, and may range from mild diarrhea to fatal erythema. Photosensitivity can occur with tetracycline-class drugs. Doryx MPC patients should minimize or avoid excessive exposure to natural or artificial sunlight, and consider using sunscreen or sunblock. Advise patients to discontinue therapy at the first evidence of skin erythema. Overgrowth of non-susceptible organisms, including fungi, may occur. Doryx MPC should be discontinued if superinfection occurs and appropriate therapy instituted. Adverse reactions observed in patients receiving tetracyclines include anorexia, nausea, vomiting, diarrhea, rash, photosensitivity, urticaria and hemolytic anemia.

For additional safety and other information, please click here for Full Prescribing Information.
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.

References:

1. Doryx® MPC prescribing information.
2. The Burden of Skin Diseases 2004, the Society for Investigative Dermatology and the American Academy of Dermatology Association.