ASX Announcement

MAYNE PHARMA LAUNCHES DORYX 50 MG TABLETS

10 August 2015, Melbourne Australia: Mayne Pharma Group Limited (ASX: MYX) is pleased to announce it has launched a 50 mg strength of Doryx® (doxycycline hyclate delayed-release tablets) and has already recorded its first sales. The Company received approval for this product in December 2014 and this will be the second dermatology product promoted by the US Specialty Brands division established earlier this year.

Doryx, a tetracycline-class antimicrobial, is indicated as 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]. Doryx, designed as a delayed-release tablet, incorporates Mayne Pharma's drug delivery technology, to minimise exposure of doxycycline to the upper GI tract[1,3,4].

Mayne Pharma's CEO, Mr. Scott Richards, said "We are very pleased to announce the launch of the new Doryx 50 mg tablet, the lowest delayed-release, enteric-coated dose for the adjunctive treatment of severe acne available in the United States. Launch timing coincides with the US "back to school" period when use of acne medications traditionally increases. We believe Dermatologists will appreciate having a greater range of options available to meet their patients' needs with Doryx 50 mg or 200 mg tablets."

"The new US Specialty Brands team responsible for the promotion of Doryx has now been in field for 13 weeks. We are very pleased with the stability of Doryx during this re-launch phase and expect to grow this franchise with the launch of the 50mg Doryx tablet."

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About Mayne Pharma

Mayne Pharma is an ASX-listed specialty pharmaceutical company that develops and manufactures branded and generic products, which it distributes globally; either directly or through distribution partners and also provides contract development and manufacturing services.

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 drug 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® (doxycycline hyclate delayed-release tablets)
The usual dose of oral doxycycline is 200 mg on the first day of treatment (administered 100 mg every 12 hours), followed by a maintenance dose of 100 mg daily. In the management of more severe infections (particularly chronic infections of the urinary tract), 100 mg every 12 hours is recommended.

Indication and Usage
Doryx® (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® and other antibacterial drugs, Doryx® should be used only as indicated.

Selected Safety Information about Doryx® (doxycycline hyclate delayed-release tablets)
Doxycycline is contraindicated in patients who have shown hypersensitivity to any of the tetracyclines. Tetracycline-class drugs, like Doryx® (doxycycline hyclate delayed-release tablets), can cause fetal harm when administered to a pregnant woman. Doryx® should be avoided if possible by nursing mothers, taking into account the importance of the drug to the mother. Doryx® 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® 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® 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® [package insert]: Greenville, NC: Mayne Pharma; 2015.
2. The Burden of Skin Diseases 2004, the Society for Investigative Dermatology and the American Academy of Dermatology Association.
3. Press AG, Hauptmann A, Hauptmann L, et al. Gastrointestinal pH profiles in patients with inflammatory bowel disease. Ailment Pharmacol Ther. 1998;12: 673-678.
4. Kircik LH, Bilowski JB. Enteric-coated doxycycline pellets, delayed release, in tablets. Suppl Pract Dermatol. 2010:1-16