ASX Announcement

NEW DATA ON MAYNE PHARMA'S TOLSURA® (SUBA®-ITRACONAZOLE) PRESENTED AT IDWEEK 2020

26 October 2020, Adelaide Australia: Mayne Pharma Group Limited (ASX: MYX) is pleased to announce that new clinical data has been presented on TOLSURA® (SUBA®-itraconazole) at IDWeek 2020, being held virtually in the US from October 21st-25th. The conference is attended by over 11,500 doctors and other healthcare professionals. During the conference there were several oral presentations describing the clinical attributes of TOLSURA.

The key presentation was the publication of data from the Investigator Initiated trial conducted by the Mycoses Study Group titled "*SUBA-itraconazole versus conventional itraconazole in the treatment of endemic mycoses: a multi-centre, open-label, randomized comparative trial*"[1]. The study is a head-to-head, randomised controlled trial to investigate TOLSURA (SUBA-itraconazole) versus conventional oral itraconazole capsules in the treatment of endemic fungal infections. Patients enrolled in the study had proven or probable invasive endemic fungal infections, with the trial designed to ascertain the pharmacokinetics, safety, efficacy, tolerability and health economics of TOLSURA compared to conventional itraconazole capsules.

The study results were presented by the study Principal Investigator, Professor Peter G. Pappas, MD. The pharmacokinetic data described showed that TOLSURA delivers itraconazole serum levels which consistently exceed those of the conventional itraconazole group even though it is dosed with 35% less drug. The higher serum levels with TOLSURA were recorded at each timepoint throughout the study and there was no increase in occurrence of common adverse events. Gastrointestinal adverse events were more prevalent in the conventional itraconazole group (26%) than the TOLSURA group (13%). It was also noted that the TOLSURA formulation allows for dosing independent of food and gastric acid, a significant point of differentiation versus other itraconazole formulations.

Professor Pappas concluded that "TOLSURA is safe, well-tolerated, and consistently leads to combined serum itraconazole levels that are higher when compared to conventional itraconazole capsules. Moreover, compared to conventional itraconazole, TOLSURA achieves these serum levels when administered at substantially lower daily doses".

Mayne Pharma's CEO Scott Richards said, "This is the first major endemic mycoses study in the US for over 20 years and provides the first controlled study in both histoplasmosis and blastomycosis patients for nearly 30 years. These data demonstrate the major clinical attributes of TOLSURA with the product consistently delivering serum levels higher than conventional itraconazole, in combination with a good safety profile. As a controlled, head-to-head study, these data provide real-world clinical evidence of the utility of TOLSURA in endemic infections."

[1] ClinicalTrials.gov Identifier: NCT03572049

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The oral presentations at IDWeek 2020 relating to TOLSURA are:

- Oral 144 – MSG-15 Pharmacokinetic, Adverse Events and tolerability data from an open label randomized clinical trial comparing oral SUBA-itraconazole to conventional itraconazole for treatment of endemic mycosis.
  Presenter – Peter G. Pappas, MD. Professor of Medicine, University of Alabama at Birmingham, Birmingham AL

- Oral presentation – New Kids on the block: Antifungal Drug Pipeline.
  Presenter – David Andes, MD. Professor of Medicine, University of Wisconsin, Madison WI

- AE-28 – What was old is new again. A novel, more bioavailable azole.
  Presenter – Shyam Subramanian, MD. Division Chief Pulmonary Critical Care Sleep Medicine, Sutter Gould Medical Foundation, Tracy CA

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Authorised for release to the ASX by the Chairman

About IDWeek

IDWeek is the joint annual meeting of the Infectious Diseases Society of America (IDSA), Society for Healthcare Epidemiology of America (SHEA), the HIV Medical Association (HIVMA), the Pediatric Infectious Diseases Society (PIDS) and the Society of Infectious Diseases Pharmacists (SIDP). IDWeek features the latest science and bench-to-bedside approaches in prevention, diagnosis, treatment, and epidemiology of infectious diseases, including HIV, across the lifespan. For more information, visit www.idweek.org.

For more information, including a complete list of abstracts, please visit:
https://www.eventscribe.com/2020/IDWeek/index.asp

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, offering patients better and more accessible medicines. Mayne Pharma also provides contract development and manufacturing services to more than 100 clients worldwide.

Mayne Pharma has a 40-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 continue to be marketed around the world.

Mayne Pharma has two facilities based in Salisbury, Australia and Greenville, USA with expertise in the formulation of complex oral and topical dose forms including potent compounds, modified-release products and poorly soluble compounds.

Please see below for U.S. Indications and Important Safety Information, including Boxed Warnings, for TOLSURA

About TOLSURA (SUBA-itraconazole) capsules

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.

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.

Boxed Warning

CONGESTIVE HEART FAILURE, CARDIAC EFFECTS AND DRUG INTERACTIONS

TOLSURA (itraconazole capsules) should not be administered for the treatment of onychomycosis in patients with evidence of ventricular dysfunction such as congestive heart failure (CHF) or a history of CHF. If signs or symptoms of congestive heart failure occur during administration of TOLSURA, discontinue administration. When itraconazole was administered intravenously to dogs and healthy human volunteers, negative inotropic effects were seen.

DRUG INTERACTIONS

Coadministration of the following drugs are contraindicated with TOLSURA (itraconazole capsules): methadone, disopyramide, dofetilide, dronedarone, quinidine, isavuconazole, ergot alkaloids (such as dihydroergotamine, ergometrine (ergonovine), ergotamine, methylergometrine (methylergonovine)), irinotecan, lurasidone, oral midazolam, pimozide, triazolam, felodipine, nisoldipine, ivabradine, ranolazine, eplerenone, cisapride, naloxegol, lomitapide, lovastatin, simvastatin, avanafil, ticagrelor. In addition, coadministration with colchicine, fesoterodine and solifenacin is contraindicated in subjects with varying degrees of renal or hepatic impairment, and coadministration with eliglustat is contraindicated in subjects that are poor or intermediate metabolizers of CYP2D6 and in subjects taking strong or moderate CYP2D6 inhibitors. Coadministration with itraconazole can cause elevated plasma concentrations of these drugs and may increase or prolong both the pharmacologic effects and/ or adverse reactions to these drugs. For example, increased plasma concentrations of some of these drugs can lead to QT prolongation and ventricular tachyarrhythmias including occurrences of torsades de pointes, a potentiallyfatal arrhythmia.

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
- Cardiac 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 hearing loss has been reported in patients. Discontinue treatment if hearing loss occurs
- Hypersensitivity to itraconazole

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, and impotence.

Please see full Prescribing Information by visiting TOLSURA.com