



MAYNE PHARMA SIGNS EUROPEAN SUBACAP® ITRACONAZOLE DISTRIBUTION AGREEMENTS

9 August 2013, Melbourne Australia: Mayne Pharma Group Limited (ASX: MYX) is pleased to announce it has signed two marketing and distribution agreements for SUBACAP®, an improved formulation of itraconazole used to treat fungal infections, in four key European pharmaceutical markets. The execution of these agreements follows an extensive search and selection process for partners that have the infrastructure, know-how and track record to successfully commercialise SUBACAP®.

ISDIN, a leading dermatology company in Southern Europe will market the product in Spain, Italy and Portugal. Glenmark, a globally integrated pharmaceutical company, will market the product in the United Kingdom.

Under the two exclusive distribution agreements, Mayne Pharma will receive upfront payments, milestone payments upon meeting certain market launch hurdles, and a percentage of net sales in each country. Mayne Pharma will manufacture the product for both distributors at its manufacturing facility in South Australia.

Product launch is expected to occur by the end of calendar 2013 in the UK, early 2014 for Spain and by the end of 2014 for Italy and Portugal following a 'repeat use' procedure to extend the existing marketing authorisation into those additional countries.

Mayne Pharma's CEO, Mr Scott Richards said "We are very pleased to announce the pending commercialisation of SUBACAP® in these key Western European pharmaceutical markets. These four countries represent US\$40m per annum in itraconazole sales; which is more than half the European itraconazole market and 8% of the global itraconazole market which is valued at US\$490m¹. Both distribution partners have established sales forces which call on a range of specialists that prescribe itraconazole including dermatologists, gynaecologists as well as GPs."

"This is a very important milestone for the Company and is the result of a great deal of work by many people. 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 SUBACAP® capsules, which have approximately twice the bioavailability and significantly reduced variability to existing products, represents a significant innovation."

"When launched, SUBACAP® will adopt localised brand names (including Lozanoc™) to maximise product recall with prescribers, pharmacists and patients. The signing of these agreements is an important step towards our goal of maximising the worldwide opportunity for SUBACAP®. The Company is continuing to progress the commercialisation of SUBACAP® in other markets, including the two key markets of Japan and United States, which represent 41%

¹ IMS Health MAT Dec 2012



ASX Announcement

of the global itraconazole market value. The Company is also in late stage discussions with a partner in Korea, the fourth largest itraconazole market globally”.

For further information contact:

Scott Richards +61 8 8209 2410

Lisa Pendlebury +61 419 548 434, lisa.pendlebury@maynepharma.com

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, NC, USA with expertise in formulation complex oral dose forms including highly potent compounds, controlled substances, modified release products and inherently unstable compounds.

About ISDIN, S.A.

ISDIN is an international laboratory specialised in innovative solutions for major dermatological needs and pathologies. Since its beginning, in 1975, ISDIN maintains a firm commitment to skin care together with dermatologists and pharmacists. Thanks to this, it currently has a broad experience in skin and mucous pathologies, responding to them with a holistic approach, combining healing, maintenance and prevention therapies. Its dedication to grow and become a leading international company in skin treatment has driven ISDIN to be the top company in the Spanish dermatological market, present in more than 15 countries in Latin America, Southern Europe, Western Asia and South Africa with approximately 600 employees worldwide.

About Glenmark Pharmaceuticals

Glenmark is a leading player in the discovery of new molecules, both NCEs (new chemical entity) and NBEs (new biological entity). The company has a significant presence in branded generic markets and its subsidiary, Glenmark Generics Limited has a fast growing and robust generics business. Glenmark employs over 10,000 people in over 80 countries and has thirteen manufacturing facilities and five R&D centres.

About SUBACAP®

SUBACAP® is an improved formulation of itraconazole, a product used to treat fungal infections. SUBACAP® has double the bioavailability and significantly reduced variability compared to the originator. SUBACAP® 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, 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.

SUBACAP® will be promoted under localised brand names including Lozanoc™ in the UK and Australia.