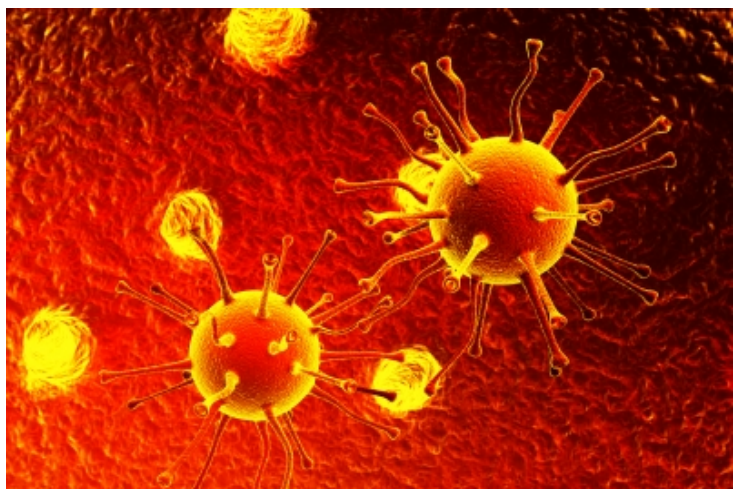


## US, Aus firms to commercialize cancer drug

11 September 2013 | News | By BioSpectrum Bureau



**Singapore:** Australian drug giant Mayne Pharma Group has announced its signing of an exclusive supply and license agreement with US-based HedgePath Pharmaceuticals (HPPI) to pursue clinical development, registration and commercialization of Mayne Pharma's patented formulation of itraconazole, known as SUBA- Itraconazole, for treatment of a variety of cancers in the US.

As part of the agreement, Mayne Pharma expects to appoint one representative to the HPPI Board. Although the agreement is effective immediately, it remains subject to certain conditions being achieved, as detailed in the current report on Form 8-K that HPPI filed with the US Securities and Exchange Commission on September 10, 2013. Subject to meeting these conditions and in return for granting HPPI exclusive US rights, Mayne Pharma is expected to acquire an equity stake in HPPI of between 30-to-45 percent.

Under the terms of the agreement, Mayne Pharma will supply HPPI with SUBA-Itraconazole for use in clinical trials and for future exclusive commercial supply following the US FDA approval.

Mayne Pharma and HPPI are collaborating through a joint development program for SUBA-Itraconazole in oncology, with the initial areas of investigation being selected indications in prostate, lung and skin cancer.

In the US, there are more than two million new cases of these three cancers reported annually and the pharmaceutical market size to treat these diseases exceeds \$5 billion and forecast to grow more than five percent per annum over the coming decade.

Mayne Pharma has granted HPPI exclusive rights to SUBA-Itraconazole for the treatment of cancer in the US, and Mayne Pharma retains rights outside the US, and also obtains an exclusive license from HPPI to utilize all current and any future development intellectual property generated by HPPI.

Mayne Pharma CEO Mr Scott Richards said in the press statement, "We are very excited to announce our collaboration with

HPPI which we believe is the best commercial vehicle for the development and exploitation of SUBA-Itraconazole as a potential treatment for certain cancers. HPPI has an experienced management team who are passionate about the potential of SUBA-Itraconazole in treating cancer. HPPI also brings relevant intellectual property to supplement that of our existing SUBA technology patent."

He also added, "Over the last 18 months, the team behind HPPI has explored the clinical potential of itraconazole as a treatment for cancer which culminated in a restructure of HPPI into a public company which has commenced trading on the OTCPink market. HPPI will be seeking market funding for the clinical development and regulatory program. We look forward to a productive partnership with HPPI as we work closely together to progress SUBA- Itraconazole through the development process."

He also said that since itraconazole is already an FDA approved drug, the company believes that the potential exists for an expedited development program due to the drug's well established safety profile. "We are further encouraged by the recently reported third party phase II data demonstrating itraconazole's anti-cancer effects in humans," he added.