



ANNOUNCEMENT

HALCYGEN FILING FOR REGISTRATION OF ANTI-FUNGAL PRODUCT IN EU IN 2010

Guidance from meeting with the UK's medicines and healthcare products regulatory agency (mhra)

Friday 28th August 2009, Melbourne Australia: HalcyGen Pharmaceuticals Limited (ASX: HGN) has met with the UK Medicines and Healthcare Products Regulatory Agency (MHRA) to progress its EU registration program for SUBA[®]-Itraconazole. SUBA[®]-Itraconazole is an improved generic formulation of the anti-fungal drug Sporanox[®].

Following a review of HalcyGen's US pharmacokinetic (PK) studies*, the agency has guided HalcyGen to undertake a single pharmacokinetic study in the European Union to demonstrate that SUBA[®]-Itraconazole performs in a similar manner against EU registered Sporanox[®] as it does with US derived Sporanox[®]. This advice concurs with guidance from the corresponding regulatory agency in Sweden (MPA, announced 22 June 2009) enabling HalcyGen the opportunity to file for registration in the EU next year.

SUBA[®]-Itraconazole is an improved anti-fungal targeting a worldwide annual \$600 million market.

Following the completion of the required PK study (anticipated by the end of the year) in conjunction with HalcyGen's US clinical data pack, Voisin Consulting will assist HalcyGen in preparing its Marketing Authorisation Application during 2010.

The advantage of HalcyGen's formulation is potentially greater safety of SUBA[®]-Itraconazole as patients are administered only 50% of the drug compared with Sporanox[®]. Further, SUBA[®]-Itraconazole shows lower inter-patient variability as compared to Sporanox[®] resulting in more predictable blood levels (the clinical advantages of SUBA[®]-Itraconazole have been described in the recent company announcement on the 3 March 2009). A

further benefit of SUBA[®]-Itraconazole is that it can be taken on an empty stomach, unlike Sporonox[®] which must be taken after a full meal.

HalcyGen's PK program enables a dual registration strategy to simultaneously seek approval in the USA through the FDA and Europe with Sweden or the UK as the Reference Member State.

HalcyGen's CEO Dr Roger Aston said, "We have now met with both Sweden's MPA and the UK's MHRA to register SUBA[®]-Itraconazole in the EU. Both agencies have offered similar guidance enabling HalcyGen to file for registration in 2010 subject to undertaking a study in the EU that is expected to be completed by the end of 2009."

"HalcyGen is now working on appointing marketing and distribution partners for the EU. Discussions are underway with several pharmaceutical companies. Once launched SUBA[®]-Itraconazole will be competing in the European itraconazole market which is currently over US\$120 million per year."

One of the key advantages of achieving early EU registration is that the approved dossier may be used for faster approval in many Asian territories as well. Asia is an important market for itraconazole. The annual sales in Japan and Korea alone are in excess of US\$200 million.

The positive progress towards EU registration has further increased the value and interest in the product for licensing.

*Pharmacokinetic Studies: Clinical pharmacokinetic studies are performed to examine the absorption, distribution, metabolism and excretion of a drug under investigation (investigational drug and approved drug) in healthy volunteers and/or patients. Pivotal pharmacokinetic studies are studies that form part of the registration dossier for a new drug application (NDA in USA or MAA in EU).

**Sporanox[®] is the market leading form of itraconazole and is owned by Janssen Pharmaceutical Products LP—part of the Johnson & Johnson Group.

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Background on HalcyGen:

HalcyGen was founded to bridge the gap between main stream pharmaceutical companies and high volume generics companies through the development and licensing of new improved proprietary generic formulations known as "Super Generics"

or "High Functionality Generics". HalcyGen's strategy is to capitalise on the value associated with the development and commercialisation of novel, improved variants of existing proprietary pharmaceuticals known as Super Generics.

The basis of the HalcyGen's strategy is a strategic licensing partnership with Hospira, Inc. The Company will initially develop and market two products in partnership with Hospira. Subject to performance and meeting certain other criteria, the Company has the opportunity to develop further products with Hospira.

Through the global exclusive license granted to HalcyGen by Hospira, Inc., for the commercialisation of SUBA[®]-Itraconazole, Hospira has a first right of refusal to manufacture SUBA[®]-Itraconazole to support sales. Hospira is a global specialty pharmaceutical and medication delivery company.