



HALCYGEN COMPLETES RECRUITMENT AND DOSING OF THIRD PHARMACOKINETIC STUDY IN THE USA FOLLOWING IND ALLOWANCE BY FDA

*SUBA-Itraconazole™ - Improved anti-fungal targeting
\$600m market*

Tuesday 20th January 2009, Melbourne Australia: HalcyGen Pharmaceuticals Limited (ASX: HGN) is pleased to announce that it has successfully completed recruitment and dosing of the third of three pivotal pharmacokinetic* studies scheduled to be performed under its Investigational New Drug application (IND) approved by the FDA (announcement 17th June 2008).

The registration strategy for SUBA-Itraconazole™ is designed to compare HalcyGen's SUBA-Itraconazole™ and the market's leading product Sporanox®**. HalcyGen's CEO, Dr Roger Aston said, "We have completed the recruitment and treatments for the third key study aimed at evaluating the pharmacokinetics of different doses of our drug, so we remain well on track with our registration program. We have now successfully completed three consecutive US trials within 6 months which has prepared the ground for reverting to the US FDA for further guidance. During the next few weeks we will be reporting the implications of the outcomes of these three trials and our strategy to seek registration of SUBA-Itraconazole.

HalcyGen has clinically evaluated SUBA-Itraconazole™, a patented formulation, in five successful pharmacokinetic studies in Australia. These studies have demonstrated that HalcyGen's formulation has significantly improved bioavailability (absorption by the gastrointestinal tract) compared with the market leader, enabling the use of a lower dose of the drug. HalcyGen's formulation also provides for more stable blood levels as compared to Sporanox®.

The current global market for itraconazole is in excess of US\$600 million per annum – HalcyGen's SUBA-Itraconazole™ is targeting this market.

*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).

****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 has been founded to bridge the gap between mainline 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.