Successful commercial scale manufacture of HalcyGen's anti-fungal SUBA™-Itraconazole for US-based phase III

Improved anti-fungal targeting $600m market

Friday 14th March 2008, Melbourne: HalcyGen Pharmaceuticals Limited (ASX: HGN) lead product anti-fungal drug SUBA™-Itraconazole has been successfully manufactured at commercial scale in preparation for phase III registration trials in the USA.

The next major milestone for HalcyGen is the FDA approval of the IND in the second quarter for the Company's pivotal Phase III trial strategy.

HalcyGen's SUBA™-Itraconazole is targeted to the $2.5 billion anti-fungals market, currently dominated by leading products such as Voricanazole, Fluconazole, Lamisil and Sporanox®. SUBA™-Itraconazole, is expected to provide the same efficacy as Sporanox® at half the oral dose. The phase III trial is designed to determine non-inferiority against Sporanox® and may provide an indication as to whether there is improved safety with HalcyGen's lower dosage form. Global sales of the anti-fungal drug Itraconazole/Sporanox® were in excess of US$600 million last year.

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.

Dr Roger Aston, HalcyGen's CEO said, "We have worked closely with Hospira to bring this product to exhibit scale manufacture and submission of the dossier for FDA review for phase III studies. We have an exciting year ahead and a clear market opportunity".

*Sporanox® is owned by Janssen Pharmaceutical Products LP—part of the Johnson & Johnson Group, Vfend (Voricanazole) and Diflucan (Fluconazole) are owned by Pfizer Inc, Lamisil is owned by Novartis.

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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.